NIDA / VA CS #1033

Lorcaserin for Cocaine Use Disorder

SOURCE DOCUMENT WORKBOOK

Version 3, 12.21.2017

___ ___ ___ - ___ ___ ___ ___

SUBJECT # ALPHA

Begin data collection within this workbook only after the subject has successfully completed screening.

Fasten together all CRFs completed for this subject at Screening and place within the back of this workbook.

SOURCE DOCUMENT WORKBOOK FOR RANDOMIZED SUBJECTS

1. This subject is now randomized. Please file all source documents in the screening packet with the subject's source document workbook.

2. Record the subject's ID # and ALPHA code on the cover and the spine of the workbook.

3. At each study visit, record the Visit Date on the front of the tabbed visit page.

4. Be careful not to omit any data points on the forms. Remember that the reliability of study findings depends on the accuracy of the data that is recorded on the source documents and subsequently entered into the eDC system.

REMEMBER THAT DATA COLLECTED ON THE SOURCE DOCUMENTS SHOULD BE ENTERED INTO MEDIDATA IN A TIMELY MANNER.

CONCOMITANT MEDICATIONS

Use the Concomitant Medications Log to track con meds that are recorded throughout the study. Every medication taken by the subject must have a corresponding entry (log line) in Medidata.

NIDA/VA CS #1033, CONCOMITANT MEDICATIONS

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

UNITS:		**ROUTE:**		**FREQUENCY:**
Caplet/Tablet	Puff	Oral	Topical/Transdermal	QD
Drop	Spray/Squirt	Nasal	Intramuscular	BID
Milligram	Tablespoon	Intravenous	Sublingual	TID
Milliliter	Teaspoon	Inhalation	Subcutaneous	QID
	Unknown/Other		Other	Other, MUST SPECIFY BELOW

Medication Name	Start	Stop Date	Mark X	Indication	Dose	Units	Route	Frequency	Recorded by	Log Line # *(from Medidata)*
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							

NIDA/VA CS #1033, CONCOMITANT MEDICATIONS

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

UNITS:		**ROUTE:**		**FREQUENCY:**
Caplet/Tablet	Puff	Oral	Topical/Transdermal	QD
Drop	Spray/Squirt	Nasal	Intramuscular	BID
Milligram	Tablespoon	Intravenous	Sublingual	TID
Milliliter	Teaspoon	Inhalation	Subcutaneous	QID
	Unknown/Other		Other	Other, MUST SPECIFY BELOW

Medication Name	Start	Stop Date	Mark X	Indication	Dose	Units	Route	Frequency	Recorded by	Log Line # *(from Medidata)*
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							

NIDA/VA CS #1033, CONCOMITANT MEDICATIONS

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

UNITS:		**ROUTE:**		**FREQUENCY:**
Caplet/Tablet	Puff	Oral	Topical/Transdermal	QD
Drop	Spray/Squirt	Nasal	Intramuscular	BID
Milligram	Tablespoon	Intravenous	Sublingual	TID
Milliliter	Teaspoon	Inhalation	Subcutaneous	QID
	Unknown/Other		Other	Other, MUST SPECIFY BELOW

Medication Name	Start	Stop Date	Mark X	Indication	Dose	Units	Route	Frequency	Recorded by	Log Line # *(from Medidata)*
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							

NIDA/VA CS #1033, CONCOMITANT MEDICATIONS

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

UNITS:		**ROUTE:**		**FREQUENCY:**
Caplet/Tablet	Puff	Oral	Topical/Transdermal	QD
Drop	Spray/Squirt	Nasal	Intramuscular	BID
Milligram	Tablespoon	Intravenous	Sublingual	TID
Milliliter	Teaspoon	Inhalation	Subcutaneous	QID
	Unknown/Other		Other	Other, MUST SPECIFY BELOW

Medication Name	Start	Stop Date	Mark X	Indication	Dose	Units	Route	Frequency	Recorded by	Log Line # *(from Medidata)*
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							

NIDA/VA CS #1033, CONCOMITANT MEDICATIONS

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

UNITS:		**ROUTE:**		**FREQUENCY:**
Caplet/Tablet	Puff	Oral	Topical/Transdermal	QD
Drop	Spray/Squirt	Nasal	Intramuscular	BID
Milligram	Tablespoon	Intravenous	Sublingual	TID
Milliliter	Teaspoon	Inhalation	Subcutaneous	QID
	Unknown/Other		Other	Other, MUST SPECIFY BELOW

Medication Name	Start	Stop Date	Mark X	Indication	Dose	Units	Route	Frequency	Recorded by	Log Line # *(from Medidata)*
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							

NIDA/VA CS #1033, CONCOMITANT MEDICATIONS

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

UNITS:		**ROUTE:**		**FREQUENCY:**
Caplet/Tablet	Puff	Oral	Topical/Transdermal	QD
Drop	Spray/Squirt	Nasal	Intramuscular	BID
Milligram	Tablespoon	Intravenous	Sublingual	TID
Milliliter	Teaspoon	Inhalation	Subcutaneous	QID
	Unknown/Other		Other	Other, MUST SPECIFY BELOW

Medication Name	Start	Stop Date	Mark X	Indication	Dose	Units	Route	Frequency	Recorded by	Log Line # *(from Medidata)*
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							
			☐							

ADVERSE EVENTS

Use the Adverse Events Log to track AEs that are recorded throughout the study. Every AE reported by the subject must have a corresponding entry (log line) in Medidata.

Adverse Events that are considered serious must be documented on the Serious Adverse Event Form and reported within 24 hours to the sponsor as detailed within the study protocol, Appendix I.

NIDA/VA CS #1033, ADVERSE EVENTS LOG

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

Severity	**Relationship**	**Action Taken**	**Outcome**
Mild Moderate Severe *If severity increases, enter a stop date for the current AE & begin a new AE.*	Not related Possibly related Definitely related	Dose Unchanged Drug Interrupted Drug Permanently Discontinued Other Alteration to Study Procedures Unknown/Lost to follow-up	Recovered/resolved Recovering/resolving Not recovered/not resolved Fatal Unknown/Lost to follow-up

Name of Adverse Event	**Start Date**	**Ongoing?**	**Stop Date**	**Severity**	**Relationship**	**Action Taken**	**Outcome**	**Is this an SAE?**	` **Assessed By** *(initials)*	**Log Line #** *in Medidata*
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		

NIDA/VA CS #1033, ADVERSE EVENTS LOG

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

Severity	Relationship	Action Taken	Outcome
Mild Moderate Severe *If severity increases, enter a stop date for the current AE & begin a new AE.*	Not related Possibly related Definitely related	Dose Unchanged Drug Interrupted Drug Permanently Discontinued Other Alteration to Study Procedures Unknown/Lost to follow-up	Recovered/resolved Recovering/resolving Not recovered/not resolved Fatal Unknown/Lost to follow-up

Name of Adverse Event	Start Date	Ongoing?	Stop Date	Severity	Relationship	Action Taken	Outcome	Is this an SAE?	` Assessed By *(initials)*	Log Line # *in Medidata*
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		

NIDA/VA CS #1033, ADVERSE EVENTS LOG

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

Severity	Relationship	Action Taken	Outcome
Mild	Not related	Dose Unchanged	Recovered/resolved
Moderate	Possibly related	Drug Interrupted	Recovering/resolving
Severe	Definitely related	Drug Permanently Discontinued	Not recovered/not resolved
If severity increases, enter a stop date for the current AE & begin a new AE.		Other Alteration to Study Procedures	Fatal
		Unknown/Lost to follow-up	Unknown/Lost to follow-up

Name of Adverse Event	Start Date	Ongoing?	Stop Date	Severity	Relationship	Action Taken	Outcome	Is this an SAE?	Assessed By *(initials)*	Log Line # *in Medidata*
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		

NIDA/VA CS #1033, ADVERSE EVENTS LOG

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

Severity	**Relationship**	**Action Taken**	**Outcome**
Mild Moderate Severe *If severity increases, enter a stop date for the current AE & begin a new AE.*	Not related Possibly related Definitely related	Dose Unchanged Drug Interrupted Drug Permanently Discontinued Other Alteration to Study Procedures Unknown/Lost to follow-up	Recovered/resolved Recovering/resolving Not recovered/not resolved Fatal Unknown/Lost to follow-up

Name of Adverse Event	Start Date	Ongoing?	Stop Date	Severity	Relationship	Action Taken	Outcome	Is this an SAE?	` Assessed By *(initials)*	Log Line # *in Medidata*
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		

NIDA/VA CS #1033, ADVERSE EVENTS LOG

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

Severity	Relationship	Action Taken	Outcome
Mild Moderate Severe *If severity increases, enter a stop date for the current AE & begin a new AE.*	Not related Possibly related Definitely related	Dose Unchanged Drug Interrupted Drug Permanently Discontinued Other Alteration to Study Procedures Unknown/Lost to follow-up	Recovered/resolved Recovering/resolving Not recovered/not resolved Fatal Unknown/Lost to follow-up

Name of Adverse Event	Start Date	Ongoing?	Stop Date	Severity	Relationship	Action Taken	Outcome	Is this an SAE?	Assessed By *(initials)*	Log Line # *in Medidata*
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		

NIDA/VA CS #1033, ADVERSE EVENTS LOG

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

Severity	**Relationship**	**Action Taken**	**Outcome**
Mild Moderate Severe *If severity increases, enter a stop date for the current AE & begin a new AE.*	Not related Possibly related Definitely related	Dose Unchanged Drug Interrupted Drug Permanently Discontinued Other Alteration to Study Procedures Unknown/Lost to follow-up	Recovered/resolved Recovering/resolving Not recovered/not resolved Fatal Unknown/Lost to follow-up

Name of Adverse Event	Start Date	Ongoing?	Stop Date	Severity	Relationship	Action Taken	Outcome	Is this an SAE?	Assessed By *(initials)*	Log Line # *in Medidata*
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		
		YES ☐ NO ☐						YES ☐ NO ☐		

___ ___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Log # on AE Form _____

NOTE: ALL serious adverse events must be documented on the Adverse Events Log Form

2. Name of Event:

NOTE: Enter diagnosis. If unknown, enter a sign / symptom.

_____

_____

3. Type of Event (mark all that apply)

TYPE OF EVENT	MARK ALL THAT APPLY
Death	☐
Life-threatening	☐
Hospitalization (initial or prolonged)	☐
Persistent or significant disability/incapacity	☐
Congenital anomaly / birth defect	☐
Other serious (important medical event)	☐

3a. If Other Serious (important medical event), specify:

_____

_____

4. Severity ☐ Mild ☐ Moderate ☐ Severe

5. Expected? ☐ Expected ☐ Unexpected

6. Relatedness ☐ Not Related ☐ Possibly ☐ Definitely

7. Description of event (include treatment):

_____

_____

_____

8. Relevant medical & psychiatric history:

_____

_____

_____

9. Relevant test results & laboratory data:

_____

_____

_____

10. Date of onset: _____ / _____ / _____ *(mm/dd/yyyy)*

11. Date reported to site: _____ / _____ / _____ *(mm/dd/yyyy)*

12. Date first dose of study drug taken: _____ / _____ / _____ *(mm/dd/yyyy)*

13. Date last dose of study drug taken: _____ / _____ / _____ *(mm/dd/yyyy)*

14. Action taken:

- ☐ Dose unchanged
- ☐ Drug interrupted
- ☐ Drug permanently discontinued
- ☐ Other alteration to study procedures
- ☐ Unknown / lost to follow-up

14a. If study drug interrupted, enter the drug stop date: _____ / _____ / _____ *(mm/dd/yyyy)*

14b. If interrupted and restarted, enter date drug restarted: _____ / _____ / _____

14c. If study drug was withdrawn, did the subject improve? ☐ Yes ☐ No

15. Was study blind broken? ☐ Yes ☐ No

IF YES:

15a. Date of unblinding _____ / _____ / _____ *(mm/dd/yyyy)*

15b. Time of unblinding ___ ___ ___ ___ (use 24 hr clock)

15c. Reason for unblinding:

_____

_____

16. Outcome:

- ☐ Recovered / Resolved
- ☐ Recovering / Resolving
- ☐ Not Recovered / Not Resolved
- ☐ Fatal
- ☐ Unknown

16a. If recovered / resolved, provide the outcome date: _____ / _____ /_____*(mm/dd/yyyy)*

16b. If fatal, provide date of death: _____ / _____ / _____*(mm/dd/yyyy)*

SAE Reviewed By _____ Date _____
(Investigator)

*Entered into eDC on*_____
date

Notes...

STUDY DAY 1 (Enrollment)

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Study Day 1:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology - Treatment
☐	Pregnancy Test (female subjects only)
☐	Vital Signs
☐	SUR (complete record for all days in screening)
☐	Behavioral Therapy* *The first computerized Alcohol Intervention Module is mandatory on Study Day 1
☐	C-SSRS (Since Last Visit)
☐	ASI-Lite
☐	BSCS

PAYMENT FOR WEEK 1:

WEEK 1	AMOUNT DUE	PAID (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

QUIT to QUIT: Computer-Based Alcohol Intervention Modules

1. Did the subject view the Quit to Quit computer-based alcohol intervention module scheduled for this week?

   ☐ Yes
   ☐ No

NOTE: The alcohol intervention is mandatory at Study Day 1 and optional at Study Day 8, week 3, & week 8. If the subject declines to continue viewing the intervention on Study Day 8, a signed Participant Acknowledgment is required.

2. Date the subject viewed the alcohol intervention module: _____ / _____ / _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — Yes ☐ No ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — Yes ☐ No ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — Yes ☐ No ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — Yes ☐ No ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — Yes ☐ No ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

Addiction Severity Index *Lite* - CF

Clinical/Training Version

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

Remember: This is an interview, not a test

≈Item numbers (circled) are to be asked at follow-up.≈
≈Items with an asterisk* are cumulative and should be rephrased at follow-up.≈
≈Items in a double border gray box are questions for the interviewer. Do not ask these questions of the client.≈

INTRODUCING THE ASI: Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological. All clients receive this same standard interview. All information gathered is confidential.

There are two time periods we will discuss:

1. The past 30 days
2. Lifetime Data

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

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

If you are uncomfortable giving an answer, then don't answer.

Please do not give inaccurate information!

INTERVIEWER INSTRUCTIONS:

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

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

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

Probe and make plenty of comments!

HOLLINGSHEAD CATEGORIES:

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

LIST OF COMMONLY USED DRUGS:

Alcohol:	Beer, wine, liquor
Methadone:	Dolophine, LAAM
Opiates:	Pain killers = Morphine, Dilaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2,3,4, Syrups = Robitussin, Fentanyl
Barbiturates:	Nembutal, Seconal, Tuinal, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinal
Sed/Hyp/Tranq:	Benzodiazepines = Valium, Librium, Ativan, Serax Tranxene, Dalmane, Halcion, Xanax, Miltown, Other = Chloral Hydrate, Quaaludes
Cocaine:	Cocaine Crystal, Free-Base Cocaine or Crack, and "Rock Cocaine"
Amphetamines:	Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin, Methamphetamine, Speed, Ice, Crystal
Cannabis:	Marijuana, Hashish
Hallucinogens:	LSD (Acid), Mescaline, Psilocybin (Mushrooms), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstacy
Inhalants:	Nitrous Oxide (Whippits), Amyl Nitrite (Poppers), Glue, Solvents, Gasoline, Toluene, Etc.

Just note if these are used: Antidepressants,
Ulcer Meds = Zantac, Tagamet
Asthma Meds = Ventolin Inhaler, Theodur
Other Meds = Antipsychotics, Lithium

ALCOHOL/DRUG USE INSTRUCTIONS:

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

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

Revised- 06/02/99 DC/TRJ

Addiction Severity Index *Lite* - Training Version

GENERAL INFORMATION

___ ___ ___ ___ Subject ID#

___ ___ ___ ___ ALPHA

G5. Date of Interview: ☐☐ / ☐☐ / ☐☐☐

G8. Class: *(circle one)* 1 = Baseline 2 = Follow-up

G12. ___*check here if assessment* REFUSED, FORGOTTEN, or NOT DONE

G11. Interview Conducted By:

_____

Date Entered into eDC_____

G18. Do you have a religious preference? ☐

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

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

1. No
2. Jail
3. Alcohol/Drug Treat.
4. Medical Treatment
5. Psychiatric Treatment
6. Other: _____

•A place, theoretically, without access to drugs/alcohol.

G20. How many days? ☐☐

•"NN" if Question G19 is No. Refers to <u>total</u> number of days detained in the past 30 days.

NOTE: Section G of the ASI-Lite has been amended to fit the protocol requirements for NIDA/VA CS #1033. Questions from Section G. that are non-applicable or redundant with other data collected have been removed.

MEDICAL STATUS

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

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

M3. Do you have any chronic medical problems which continue to interfere with your life? 0 -No 1 - Yes ☐

- ***If "Yes", specify in comments.***
- A chronic medical condition is a serious physical condition that requires regular care, (i.e., medication, dietary restriction) preventing full advantage of their abilities.

M4. Are you taking any prescribed medication on a regular basis for a physical problem? 0 - No 1 - Yes ☐

- ***If Yes, specify in comments.***
- Medication prescribed by a MD for medical conditions; ***not psychiatric medicines***. Include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems.

M5. Do you receive a pension for a physical disability? 0 - No 1 - Yes ☐

- ***If Yes, specify in comments.***
- Include Workers' compensation, exclude psychiatric disability.

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

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

For Questions M7 & M8, ask the patient to use the Patient Rating scale.

M7. How troubled or bothered have you been by ☐

- Restrict response to problem days of Question M6.

M8. How important to you *now* is treatment for ☐

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

CONFIDENCE RATINGS

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

M10. Patient's misrepresentation? ☐

M11. Patient's inability to understand? ☐

MEDICAL COMMENTS

(Include question number with your notes)

EMPLOYMENT/SUPPORT STATUS

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

Years ☐☐ Months ☐☐

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

Months ☐☐

E4. Do you have a valid driver's license?
- Valid license; not suspended/revoked.

0 - No 1 - Yes ☐

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

0 - No 1 - Yes ☐

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

☐☐ / ☐☐
Yrs / Mos

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

E9 Does someone contribute the majority of your support?

0 - No 1 - Yes ☐

E10. Usual employment pattern, past three years? ☐

1. Full time (35+ hours)
2. Part time (regular hours)
3. Part time (irregular hours)
4. Student
5. Service
6. Retired/Disability
7. Unemployed
8. In controlled environment

- Answer should represent the *majority* of the last 3 years, not just the most recent selection. If there are equal times for more than one category, select that which best represents more current situation.

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

EMPLOYMENT/SUPPORT COMMENTS
(Include question number with your notes)

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

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

E13. Unemployment Compensation? ☐☐☐☐☐

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

E15. Pensions, benefits or Social Security? ☐☐☐☐☐
- Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.

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

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

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

E19. How many days have you experienced employment problems in the past 30 ? ☐☐
- Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized.

For Question E20, ask the patient to use the Patient Rating scale.

E20. How troubled or bothered have you been by these ☐
- If the patient has been incarcerated or detained during the

E21. How important to you *now* is counseling for ☐
- The patient's ratings in Questions E20-21 refer to Question E19.
- Stress help in finding or preparing for a job, not giving them a job.

CONFIDENCE RATINGS

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

E23. Patient's misrepresentation 0-No 1-Yes ☐

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

EMPLOYMENT/SUPPORT COMMENTS

(Include question number with your notes)

ALCOHOL/DRUGS

Route of Administration Types:

1. Oral 2. Nasal 3. Smoking 4. Non-IV injection 5. IV

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

		Past 30 Days	Lifetime (years)	Route of Admin
D1	Alcohol (any use at all)	☐☐	☐☐	■
D2	Alcohol (to intoxication)	☐☐	☐☐	■
D3	Heroin	☐☐	☐☐	☐
D4	Methadone	☐☐	☐☐	☐
D5	Other Opiates/Analgesics	☐☐	☐☐	☐
D6	Barbiturates	☐☐	☐☐	☐
D7	Sedatives/Hypnotics/ Tranquilizers	☐☐	☐☐	☐
D8	Cocaine	☐☐	☐☐	☐
D9	Amphetamines	☐☐	☐☐	☐
D10	Cannabis	☐☐	☐☐	☐
D11	Hallucinogens	☐☐	☐☐	☐
D12	Inhalants	☐☐	☐☐	☐
D13	More than 1 substance per day (including alcohol)	☐☐	☐☐	■

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

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

ALCOHOL/DRUGS COMMENTS

(Include question number with your notes)

ALCOHOL/DRUGS (cont.)

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

D19*. Alcohol abuse? ☐☐

D20*. Drug abuse? ☐☐

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

How many of these were detox only:

D21. Alcohol? ☐☐

D22. Drugs? ☐☐

- If D19 = "00", then question D21 is "NN"
  If D20 = '00', then question D22 is "NN"

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

D23. Alcohol? ☐☐☐☐☐

D24. Drugs? ☐☐☐☐☐

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

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

For Questions D28-D31, ask the patient to use the Patient Rating scale.

How many days in the past 30 have you experienced:

D26. Alcohol problems? ☐☐

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

D28. Alcohol problems? ☐

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

D30. Alcohol problems? ☐

How many days in the past 30 have you experienced:

D27. Drug problems? ☐☐
- Include only: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.

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

D29. Drug problems? ☐

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

D31. Drug problems? ☐

CONFIDENCE RATINGS

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

D34. Patient's misrepresentation? 0-No 1-Yes ☐

D35. Patient's inability to understand? 0-No 1-Yes ☐

ALCOHOL/DRUGS COMMENTS

(Include question number with your notes)

LEGAL STATUS

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

L2. Are you on parole or probation? 0 - No 1 -Yes ☐
- Note duration and level in comments.

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

L3 * Shoplift/Vandal	☐☐	L10* Assault	☐☐
L4 * Parole/Probation	☐☐	L11* Arson	☐☐
L5 * Drug Charges	☐☐	L12* Rape	☐☐
L6 * Forgery	☐☐	L13* Homicide/Mansl.	☐☐
L7* Weapons Offense	☐☐	L14* Prostitution	☐☐
L8* Burglary/Larceny/B&E	☐☐	L15* Contempt of Court	☐☐
L9 * Robbery	☐☐	L16* Other: _____	☐☐

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

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

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

L18* Disorderly conduct, vagrancy, public intoxication? ☐☐

L19* Driving while intoxicated? ☐☐

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

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

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

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

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

LEGAL COMMENTS

(Include question number with your notes)

L27. How many days in the past 30 have you engaged in illegal activities for profit? ☐☐

- Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with Question E17 under Employment/Family Support Section.

For Questions L28-29, ask the patient to use the Patient Rating scale.

L28. How serious do you feel your present legal problems are? ☐

- Exclude civil problems

L29. How important to you *now* is counseling or referral for these legal problems? ☐

- Patient is rating a need for ***additional*** referral to legal counsel for defense against criminal charges.

CONFIDENCE RATINGS

Is the above information significantly distorted by:

L31. Patient's misrepresentation? 0 - No 1- Yes ☐

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

LEGAL COMMENTS

(Include question number with your notes)

FAMILY/SOCIAL RELATIONSHIPS

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

F3. Are you satisfied with this situation? ☐
0-No 1-Indifferent 2-Yes
● Satisfied = generally liking the situation. - Refers to Questions F1 & F2.

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

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

Do you live with anyone who:

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

F8 Uses non-prescribed drugs? 0-No 1-Yes ☐

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

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

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

	0 - No 1 - Yes Past 30 days	In Your Life
F18. Mother	☐	☐
F19. Father	☐	☐
F20. Brother/Sister	☐	☐
F21. Sexual Partner/Spouse	☐	☐
F22. Children	☐	☐
F23. Other Significant Family (specify)_____	☐	☐
F24. Close Friends	☐	☐
F25. Neighbors	☐	☐
F26. Co-workers		

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

Did anyone abuse you? 0- No 1-Yes

	Past 30 days	In Your Life
F28. Physically? ● Caused you physical harm.	☐	☐
F29. Sexually? ● Forced sexual advances/acts.	☐	☐

FAMILY/SOCIAL COMMENTS

(Include question number with your notes)

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

F30. With your family? ☐☐

For Questions F32-34, ask the patient to use the Patient Rating scale.

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

F32. Family problems ?

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

F34. Family problems

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

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

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

For Questions F33-35, ask the patient to use the Patient Rating scale.

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

F33. Social problems?

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

F35. Social problems

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

CONFIDENCE RATING

Is the above information significantly distorted by:

F37. Patient's misrepresentation? 0-No 1-Yes

F38. Patient's inability to understand?

FAMILY/SOCIAL COMMENTS

(Include question number with your notes)

PSYCHIATRIC STATUS

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

P1.* In a hospital or inpatient setting? ☐☐

P2.* Outpatient/private patient? ☐☐

- Do not include substance abuse, employment, or family counseling.

Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days.

- Enter diagnosis in comments if known.

P3. Do you receive a pension for a psychiatric disability? ☐

0-No 1-Yes

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

	0-No 1-Yes	
	Past 30 Days	Lifetime
P4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?	☐	☐
P5. Experienced serious anxiety/ tension,	☐	☐
P6. Experienced hallucinations-saw things or heard voices that were not there?	☐	☐
P7. Experienced trouble understanding,	☐	☐

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

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

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

- This refers to problems noted in Questions P4-P10.

For Questions P13-P14, ask the patient to use the Patient Rating scale

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

- Patient should be rating the problem days from Question P12.

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

CONFIDENCE RATING

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

P22 Patient's misrepresentation? 0-No 1-Yes ☐

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

PSYCHIATRIC STATUS COMMENTS

(Include question number with your comments)

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

STUDY DAY 8 (Randomization)

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Study Day 8:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology - Treatment
☐	Pregnancy Test (female subjects only)
☐	Blood/Plasma Samples
☐	Study Day 8 – Randomization
☐	Vital Signs
☐	SUR
☐	Behavioral Therapy* ***Ss who decline the second computerized Alcohol Intervention Module must opt out in writing.**
☐	C-SSRS (Since Last Visit)
☐	BSCS
☐	Beck Depression Inventory II (BDI-II)

PAYMENT FOR WEEK 2:

WEEK 2	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
BLOOD/PLASMA SAMPLES

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Were any blood and/or plasma samples drawn at today's visit? ☐ YES ☐ NO

If **YES**, Date Sample(s) Collected _____ / _____ / _____

INDICATE WHAT TYPE OF SAMPLES WERE COLLECTED AT TODAY'S VISIT (*mark all that apply*)

1. Plasma (*Xenobiotics*) ☐
2. Blood Chemistry (*Q2*) ☐
3. Hematology (*Q2*) ☐

SCHEDULE OF COLLECTION

	Screen	Study Day 1	Study Day 8	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	ET	Wk 14	Wk 16
Plasma			X	X				X									
Blood Chem	X							X							X		X
Hematology	X							X							X		X

If samples are not collected on the scheduled date, please collect the sample at the next visit and make an entry onto the BLOOD/PLASMA Sample form in Medidata.

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033
STUDY DAY 8

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form must be completed on Study Day 8. Any subject who fails to show up on Study Day 8, must have their participation in the study terminated.

1. Number of subject-reported cocaine use days during the 30 days immediately prior to screening

   ☐☐ days

2. Did subject continue viewing the computer-based Alcohol Intervention on Study Day 8?

   ☐ Yes ☐ No (opted out in writing)

3. Does the subject have a diagnosis of current Alcohol Use Disorder per the SCID?

   ☐ Yes ☐ No

4. Does the subject have a diagnosis of current Sedative, Hypnotic, or Anxiolytic Use Disorder per the SCID?

   ☐ Yes ☐ No

5. Is the subject willing to be randomized into the study?

   ☐ Yes ☐ No (terminate from study)

NOTE: ***INFORMATION CONTAINED WITHIN THIS FORM IS REQUIRED TO BE ENTERED INTO THE WEB-BASED RANDOMIZATION SYSTEM. AN E-MAIL CONFIRMING RANDOMIZATION AND TREATMENT KIT ASSIGNMENT WILL SERVE AS SOURCE DOCUMENTATION.***

Form Completed By _____ Date _____
(Print Name)

Date Entered into eDC _____

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
STUDY WEEK 1

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

One "standard drink" is equal to:
- 12 oz. of beer
- 4 oz. of wine
- 2.5 oz. of fortified wine
- 1 oz. of hard liquor

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively beginning on Study Day 8. Leave no gaps between dates. Continue on next weekly form.

	Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	#
STUDY DAY 1 →		☐	☐	☐	☐	☐		**YES NO**	
		☐	☐	☐	☐	☐		**YES NO**	
		☐	☐	☐	☐	☐		**YES NO**	
		☐	☐	☐	☐	☐		**YES NO**	
		☐	☐	☐	☐	☐		**YES NO**	
		☐	☐	☐	☐	☐		**YES NO**	
		☐	☐	☐	☐	☐		**YES NO**	

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

QUIT to QUIT: Computer-Based Alcohol Intervention Modules

1. Did the subject view the Quit to Quit computer-based alcohol intervention module scheduled for this week?

   ☐ Yes
   ☐ No

NOTE: The alcohol intervention is mandatory at Study Day 1 and optional at Study Day 8, week 3, & week 8. If the subject declines to continue viewing the intervention on Study Day 8, a signed Participant Acknowledgment is required.

2. Date the subject viewed the alcohol intervention module: _____ / _____ / _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT # ALPHA

STAFF INSTRUCTIONS: This form is used to record the participant's decision to continue viewing the alcohol intervention on Study Day 8. The decision (yes/no) to continue to view the alcohol intervention that is recorded at randomization should come from this form. A signature will be regarded as a "no" response in the randomization system. This form is to be kept strictly on-site and will not be sent to the coordinating center.

PARTICIPANT ACKNOWLEDGMENT:

It has been explained to me that quitting alcohol could help me to succeed in quitting cocaine, and I understand that the Quit to Quit program is designed to help me quit alcohol. I have been offered the opportunity to continue viewing the Quit to Quit program today, but I do not wish to continue. By signing below, I decline to continue viewing the Quit to Quit computer-based alcohol intervention.

_____ _____
Participant Signature Date

_____ _____
Signature Obtained By (staff) Date

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

NIDA/VA CS #1033
BECK DEPRESSION INVENTORY II

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Patterns) or Item 18 (Changes in Appetite).

1. Sadness

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time and I can't snap out of it.
3 I am so sad or unhappy that I can't stand it.

2. Pessimisim

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

0 I do not feel like a failure.
1 I feel I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

0 I don't cry any more than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

11. Agitation

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.
1 I do not consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.

1a I sleep somewhat more than usual
1b I sleep somewhat less than usual.

2a I sleep a lot more than usual.
2b I sleep a lot less than usual.

3a I sleep most of the day.
3b I wake up 1 – 2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.

2a My appetite is much less than before.
2b My appetite is much greater than usual.

3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

THANK YOU.

THIS FORM IS COMPLETE.

STAFF USE ONLY:

Form Reviewed By (staff) _____ Date _____

Total Score: _____

*see Study Operations Manual for instructions on scoring the BDI-II

Notes...

Week 3

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 3:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology - Treatment
☐	Pregnancy Test (female subjects only)
☐	Blood/Plasma Samples
☐	Vital Signs
☐	SUR
☐	Behavioral Therapy* ***The third computerized Alcohol Intervention (optional) is due.**
☐	C-SSRS (Since Last Visit)
☐	BSCS

PAYMENT FOR WEEK 3:

WEEK 3	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
BLOOD/PLASMA SAMPLES

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Were any blood and/or plasma samples drawn at today's visit? ☐ YES ☐ NO

If **YES**, Date Sample(s) Collected ____ / ____ / _____

INDICATE WHAT TYPE OF SAMPLES WERE COLLECTED AT TODAY'S VISIT (*mark all that apply*)

1. Plasma (*Xenobiotics*) ☐
2. Blood Chemistry (*Q2*) ☐
3. Hematology (*Q2*) ☐

SCHEDULE OF COLLECTION

	Screen	Study Day 1	Study Day 8	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	ET	Wk 14	Wk 16
Plasma			X	X				X									
Blood Chem	X							X							X		X
Hematology	X							X							X		X

If samples are not collected on the scheduled date, please collect the sample at the next visit and make an entry onto the BLOOD/PLASMA Sample form in Medidata.

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ____ Date Entered into eDC ______________________
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

QUIT to QUIT: Computer-Based Alcohol Intervention Modules

1. Did the subject view the Quit to Quit computer-based alcohol intervention module scheduled for this week?

   ☐ Yes
   ☐ No

NOTE: The alcohol intervention is mandatory at Study Day 1 and optional at Study Day 8, week 3, & week 8. If the subject declines to continue viewing the intervention on Study Day 8, a signed Participant Acknowledgment is required.

2. Date the subject viewed the alcohol intervention module: _____ / _____ / _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

Week 4

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 4:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology - Treatment
☐	Pregnancy Test (female subjects only)
☐	Vital Signs
☐	SUR
☐	Behavioral Therapy
☐	C-SSRS (Since Last Visit)
☐	BSCS
☐	Beck Depression Inventory II (BDI-II)

PAYMENT FOR WEEK 4:

WEEK 4	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
- 12 oz. of beer
- 4 oz. of wine
- 2.5 oz. of fortified wine
- 1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ________________________________ Date Entered into eDC ____________________
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

NIDA/VA CS #1033
BECK DEPRESSION INVENTORY II

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Patterns) or Item 18 (Changes in Appetite).

1. Sadness

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time and I can't snap out of it.
3 I am so sad or unhappy that I can't stand it.

2. Pessimisim

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

0 I do not feel like a failure.
1 I feel I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

0 I don't cry any more than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

11. Agitation

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.
1 I do not consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.

1a I sleep somewhat more than usual
1b I sleep somewhat less than usual.

2a I sleep a lot more than usual.
2b I sleep a lot less than usual.

3a I sleep most of the day.
3b I wake up 1 – 2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.

2a My appetite is much less than before.
2b My appetite is much greater than usual.

3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

THANK YOU.

THIS FORM IS COMPLETE.

STAFF USE ONLY:

Form Reviewed By (staff) _____ Date _____

Total Score: _____

*see Study Operations Manual for instructions on scoring the BDI-II

Notes...

Week 5

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 5:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology - Treatment
☐	Pregnancy Test (female subjects only)
☐	Vital Signs
☐	SUR
☐	Behavioral Therapy
☐	C-SSRS (Since Last Visit)
☐	BSCS

PAYMENT FOR WEEK 5:

WEEK 5	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ____ Date Entered into eDC ______________________
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

Week 6

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 6:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology
☐	Pregnancy Test (female subjects only)
☐	Vital Signs
☐	SUR
☐	Behavioral Therapy
☐	C-SSRS (Since Last Visit)
☐	BSCS
☐	Beck Depression Inventory II (BDI-II)

PAYMENT FOR WEEK 6:

WEEK 6	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
BONUS: Attended 4 weekly visits in a row (3, 4, 5, 6)	$20	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
- 12 oz. of beer
- 4 oz. of wine
- 2.5 oz. of fortified wine
- 1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ______________________________ Date Entered into eDC ____________________
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

NIDA/VA CS #1033
BECK DEPRESSION INVENTORY II

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Patterns) or Item 18 (Changes in Appetite).

1. Sadness

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time and I can't snap out of it.
3 I am so sad or unhappy that I can't stand it.

2. Pessimisim

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

0 I do not feel like a failure.
1 I feel I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

0 I don't cry any more than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

11. Agitation

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.
1 I do not consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.

1a I sleep somewhat more than usual
1b I sleep somewhat less than usual.

2a I sleep a lot more than usual.
2b I sleep a lot less than usual.

3a I sleep most of the day.
3b I wake up 1 – 2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.

2a My appetite is much less than before.
2b My appetite is much greater than usual.

3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

THANK YOU.

THIS FORM IS COMPLETE.

STAFF USE ONLY:

Form Reviewed By (staff) _____ Date _____

Total Score: _____

*see Study Operations Manual for instructions on scoring the BDI-II

Notes...

Week 7

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 7:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology * *includes sample for Q^2 medical urinalysis
☐	Pregnancy Test (female subjects only)
☐	Blood/Plasma Samples
☐	Vital Signs
☐	ECG
☐	SUR
☐	Behavioral Therapy
☐	C-SSRS (Since Last Visit)
☐	BSCS

PAYMENT FOR WEEK 7:

WEEK 7	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
BLOOD/PLASMA SAMPLES

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Were any blood and/or plasma samples drawn at today's visit? ☐ YES ☐ NO

If **YES**, Date Sample(s) Collected ____ / ____ / _____

INDICATE WHAT TYPE OF SAMPLES WERE COLLECTED AT TODAY'S VISIT (*mark all that apply*)

1. Plasma (*Xenobiotics*) ☐
2. Blood Chemistry (*Q2*) ☐
3. Hematology (*Q2*) ☐

SCHEDULE OF COLLECTION

	Screen	Study Day 1	Study Day 8	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	ET	Wk 14	Wk 16
Plasma			X	X				X									
Blood Chem	X							X							X		X
Hematology	X							X							X		X

If samples are not collected on the scheduled date, please collect the sample at the next visit and make an entry onto the BLOOD/PLASMA Sample form in Medidata.

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS # 1033
ECG

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

ECG PAPER STRIP WILL ALSO SERVE AS SOURCE

1. Was an ECG performed? ☐ Yes ☐ No

IF YES, please record the results below:

2. Date of ECG _____ / _____ / _____
3. Ventricular Rate _____ bpm
4. PR _____ ms
5. QRS _____ ms
6. QTc _____ ms
7. ECG overall results were: ☐ Normal ☐ Abnormal

IF ABNORMAL, MARK ALL ABNORMALITIES NOTED BELOW:

	Abnormal Condition	Mark with an (X)
8.	1st degree A-V block	
9.	2nd degree A-V block	
10.	3rd degree A-V block	
11.	Acute infarction	
12.	Increased QRS voltage	
13.	Left ventricular hypertrophy	
14.	Myocardial ischemia	
15.	Old Infarction	
16.	Other nonspecific ST/T	
17.	Poor R-wave progression	
18.	Qtc prolongation	

	Abnormal Condition	Mark with an (X)
19.	Right ventricular hypertrophy	
20.	Sinus tachycardia	
21.	Sinus bradycardia	
22.	Subacute infarction	
23.	Supraventricular premature beat	
24.	Supraventricular tachycardia	
25.	Symmetrical t-wave inversions	
26.	Ventricular premature beat	
27.	Ventricular tachycardia	
28.	Other, specify _____	
29.	Other, specify _____	

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ____ Date Entered into eDC ______________________
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

Week 8

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 8:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology
☐	Pregnancy Test (female subjects only)
☐	Vital Signs
☐	SUR
☐	Behavioral Therapy* ***The fourth computerized Alcohol Intervention (optional) is due.**
☐	C-SSRS (Since Last Visit)
☐	BSCS
☐	Beck Depression Inventory II (BDI-II)

PAYMENT FOR WEEK 8:

WEEK 8	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ______________________________________ Date Entered into eDC ____________________
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

NIDA/VA CS #1033
BECK DEPRESSION INVENTORY II

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Patterns) or Item 18 (Changes in Appetite).

1. Sadness

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time and I can't snap out of it.
3 I am so sad or unhappy that I can't stand it.

2. Pessimisim

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

0 I do not feel like a failure.
1 I feel I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

0 I don't cry any more than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

11. Agitation

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.
1 I do not consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.

1a I sleep somewhat more than usual
1b I sleep somewhat less than usual.

2a I sleep a lot more than usual.
2b I sleep a lot less than usual.

3a I sleep most of the day.
3b I wake up 1 – 2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.

2a My appetite is much less than before.
2b My appetite is much greater than usual.

3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

THANK YOU.

THIS FORM IS COMPLETE.

STAFF USE ONLY:

Form Reviewed By (staff) _____ Date _____

Total Score: _____

*see Study Operations Manual for instructions on scoring the BDI-II

Notes...

Week 9

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 9:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology
☐	Pregnancy Test (female subjects only)
☐	Vital Signs
☐	SUR
☐	Behavioral Therapy
☐	C-SSRS (Since Last Visit)
☐	BSCS

PAYMENT FOR WEEK 9:

WEEK 9	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
- 12 oz. of beer
- 4 oz. of wine
- 2.5 oz. of fortified wine
- 1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ______________________________ Date Entered into eDC ____________________
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

Week 10

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 10:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology
☐	Pregnancy Test (female subjects only)
☐	Vital Signs
☐	SUR
☐	Behavioral Therapy
☐	C-SSRS (Since Last Visit)
☐	BSCS
☐	Beck Depression Inventory II (BDI-II)

PAYMENT FOR WEEK 10:

WEEK 10	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
BONUS: Attended 4 weekly visits in a row (7, 8, 9, 10)	$30	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By _______________________________________ Date Entered into eDC ____________________
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

NIDA/VA CS #1033
BECK DEPRESSION INVENTORY II

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Patterns) or Item 18 (Changes in Appetite).

1. Sadness

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time and I can't snap out of it.
3 I am so sad or unhappy that I can't stand it.

2. Pessimisim

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

0 I do not feel like a failure.
1 I feel I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

0 I don't cry any more than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

11. Agitation

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.
1 I do not consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.

1a I sleep somewhat more than usual
1b I sleep somewhat less than usual.

2a I sleep a lot more than usual.
2b I sleep a lot less than usual.

3a I sleep most of the day.
3b I wake up 1 – 2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.

2a My appetite is much less than before.
2b My appetite is much greater than usual.

3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

THANK YOU.

THIS FORM IS COMPLETE.

STAFF USE ONLY:

Form Reviewed By (staff) _____ Date _____

Total Score: _____

*see Study Operations Manual for instructions on scoring the BDI-II

Notes...

Week 11

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 11:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology
☐	Pregnancy Test (female subjects only)
☐	Vital Signs
☐	SUR
☐	Behavioral Therapy
☐	C-SSRS (Since Last Visit)
☐	BSCS

PAYMENT FOR WEEK 11:

WEEK 11	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ________________________________ Date Entered into eDC ____________________
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

Week 12

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 12:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology
☐	Pregnancy Test (female subjects only)
☐	Vital Signs
☐	SUR
☐	Behavioral Therapy
☐	C-SSRS (Since Last Visit)
☐	BSCS
☐	Beck Depression Inventory II (BDI-II)

PAYMENT FOR WEEK 12:

WEEK 12	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ______________________________ Date Entered into eDC ______________
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

NIDA/VA CS #1033
BECK DEPRESSION INVENTORY II

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Patterns) or Item 18 (Changes in Appetite).

1. Sadness

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time and I can't snap out of it.
3 I am so sad or unhappy that I can't stand it.

2. Pessimisim

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

0 I do not feel like a failure.
1 I feel I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

0 I don't cry any more than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

11. Agitation

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.
1 I do not consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.

1a I sleep somewhat more than usual
1b I sleep somewhat less than usual.

2a I sleep a lot more than usual.
2b I sleep a lot less than usual.

3a I sleep most of the day.
3b I wake up 1 – 2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.

2a My appetite is much less than before.
2b My appetite is much greater than usual.

3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

THANK YOU.

THIS FORM IS COMPLETE.

STAFF USE ONLY:

Form Reviewed By (staff) _____ Date _____

Total Score: _____

*see Study Operations Manual for instructions on scoring the BDI-II

Notes...

Week 13

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 13:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology
☐	Pregnancy Test (female subjects only)
☐	Vital Signs
☐	SUR
☐	Behavioral Therapy
☐	C-SSRS (Since Last Visit)
☐	ASI-Lite
☐	BSCS

PAYMENT FOR WEEK 13:

WEEK 13	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ____________________________________ Date Entered into eDC ____________________
(Print Name)

Notes...

NIDA/VA CS # 1033
COGNITIVE BEHAVIORAL THERAPY

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?

   ☐ Yes
   ☐ No

2. If Yes, date of session _____ / _____ / _____

3. Length of session (minutes) _____ mins

4. Other behavioral method used to reduce cocaine use?

   ☐ Motivational Books
   ☐ Audio Tapes / CDs
   ☐ Hypnosis
   ☐ Acupuncture
   ☐ Other, Specify _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

Addiction Severity Index *Lite* - CF

Clinical/Training Version

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

Remember: This is an interview, not a test

≈Item numbers (circled) are to be asked at follow-up.≈
≈Items with an asterisk* are cumulative and should be rephrased at follow-up.≈
≈Items in a double border gray box are questions for the interviewer. Do not ask these questions of the client.≈

INTRODUCING THE ASI: Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological. All clients receive this same standard interview. All information gathered is confidential.

There are two time periods we will discuss:

1. The past 30 days
2. Lifetime Data

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

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

If you are uncomfortable giving an answer, then don't answer.

Please do not give inaccurate information!

INTERVIEWER INSTRUCTIONS:

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

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

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

Probe and make plenty of comments!

HOLLINGSHEAD CATEGORIES:

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

LIST OF COMMONLY USED DRUGS:

Alcohol:	Beer, wine, liquor
Methadone:	Dolophine, LAAM
Opiates:	Pain killers = Morphine, Dilaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2,3,4, Syrups = Robitussin, Fentanyl
Barbiturates:	Nembutal, Seconal, Tuinal, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinal
Sed/Hyp/Tranq:	Benzodiazepines = Valium, Librium, Ativan, Serax Tranxene, Dalmane, Halcion, Xanax, Miltown, Other = Chloral Hydrate, Quaaludes
Cocaine:	Cocaine Crystal, Free-Base Cocaine or Crack, and "Rock Cocaine"
Amphetamines:	Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin, Methamphetamine, Speed, Ice, Crystal
Cannabis:	Marijuana, Hashish
Hallucinogens:	LSD (Acid), Mescaline, Psilocybin (Mushrooms), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstacy
Inhalants:	Nitrous Oxide (Whippits), Amyl Nitrite (Poppers), Glue, Solvents, Gasoline, Toluene, Etc.

Just note if these are used: Antidepressants,
Ulcer Meds = Zantac, Tagamet
Asthma Meds = Ventolin Inhaler, Theodur
Other Meds = Antipsychotics, Lithium

ALCOHOL/DRUG USE INSTRUCTIONS:

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

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

Revised- 06/02/99 DC/TRJ

Addiction Severity Index *Lite* - Training Version

GENERAL INFORMATION

___ ___ ___ ___ Subject ID#

___ ___ ___ ___ ALPHA

G5. Date of Interview: ☐☐ / ☐☐ / ☐☐☐

G8. Class: *(circle one)* 1 = Baseline 2 = Follow-up

G12. ___*check here if assessment* REFUSED, FORGOTTEN, or NOT DONE

G11. Interview Conducted By:

_____

Date Entered into eDC_____

G18. Do you have a religious preference? ☐

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

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

1. No
2. Jail
3. Alcohol/Drug Treat.
4. Medical Treatment
5. Psychiatric Treatment
6. Other: _____

•A place, theoretically, without access to drugs/alcohol.

G20. How many days? ☐☐

•"NN" if Question G19 is No. Refers to <u>total</u> number of days detained in the past 30 days.

NOTE: Section G of the ASI-Lite has been amended to fit the protocol requirements for NIDA/VA CS #1033. Questions from Section G. that are non-applicable or redundant with other data collected have been removed.

MEDICAL STATUS

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

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

M3. Do you have any chronic medical problems which continue to interfere with your life? 0 -No 1 - Yes ☐

- ***If "Yes", specify in comments.***
- A chronic medical condition is a serious physical condition that requires regular care, (i.e., medication, dietary restriction) preventing full advantage of their abilities.

M4. Are you taking any prescribed medication on a regular basis for a physical problem? 0 - No 1 - Yes ☐

- ***If Yes, specify in comments.***
- Medication prescribed by a MD for medical conditions; ***not psychiatric medicines***. Include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems.

M5. Do you receive a pension for a physical disability? 0 - No 1 - Yes ☐

- ***If Yes, specify in comments.***
- Include Workers' compensation, exclude psychiatric disability.

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

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

For Questions M7 & M8, ask the patient to use the Patient Rating scale.

M7. How troubled or bothered have you been by ☐

- Restrict response to problem days of Question M6.

M8. How important to you *now* is treatment for ☐

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

CONFIDENCE RATINGS

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

M10. Patient's misrepresentation? ☐

M11. Patient's inability to understand? ☐

MEDICAL COMMENTS

(Include question number with your notes)

EMPLOYMENT/SUPPORT STATUS

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

Years ☐☐ Months ☐☐

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

Months ☐☐

E4. Do you have a valid driver's license?
- Valid license; not suspended/revoked.

0 - No 1 - Yes ☐

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

0 - No 1 - Yes ☐

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

☐☐ / ☐☐
Yrs / Mos

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

E9 Does someone contribute the majority of your support?

0 - No 1 - Yes ☐

E10. Usual employment pattern, past three years? ☐

1. Full time (35+ hours)
2. Part time (regular hours)
3. Part time (irregular hours)
4. Student
5. Service
6. Retired/Disability
7. Unemployed
8. In controlled environment

- Answer should represent the *majority* of the last 3 years, not just the most recent selection. If there are equal times for more than one category, select that which best represents more current situation.

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

EMPLOYMENT/SUPPORT COMMENTS
(Include question number with your notes)

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

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

E13. Unemployment Compensation? ☐☐☐☐☐

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

E15. Pensions, benefits or Social Security? ☐☐☐☐☐
- Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.

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

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

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

E19. How many days have you experienced employment problems in the past 30 ? ☐☐
- Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized.

For Question E20, ask the patient to use the Patient Rating scale.

E20. How troubled or bothered have you been by these ☐
- If the patient has been incarcerated or detained during the

E21. How important to you *now* is counseling for ☐
- The patient's ratings in Questions E20-21 refer to Question E19.
- Stress help in finding or preparing for a job, not giving them a job.

CONFIDENCE RATINGS

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

E23. Patient's misrepresentation 0-No 1-Yes ☐

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

EMPLOYMENT/SUPPORT COMMENTS

(Include question number with your notes)

ALCOHOL/DRUGS

Route of Administration Types:

1. Oral 2. Nasal 3. Smoking 4. Non-IV injection 5. IV

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

		Past 30 Days	Lifetime (years)	Route of Admin
D1	Alcohol (any use at all)	☐☐	☐☐	■
D2	Alcohol (to intoxication)	☐☐	☐☐	■
D3	Heroin	☐☐	☐☐	☐
D4	Methadone	☐☐	☐☐	☐
D5	Other Opiates/Analgesics	☐☐	☐☐	☐
D6	Barbiturates	☐☐	☐☐	☐
D7	Sedatives/Hypnotics/ Tranquilizers	☐☐	☐☐	☐
D8	Cocaine	☐☐	☐☐	☐
D9	Amphetamines	☐☐	☐☐	☐
D10	Cannabis	☐☐	☐☐	☐
D11	Hallucinogens	☐☐	☐☐	☐
D12	Inhalants	☐☐	☐☐	☐
D13	More than 1 substance per day (including alcohol)	☐☐	☐☐	■

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

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

ALCOHOL/DRUGS COMMENTS

(Include question number with your notes)

ALCOHOL/DRUGS (cont.)

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

D19*. Alcohol abuse? ☐☐

D20*. Drug abuse? ☐☐

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

How many of these were detox only:

D21. Alcohol? ☐☐

D22. Drugs? ☐☐

- If D19 = "00", then question D21 is "NN"
  If D20 = '00', then question D22 is "NN"

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

D23. Alcohol? ☐☐☐☐☐

D24. Drugs? ☐☐☐☐☐

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

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

For Questions D28-D31, ask the patient to use the Patient Rating scale.

How many days in the past 30 have you experienced:

D26. Alcohol problems? ☐☐

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

D28. Alcohol problems? ☐

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

D30. Alcohol problems? ☐

How many days in the past 30 have you experienced:

D27. Drug problems? ☐☐
- Include only: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.

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

D29. Drug problems? ☐

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

D31. Drug problems? ☐

CONFIDENCE RATINGS

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

D34. Patient's misrepresentation? 0-No 1-Yes ☐

D35. Patient's inability to understand? 0-No 1-Yes ☐

ALCOHOL/DRUGS COMMENTS

(Include question number with your notes)

LEGAL STATUS

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

L2. Are you on parole or probation? 0 - No 1 -Yes ☐
- Note duration and level in comments.

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

L3 * Shoplift/Vandal	☐☐	L10* Assault	☐☐
L4 * Parole/Probation	☐☐	L11* Arson	☐☐
L5 * Drug Charges	☐☐	L12* Rape	☐☐
L6 * Forgery	☐☐	L13* Homicide/Mansl.	☐☐
L7* Weapons Offense	☐☐	L14* Prostitution	☐☐
L8* Burglary/Larceny/B&E	☐☐	L15* Contempt of Court	☐☐
L9 * Robbery	☐☐	L16* Other: _____	☐☐

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

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

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

L18* Disorderly conduct, vagrancy, public intoxication? ☐☐

L19* Driving while intoxicated? ☐☐

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

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

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

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

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

LEGAL COMMENTS

(Include question number with your notes)

L27. How many days in the past 30 have you engaged in illegal activities for profit? ☐☐

- Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with Question E17 under Employment/Family Support Section.

For Questions L28-29, ask the patient to use the Patient Rating scale.

L28. How serious do you feel your present legal problems are? ☐

- Exclude civil problems

L29. How important to you *now* is counseling or referral for these legal problems? ☐

- Patient is rating a need for ***additional*** referral to legal counsel for defense against criminal charges.

CONFIDENCE RATINGS

Is the above information significantly distorted by:

L31. Patient's misrepresentation? 0 - No 1- Yes ☐

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

LEGAL COMMENTS

(Include question number with your notes)

FAMILY/SOCIAL RELATIONSHIPS

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

F3. Are you satisfied with this situation? ☐
0-No 1-Indifferent 2-Yes
● Satisfied = generally liking the situation. - Refers to Questions F1 & F2.

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

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

Do you live with anyone who:

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

F8 Uses non-prescribed drugs? 0-No 1-Yes ☐

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

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

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

	0 - No 1 - Yes Past 30 days	In Your Life
F18. Mother	☐	☐
F19. Father	☐	☐
F20. Brother/Sister	☐	☐
F21. Sexual Partner/Spouse	☐	☐
F22. Children	☐	☐
F23. Other Significant Family (specify)_____	☐	☐
F24. Close Friends	☐	☐
F25. Neighbors	☐	☐
F26. Co-workers		

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

Did anyone abuse you? 0- No 1-Yes

	Past 30 days	In Your Life
F28. Physically? ● Caused you physical harm.	☐	☐
F29. Sexually? ● Forced sexual advances/acts.	☐	☐

FAMILY/SOCIAL COMMENTS

(Include question number with your notes)

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

F30. With your family? ☐☐

For Questions F32-34, ask the patient to use the Patient Rating scale.

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

F32. Family problems ?

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

F34. Family problems

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

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

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

For Questions F33-35, ask the patient to use the Patient Rating scale.

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

F33. Social problems?

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

F35. Social problems

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

CONFIDENCE RATING

Is the above information significantly distorted by:

F37. Patient's misrepresentation? 0-No 1-Yes

F38. Patient's inability to understand?

FAMILY/SOCIAL COMMENTS

(Include question number with your notes)

PSYCHIATRIC STATUS

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

P1.* In a hospital or inpatient setting? ☐☐

P2.* Outpatient/private patient? ☐☐

- Do not include substance abuse, employment, or family counseling.

Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days.

- Enter diagnosis in comments if known.

P3. Do you receive a pension for a psychiatric disability? ☐

0-No 1-Yes

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

	0-No 1-Yes	
	Past 30 Days	Lifetime
P4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?	☐	☐
P5. Experienced serious anxiety/ tension,	☐	☐
P6. Experienced hallucinations-saw things or heard voices that were not there?	☐	☐
P7. Experienced trouble understanding,	☐	☐

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

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

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

- This refers to problems noted in Questions P4-P10.

For Questions P13-P14, ask the patient to use the Patient Rating scale

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

- Patient should be rating the problem days from Question P12.

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

CONFIDENCE RATING

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

P22 Patient's misrepresentation? 0-No 1-Yes ☐

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

PSYCHIATRIC STATUS COMMENTS

(Include question number with your comments)

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

Week 14

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 14:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology
☐	Pregnancy Test (female subjects only)
☐	Vital Signs
☐	SUR
☐	C-SSRS (Since Last Visit)
☐	Beck Depression Inventory II (BDI-II)

PAYMENT FOR WEEK 14:

WEEK 14	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
BONUS: **Attended 4 weekly visits in a row (11, 12, 13, 14)**	$40	YES	NO
Report Cocaine, Smoking and Alcohol Use Since Last Visit	$5	YES	NO
Return Pill Bottle	$5	YES	NO
# Capsules Returned = # of Expected +/- 3 (requires bottle return)	$15	YES	NO
Use Device to Report all Cocaine & Alcohol Use Since Last Visit	$15	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ______________________________ Date Entered into eDC ____________________
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

NIDA/VA CS #1033
BECK DEPRESSION INVENTORY II

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Patterns) or Item 18 (Changes in Appetite).

1. Sadness

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time and I can't snap out of it.
3 I am so sad or unhappy that I can't stand it.

2. Pessimisim

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

0 I do not feel like a failure.
1 I feel I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

0 I don't cry any more than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

11. Agitation

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.
1 I do not consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.

1a I sleep somewhat more than usual
1b I sleep somewhat less than usual.

2a I sleep a lot more than usual.
2b I sleep a lot less than usual.

3a I sleep most of the day.
3b I wake up 1 – 2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.

2a My appetite is much less than before.
2b My appetite is much greater than usual.

3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

THANK YOU.

THIS FORM IS COMPLETE.

STAFF USE ONLY:

Form Reviewed By (staff) _____ Date _____

Total Score: _____

*see Study Operations Manual for instructions on scoring the BDI-II

Notes...

Week 16

VISIT DATE: __ __ / __ __ / __ __

The following forms and assessments are due at Week 16:

☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology* *includes Q^2 sample for medical urinalysis
☐	Pregnancy Test (female subjects only)
☐	Blood/Plasma Samples
☐	Vital Signs
☐	Physical Exam
☐	ECG
☐	SUR
☐	C-SSRS (Since Last Visit)

PAYMENT FOR WEEK 16:

WEEK 16	**AMOUNT DUE**	**PAID** (CIRCLE ONE)	
Attend Visit	$15	YES	NO
Returned Device	$50	YES	NO

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
BLOOD/PLASMA SAMPLES

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Were any blood and/or plasma samples drawn at today's visit? ☐ YES ☐ NO

If **YES**, Date Sample(s) Collected ____ / ____ / _____

INDICATE WHAT TYPE OF SAMPLES WERE COLLECTED AT TODAY'S VISIT (*mark all that apply*)

1. Plasma (*Xenobiotics*) ☐
2. Blood Chemistry (*Q2*) ☐
3. Hematology (*Q2*) ☐

SCHEDULE OF COLLECTION

	Screen	Study Day 1	Study Day 8	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	ET	Wk 14	Wk 16
Plasma			X	X				X									
Blood Chem	X							X							X		X
Hematology	X							X							X		X

If samples are not collected on the scheduled date, please collect the sample at the next visit and make an entry onto the BLOOD/PLASMA Sample form in Medidata.

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS # 1033
PHYSICAL EXAM

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Indicate here if the Physical Exam was NOT conducted: ☐

1. Date of Physical Exam _____ / _____ / _____

2. Height (inches) ___ ___ ___ . ___

	EXAMINATION	FINDINGS		DESCRIPTION
		NORMAL	ABNORMAL	Items marked "ABNORMAL" require a DESCRIPTION *Please Print Clearly*
3.	General Appearance	☐	☐	
4.	Skin	☐	☐	
5.	HEENT (incl. thyroid, neck)	☐	☐	
6.	Lymph Nodes	☐	☐	
7.	Lungs	☐	☐	
8.	Cardiovascular	☐	☐	
9.	Abdomen (incl. liver, spleen)	☐	☐	
10.	Extremities/Musculoskeletal	☐	☐	
11.	Neuropsychiatric: Mental Status	☐	☐	
12.	Neuropsychiatric: Sensory/Motor	☐	☐	

Physical Performed By (Signature) _____ Date_____

Entered into eDC System By _____ Date Entered into eDC _____

Notes...

NIDA/VA CS # 1033
ECG

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

ECG PAPER STRIP WILL ALSO SERVE AS SOURCE

1. Was an ECG performed? ☐ Yes ☐ No

IF YES, please record the results below:

2. Date of ECG _____ / _____ / _____
3. Ventricular Rate _____ bpm
4. PR _____ ms
5. QRS _____ ms
6. QTc _____ ms
7. ECG overall results were: ☐ Normal ☐ Abnormal

IF ABNORMAL, MARK ALL ABNORMALITIES NOTED BELOW:

	Abnormal Condition	Mark with an (X)
8.	1st degree A-V block	
9.	2nd degree A-V block	
10.	3rd degree A-V block	
11.	Acute infarction	
12.	Increased QRS voltage	
13.	Left ventricular hypertrophy	
14.	Myocardial ischemia	
15.	Old Infarction	
16.	Other nonspecific ST/T	
17.	Poor R-wave progression	
18.	Qtc prolongation	

	Abnormal Condition	Mark with an (X)
19.	Right ventricular hypertrophy	
20.	Sinus tachycardia	
21.	Sinus bradycardia	
22.	Subacute infarction	
23.	Supraventricular premature beat	
24.	Supraventricular tachycardia	
25.	Symmetrical t-wave inversions	
26.	Ventricular premature beat	
27.	Ventricular tachycardia	
28.	Other, specify _____	
29.	Other, specify _____	

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
- 12 oz. of beer
- 4 oz. of wine
- 2.5 oz. of fortified wine
- 1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA**
WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ____ Date Entered into eDC ____________________
(Print Name)

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ____ Date Entered into eDC ______________________
(Print Name)

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
- 12 oz. of beer
- 4 oz. of wine
- 2.5 oz. of fortified wine
- 1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ______________________________ Date Entered into eDC ______________
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

VISIT DATE: __ __ / __ __ / __ __

To add an Early Termination Visit in Medidata, use the "Add Event" menu on the bottom of the subject's home page and select "Early Termination". The ET folder will appear.

The following forms and assessments are due at Early Term:

☐	Early Termination Form
☐	Adverse Events
☐	Concomitant Medications
☐	Urine Toxicology* *includes Q^2 sample for medical urinalysis
☐	Pregnancy Test
☐	Blood/Plasma Samples
☐	Vital Signs
☐	Physical Exam
☐	ECG
☐	SUR *complete SUR data retrospectively from the last date of entry until the ET visit
☐	C-SSRS (Since Last Visit)
☐	ASI-Lite
☐	BSCS
☐	Beck Depression Inventory II (BDI-II)

Notes…

EARLY TERM

NIDA/VA CS # 1033
EARLY TERMINATION

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Choose the **PRIMARY** reason subject was terminated early from the study:

☐ Serious or unexpected adverse event [*complete SAE form, notify NIDA*] (Specify):

_____

☐ Medical or psychiatric concern [*record on AE log*] (Specify):

_____

☐ Pregnancy [*record as an AE, notify NIDA*]

☐ Exclusion criterion emerged after subject was enrolled in study (Specify):

_____

☐ Protocol noncompliance (Specify):

_____

☐ Incarceration

☐ Subject requested withdrawal from the study (Specify):

_____

☐ Could not tolerate study drug [*record on AE log*]

☐ Other reason (Specify):

_____

☐ Subject failed to return on study Day 8

☐ Subject went 14 days without study meds

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

Investigator's Signature _____ Date _____
(Print Name)

Date entered into eDC _____

Notes...

VISIT DATE: ___ ___ / ___ ___ / ___ ___ ___ ___ ___ ___ -___ ___ ___ ___

Month Day Year Subject ID# ALPHA

PROGRESS NOTES: ADVERSE EVENTS & CON MEDS Use the prompts below to assess AEs* and Con Meds at the weekly study visit. **must be assessed by medically trained study staff, a physician must assign relatedness on the AE Log.*	**ASSESSED BY** (initials)
How have you been feeling since I saw you last? *Each week, a study physician must review all new AEs reported the previous week and any events that were reported as continuing (protocol,§13.10).* Physician's Signature:_____ Date:_____	
Have there been any changes to your current medications?	
Have you started any new medications since I last saw you?	
Detailed information regarding AEs and con meds should be recorded on the AE & Con Meds logs located in the front of the subject's workbook.	

Notes...

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a weekly Urine Sample Collected? ☐ YES ☐ NO

2. Date Urine Sample Collected ____ / ____ / ____
mm dd yy

3. Cotinine Test Result ☐ Positive ☐ Negative

4. EtG Test Result ☐ Positive ☐ Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology?
Specify a reason if a sample was not prepared.
☐ Yes
☐ No (Specify) _____

6. Was a back-up sample frozen?
Specify a reason if a back-up was not frozen.
☐ Yes
☐ No (Specify) _____

7. Was the sample prepared for **Q2** for medical urinalysis?
Please specify if the sample was not prepared.
☐ Yes
☐ No (Specify) _____
☐ Not Required
(required only in weeks 7 & 16)

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS #1033
PREGNANCY TEST

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

1. Was a Urine Pregnancy Test Performed?
   **required only for female subjects*

☐ YES

☐ NO, specify reason

_____

2. Date Urine Pregnancy Test Performed

____ / ____ / ____
mm dd yy

3. Pregnancy Test Result

☐ Positive

☐ Negative

Urine Results Recorded By_____
(Print Name)

Entered into eDC on_____
(Date)

Notes...

NIDA/VA CS # 1033
BLOOD/PLASMA SAMPLES

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Were any blood and/or plasma samples drawn at today's visit? ☐ YES ☐ NO

If **YES**, Date Sample(s) Collected ____ / ____ / _____

INDICATE WHAT TYPE OF SAMPLES WERE COLLECTED AT TODAY'S VISIT (*mark all that apply*)

1. Plasma (*Xenobiotics*) ☐
2. Blood Chemistry (*Q2*) ☐
3. Hematology (*Q2*) ☐

SCHEDULE OF COLLECTION

	Screen	Study Day 1	Study Day 8	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	ET	Wk 14	Wk 16
Plasma			X	X				X									
Blood Chem	X							X							X		X
Hematology	X							X							X		X

If samples are not collected on the scheduled date, please collect the sample at the next visit and make an entry onto the BLOOD/PLASMA Sample form in Medidata.

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS # 1033
VITAL SIGNS

___ ___ ___ ___ -___ ___ ___ ___
SUBJECT ID# ALPHA

1. Were vital signs recorded at this visit?

☐ Yes
☐ No

2. Date Evaluated _____ / _____ / _____

3. Temperature _____ °F

Sitting Blood Pressure *(Subject must sit for 3 minutes prior to taking sitting BP.)*

4. Systolic Blood Pressure, Sitting _____ mm Hg

5. Diastolic Blood Pressure, Sitting _____ mm Hg

6. Pulse Rate _____ bpm

7. Respiratory Rate _____ breaths / min

8. Weight *(to nearest pound)* _____ lbs

9. BMI _____

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS # 1033
PHYSICAL EXAM

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

Indicate here if the Physical Exam was NOT conducted: ☐

1. Date of Physical Exam _____ / _____ / _____

2. Height (inches) ___ ___ ___ . ___

	EXAMINATION	FINDINGS		DESCRIPTION
		NORMAL	ABNORMAL	Items marked "ABNORMAL" require a DESCRIPTION *Please Print Clearly*
3.	General Appearance	☐	☐	
4.	Skin	☐	☐	
5.	HEENT (incl. thyroid, neck)	☐	☐	
6.	Lymph Nodes	☐	☐	
7.	Lungs	☐	☐	
8.	Cardiovascular	☐	☐	
9.	Abdomen (incl. liver, spleen)	☐	☐	
10.	Extremities/Musculoskeletal	☐	☐	
11.	Neuropsychiatric: Mental Status	☐	☐	
12.	Neuropsychiatric: Sensory/Motor	☐	☐	

Physical Performed By (Signature) _____ Date_____

Entered into eDC System By _____ Date Entered into eDC _____

Notes...

NIDA/VA CS # 1033
ECG

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

ECG PAPER STRIP WILL ALSO SERVE AS SOURCE

1. Was an ECG performed? ☐ Yes ☐ No

IF YES, please record the results below:

2. Date of ECG _____ / _____ / _____
3. Ventricular Rate _____ bpm
4. PR _____ ms
5. QRS _____ ms
6. QTc _____ ms
7. ECG overall results were: ☐ Normal ☐ Abnormal

IF ABNORMAL, MARK ALL ABNORMALITIES NOTED BELOW:

	Abnormal Condition	Mark with an (X)
8.	1st degree A-V block	
9.	2nd degree A-V block	
10.	3rd degree A-V block	
11.	Acute infarction	
12.	Increased QRS voltage	
13.	Left ventricular hypertrophy	
14.	Myocardial ischemia	
15.	Old Infarction	
16.	Other nonspecific ST/T	
17.	Poor R-wave progression	
18.	Qtc prolongation	

	Abnormal Condition	Mark with an (X)
19.	Right ventricular hypertrophy	
20.	Sinus tachycardia	
21.	Sinus bradycardia	
22.	Subacute infarction	
23.	Supraventricular premature beat	
24.	Supraventricular tachycardia	
25.	Symmetrical t-wave inversions	
26.	Ventricular premature beat	
27.	Ventricular tachycardia	
28.	Other, specify _____	
29.	Other, specify _____	

Form Completed By _____ Date Entered into eDC _____
(Print Name)

Notes...

NIDA/VA CS #1033, SUBSTANCE USE REPORT (SUR)
WEEKLY (STUDY WEEKS 2 – 16)

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

This form will be used weekly to capture a **continuous record of substance use** for every day from Study Day 1 through the subject's final clinic visit.

Data are captured retrospectively for all days leading back to the last entry.

Daily cocaine and drinking data should be entered on this form only for days they are NOT entered into the AiView device by the subject.

One "standard drink" is equal to:
12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

☐ **CHECK HERE & LEAVE BLANK**
IF **ALL WEEKLY COCAINE & DRINKING DATA** WAS CAPTURED IN AiVIEW.

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	Check	#	Check
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

Form Completed By ______________________________ Date Entered into eDC ____________________
(Print Name)

Notes...

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL IDEATION

Ask questions 1 and 2. If both are negative, proceed to "Suicidal Behavior" section. If the answer to question 2 is "yes", ask questions 3, 4 and 5. If the answer to question 1 and/or 2 is "yes", complete "Intensity of Ideation" section below.

Since Last Visit

1. Wish to be Dead — **Yes** ☐ **No** ☐

Subject endorses thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.
Have you wished you were dead or wished you could go to sleep and not wake up?

If yes, describe:

2. Non-Specific Active Suicidal Thoughts — **Yes** ☐ **No** ☐

General, non-specific thoughts of wanting to end one's life/commit suicide (e.g., *"I've thought about killing myself"*) without thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.
Have you actually had any thoughts of killing yourself?

If yes, describe:

3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act — **Yes** ☐ **No** ☐

Subject endorses thoughts of suicide and has thought of at least one method during the assessment period. This is different than a specific plan with time, place or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, *"I thought about taking an overdose but I never made a specific plan as to when, where or how I would actually do it…and I would never go through with it."*
Have you been thinking about how you might do this?

If yes, describe:

4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan — **Yes** ☐ **No** ☐

Active suicidal thoughts of killing oneself and subject reports having some intent to act on such thoughts, as opposed to *"I have the thoughts but I definitely will not do anything about them."*
Have you had these thoughts and had some intention of acting on them?

If yes, describe:

5. Active Suicidal Ideation with Specific Plan and Intent — **Yes** ☐ **No** ☐

Thoughts of killing oneself with details of plan fully or partially worked out and subject has some intent to carry it out.
Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?

If yes, describe:

INTENSITY OF IDEATION

The following features should be rated with respect to the most severe type of ideation (i.e., 1-5 from above, with 1 being the least severe and 5 being the most severe).

Most Severe

Most Severe Ideation: _____ _____

Type # (1-5) ***Description of Ideation***

Frequency ____
How many times have you had these thoughts?
(1) Less than once a week (2) Once a week (3) 2-5 times in week (4) Daily or almost daily (5) Many times each day

Duration ____
When you have the thoughts, how long do they last?
(1) Fleeting - few seconds or minutes
(2) Less than 1 hour/some of the time
(3) 1-4 hours/a lot of time
(4) 4-8 hours/most of day
(5) More than 8 hours/persistent or continuous

Controllability ____
Could/can you stop thinking about killing yourself or wanting to die if you want to?
(1) Easily able to control thoughts
(2) Can control thoughts with little difficulty
(3) Can control thoughts with some difficulty
(4) Can control thoughts with a lot of difficulty
(5) Unable to control thoughts
(0) Does not attempt to control thoughts

Deterrents ____
Are there things - anyone or anything (e.g., family, religion, pain of death) - that stopped you from wanting to die or acting on thoughts of committing suicide?
(1) Deterrents definitely stopped you from attempting suicide
(2) Deterrents probably stopped you
(3) Uncertain that deterrents stopped you
(4) Deterrents most likely did not stop you
(5) Deterrents definitely did not stop you
(0) Does not apply

Reasons for Ideation ____
What sort of reasons did you have for thinking about wanting to die or killing yourself? Was it to end the pain or stop the way you were feeling (in other words you couldn't go on living with this pain or how you were feeling) or was it to get attention, revenge or a reaction from others? Or both?
(1) Completely to get attention, revenge or a reaction from others
(2) Mostly to get attention, revenge or a reaction from others
(3) Equally to get attention, revenge or a reaction from others and to end/stop the pain
(4) Mostly to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(5) Completely to end or stop the pain (you couldn't go on living with the pain or how you were feeling)
(0) Does not apply

COLUMBIA SUICIDE SEVERITY RATING SCALE (Since Last Visit) Ss ID/ALPHA: __ __ __ __ - __ __ __ __

SUICIDAL BEHAVIOR *(Check all that apply, so long as these are separate events; must ask about all types)*	Since Last Visit
Actual Attempt: A potentially self-injurious act committed with at least some wish to die, *as a result of act.* Behavior was in part thought of as method to kill oneself. Intent does not have to be 100%. If there is ***any*** intent/desire to die associated with the act, then it can be considered an actual suicide attempt. ***There does not have to be any injury or harm***, just the potential for injury or harm. If person pulls trigger while gun is in mouth but gun is broken so no injury results, this is considered an attempt. Inferring Intent: Even if an individual denies intent/wish to die, it may be inferred clinically from the behavior or circumstances. For example, a highly lethal act that is clearly not an accident so no other intent but suicide can be inferred (e.g., gunshot to head, jumping from window of a high floor/story). Also, if someone denies intent to die, but they thought that what they did could be lethal, intent may be inferred. ***Have you made a suicide attempt?*** ***Have you done anything to harm yourself?*** ***Have you done anything dangerous where you could have died?*** ***What did you do?*** ***Did you_____ as a way to end your life?*** ***Did you want to die (even a little) when you_____?*** ***Were you trying to end your life when you _____?*** ***Or did you think it was possible you could have died from_____?*** ***Or did you do it purely for other reasons / without ANY intention of killing yourself (like to relieve stress, feel better, get sympathy, or get something else to happen)?*** (Self-Injurious Behavior without suicidal intent) If yes, describe: **Has subject engaged in Non-Suicidal Self-Injurious Behavior?**	**Yes** ☐ **No** ☐ Total # of Attempts _____ **Yes** ☐ **No** ☐
Interrupted Attempt: When the person is interrupted (by an outside circumstance) from starting the potentially self-injurious act *(if not for that, actual attempt would have occurred).* Overdose: Person has pills in hand but is stopped from ingesting. Once they ingest any pills, this becomes an attempt rather than an interrupted attempt. Shooting: Person has gun pointed toward self, gun is taken away by someone else, or is somehow prevented from pulling trigger. Once they pull the trigger, even if the gun fails to fire, it is an attempt. Jumping: Person is poised to jump, is grabbed and taken down from ledge. Hanging: Person has noose around neck but has not yet started to hang - is stopped from doing so. ***Has there been a time when you started to do something to end your life but someone or something stopped you before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of interrupted _____
Aborted or Self-Interrupted Attempt: When person begins to take steps toward making a suicide attempt, but stops themselves before they actually have engaged in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops him/herself, instead of being stopped by something else. ***Has there been a time when you started to do something to try to end your life but you stopped yourself before you actually did anything?*** If yes, describe:	**Yes** ☐ **No** ☐ Total # of aborted or self-interrupted _____
Preparatory Acts or Behavior: Acts or preparation towards imminently making a suicide attempt. This can include anything beyond a verbalization or thought, such as assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note). ***Have you taken any steps towards making a suicide attempt or preparing to kill yourself (such as collecting pills, getting a gun, giving valuables away or writing a suicide note)?*** If yes, describe:	**Yes** ☐ **No** ☐
Suicidal Behavior: Suicidal behavior was present during the assessment period?	**Yes** ☐ **No** ☐
Suicide:	**Yes** ☐ **No** ☐
Answer for Actual Attempts Only	Most Lethal Attempt Date:
Actual Lethality/Medical Damage: 0. No physical damage or very minor physical damage (e.g., surface scratches). 1. Minor physical damage (e.g., lethargic speech; first-degree burns; mild bleeding; sprains). 2. Moderate physical damage; medical attention needed (e.g., conscious but sleepy, somewhat responsive; second-degree burns; bleeding of major vessel). 3. Moderately severe physical damage; *medical* hospitalization and likely intensive care required (e.g., comatose with reflexes intact; third-degree burns less than 20% of body; extensive blood loss but can recover; major fractures). 4. Severe physical damage; *medical* hospitalization with intensive care required (e.g., comatose without reflexes; third-degree burns over 20% of body; extensive blood loss with unstable vital signs; major damage to a vital area). 5. Death	*Enter Code* _____
Potential Lethality: Only Answer if Actual Lethality=0 Likely lethality of actual attempt if no medical damage (the following examples, while having no actual medical damage, had potential for very serious lethality: put gun in mouth and pulled the trigger but gun fails to fire so no medical damage; laying on train tracks with oncoming train but pulled away before run over). 0 = Behavior not likely to result in injury 1 = Behavior likely to result in injury but not likely to cause death 2 = Behavior likely to result in death despite available medical care	*Enter Code* _____

C-SSRS Conducted By (Signature):_____ **Date:**_____

Addiction Severity Index *Lite* - CF

Clinical/Training Version

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

Remember: This is an interview, not a test

≈Item numbers (circled) are to be asked at follow-up.≈
≈Items with an asterisk* are cumulative and should be rephrased at follow-up.≈
≈Items in a double border gray box are questions for the interviewer. Do not ask these questions of the client.≈

INTRODUCING THE ASI: Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological. All clients receive this same standard interview. All information gathered is confidential.

There are two time periods we will discuss:

1. The past 30 days
2. Lifetime Data

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

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

If you are uncomfortable giving an answer, then don't answer.

Please do not give inaccurate information!

INTERVIEWER INSTRUCTIONS:

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

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

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

Probe and make plenty of comments!

HOLLINGSHEAD CATEGORIES:

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

LIST OF COMMONLY USED DRUGS:

Alcohol:	Beer, wine, liquor
Methadone:	Dolophine, LAAM
Opiates:	Pain killers = Morphine, Dilaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2,3,4, Syrups = Robitussin, Fentanyl
Barbiturates:	Nembutal, Seconal, Tuinal, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinal
Sed/Hyp/Tranq:	Benzodiazepines = Valium, Librium, Ativan, Serax Tranxene, Dalmane, Halcion, Xanax, Miltown, Other = Chloral Hydrate, Quaaludes
Cocaine:	Cocaine Crystal, Free-Base Cocaine or Crack, and "Rock Cocaine"
Amphetamines:	Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin, Methamphetamine, Speed, Ice, Crystal
Cannabis:	Marijuana, Hashish
Hallucinogens:	LSD (Acid), Mescaline, Psilocybin (Mushrooms), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstacy
Inhalants:	Nitrous Oxide (Whippits), Amyl Nitrite (Poppers), Glue, Solvents, Gasoline, Toluene, Etc.

Just note if these are used: Antidepressants,
Ulcer Meds = Zantac, Tagamet
Asthma Meds = Ventolin Inhaler, Theodur
Other Meds = Antipsychotics, Lithium

ALCOHOL/DRUG USE INSTRUCTIONS:

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

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

Revised- 06/02/99 DC/TRJ

Addiction Severity Index *Lite* - Training Version

GENERAL INFORMATION

___ ___ ___ ___ Subject ID#

___ ___ ___ ___ ALPHA

G5. Date of Interview: ☐☐ / ☐☐ / ☐☐☐

G8. Class: *(circle one)* 1 = Baseline 2 = Follow-up

G12. ___*check here if assessment* REFUSED, FORGOTTEN, or NOT DONE

G11. Interview Conducted By:

_____

Date Entered into eDC_____

G18. Do you have a religious preference? ☐

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

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

1. No
2. Jail
3. Alcohol/Drug Treat.
4. Medical Treatment
5. Psychiatric Treatment
6. Other: _____

•A place, theoretically, without access to drugs/alcohol.

G20. How many days? ☐☐

•"NN" if Question G19 is No. Refers to <u>total</u> number of days detained in the past 30 days.

NOTE: Section G of the ASI-Lite has been amended to fit the protocol requirements for NIDA/VA CS #1033. Questions from Section G. that are non-applicable or redundant with other data collected have been removed.

MEDICAL STATUS

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

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

M3. Do you have any chronic medical problems which continue to interfere with your life? 0 -No 1 - Yes ☐

- ***If "Yes", specify in comments.***
- A chronic medical condition is a serious physical condition that requires regular care, (i.e., medication, dietary restriction) preventing full advantage of their abilities.

M4. Are you taking any prescribed medication on a regular basis for a physical problem? 0 - No 1 - Yes ☐

- ***If Yes, specify in comments.***
- Medication prescribed by a MD for medical conditions; ***not psychiatric medicines***. Include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems.

M5. Do you receive a pension for a physical disability? 0 - No 1 - Yes ☐

- ***If Yes, specify in comments.***
- Include Workers' compensation, exclude psychiatric disability.

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

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

For Questions M7 & M8, ask the patient to use the Patient Rating scale.

M7. How troubled or bothered have you been by ☐

- Restrict response to problem days of Question M6.

M8. How important to you *now* is treatment for ☐

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

CONFIDENCE RATINGS

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

M10. Patient's misrepresentation? ☐

M11. Patient's inability to understand? ☐

MEDICAL COMMENTS

(Include question number with your notes)

EMPLOYMENT/SUPPORT STATUS

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

Years ☐☐ Months ☐☐

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

Months ☐☐

E4. Do you have a valid driver's license?
- Valid license; not suspended/revoked.

0 - No 1 - Yes ☐

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

0 - No 1 - Yes ☐

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

☐☐ / ☐☐
Yrs / Mos

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

E9 Does someone contribute the majority of your support?

0 - No 1 - Yes ☐

E10. Usual employment pattern, past three years? ☐

1. Full time (35+ hours)
2. Part time (regular hours)
3. Part time (irregular hours)
4. Student
5. Service
6. Retired/Disability
7. Unemployed
8. In controlled environment

- Answer should represent the *majority* of the last 3 years, not just the most recent selection. If there are equal times for more than one category, select that which best represents more current situation.

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

EMPLOYMENT/SUPPORT COMMENTS
(Include question number with your notes)

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

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

E13. Unemployment Compensation? ☐☐☐☐☐

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

E15. Pensions, benefits or Social Security? ☐☐☐☐☐
- Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.

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

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

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

E19. How many days have you experienced employment problems in the past 30 ? ☐☐
- Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized.

For Question E20, ask the patient to use the Patient Rating scale.

E20. How troubled or bothered have you been by these ☐
- If the patient has been incarcerated or detained during the

E21. How important to you *now* is counseling for ☐
- The patient's ratings in Questions E20-21 refer to Question E19.
- Stress help in finding or preparing for a job, not giving them a job.

CONFIDENCE RATINGS

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

E23. Patient's misrepresentation 0-No 1-Yes ☐

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

EMPLOYMENT/SUPPORT COMMENTS

(Include question number with your notes)

ALCOHOL/DRUGS

Route of Administration Types:

1. Oral 2. Nasal 3. Smoking 4. Non-IV injection 5. IV

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

		Past 30 Days	Lifetime (years)	Route of Admin
D1	Alcohol (any use at all)	☐☐	☐☐	■
D2	Alcohol (to intoxication)	☐☐	☐☐	■
D3	Heroin	☐☐	☐☐	☐
D4	Methadone	☐☐	☐☐	☐
D5	Other Opiates/Analgesics	☐☐	☐☐	☐
D6	Barbiturates	☐☐	☐☐	☐
D7	Sedatives/Hypnotics/ Tranquilizers	☐☐	☐☐	☐
D8	Cocaine	☐☐	☐☐	☐
D9	Amphetamines	☐☐	☐☐	☐
D10	Cannabis	☐☐	☐☐	☐
D11	Hallucinogens	☐☐	☐☐	☐
D12	Inhalants	☐☐	☐☐	☐
D13	More than 1 substance per day (including alcohol)	☐☐	☐☐	■

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

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

ALCOHOL/DRUGS COMMENTS

(Include question number with your notes)

ALCOHOL/DRUGS (cont.)

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

D19*. Alcohol abuse? ☐☐

D20*. Drug abuse? ☐☐

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

How many of these were detox only:

D21. Alcohol? ☐☐

D22. Drugs? ☐☐

- If D19 = "00", then question D21 is "NN"
  If D20 = '00', then question D22 is "NN"

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

D23. Alcohol? ☐☐☐☐☐

D24. Drugs? ☐☐☐☐☐

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

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

For Questions D28-D31, ask the patient to use the Patient Rating scale.

How many days in the past 30 have you experienced:

D26. Alcohol problems? ☐☐

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

D28. Alcohol problems? ☐

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

D30. Alcohol problems? ☐

How many days in the past 30 have you experienced:

D27. Drug problems? ☐☐
- Include only: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.

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

D29. Drug problems? ☐

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

D31. Drug problems? ☐

CONFIDENCE RATINGS

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

D34. Patient's misrepresentation? 0-No 1-Yes ☐

D35. Patient's inability to understand? 0-No 1-Yes ☐

ALCOHOL/DRUGS COMMENTS

(Include question number with your notes)

LEGAL STATUS

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

L2. Are you on parole or probation? 0 - No 1 -Yes ☐
- Note duration and level in comments.

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

L3 * Shoplift/Vandal	☐☐	L10* Assault	☐☐
L4 * Parole/Probation	☐☐	L11* Arson	☐☐
L5 * Drug Charges	☐☐	L12* Rape	☐☐
L6 * Forgery	☐☐	L13* Homicide/Mansl.	☐☐
L7* Weapons Offense	☐☐	L14* Prostitution	☐☐
L8* Burglary/Larceny/B&E	☐☐	L15* Contempt of Court	☐☐
L9 * Robbery	☐☐	L16* Other: _____	☐☐

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

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

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

L18* Disorderly conduct, vagrancy, public intoxication? ☐☐

L19* Driving while intoxicated? ☐☐

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

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

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

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

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

LEGAL COMMENTS

(Include question number with your notes)

L27. How many days in the past 30 have you engaged in illegal activities for profit? ☐☐

- Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with Question E17 under Employment/Family Support Section.

For Questions L28-29, ask the patient to use the Patient Rating scale.

L28. How serious do you feel your present legal problems are? ☐

- Exclude civil problems

L29. How important to you *now* is counseling or referral for these legal problems? ☐

- Patient is rating a need for ***additional*** referral to legal counsel for defense against criminal charges.

CONFIDENCE RATINGS

Is the above information significantly distorted by:

L31. Patient's misrepresentation? 0 - No 1- Yes ☐

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

LEGAL COMMENTS

(Include question number with your notes)

FAMILY/SOCIAL RELATIONSHIPS

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

F3. Are you satisfied with this situation? ☐
0-No 1-Indifferent 2-Yes
● Satisfied = generally liking the situation. - Refers to Questions F1 & F2.

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

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

Do you live with anyone who:

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

F8 Uses non-prescribed drugs? 0-No 1-Yes ☐

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

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

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

	0 - No 1 - Yes Past 30 days	In Your Life
F18. Mother	☐	☐
F19. Father	☐	☐
F20. Brother/Sister	☐	☐
F21. Sexual Partner/Spouse	☐	☐
F22. Children	☐	☐
F23. Other Significant Family (specify)_____	☐	☐
F24. Close Friends	☐	☐
F25. Neighbors	☐	☐
F26. Co-workers		

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

Did anyone abuse you? 0- No 1-Yes

	Past 30 days	In Your Life
F28. Physically? ● Caused you physical harm.	☐	☐
F29. Sexually? ● Forced sexual advances/acts.	☐	☐

FAMILY/SOCIAL COMMENTS

(Include question number with your notes)

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

F30. With your family? ☐☐

For Questions F32-34, ask the patient to use the Patient Rating scale.

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

F32. Family problems ?

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

F34. Family problems

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

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

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

For Questions F33-35, ask the patient to use the Patient Rating scale.

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

F33. Social problems?

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

F35. Social problems

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

CONFIDENCE RATING

Is the above information significantly distorted by:

F37. Patient's misrepresentation? 0-No 1-Yes

F38. Patient's inability to understand?

FAMILY/SOCIAL COMMENTS

(Include question number with your notes)

PSYCHIATRIC STATUS

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

P1.* In a hospital or inpatient setting? ☐☐

P2.* Outpatient/private patient? ☐☐

- Do not include substance abuse, employment, or family counseling.

Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days.

- Enter diagnosis in comments if known.

P3. Do you receive a pension for a psychiatric disability? ☐

0-No 1-Yes

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

	0-No 1-Yes	
	Past 30 Days	Lifetime
P4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?	☐	☐
P5. Experienced serious anxiety/ tension,	☐	☐
P6. Experienced hallucinations-saw things or heard voices that were not there?	☐	☐
P7. Experienced trouble understanding,	☐	☐

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

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

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

- This refers to problems noted in Questions P4-P10.

For Questions P13-P14, ask the patient to use the Patient Rating scale

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

- Patient should be rating the problem days from Question P12.

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

CONFIDENCE RATING

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

P22 Patient's misrepresentation? 0-No 1-Yes ☐

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

PSYCHIATRIC STATUS COMMENTS

(Include question number with your comments)

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

You will complete this form weekly during study weeks 1 – 13. Please answer the following questions about your cocaine craving by circling the most appropriate response.

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

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

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

0	1	2	3	4
Never	Almost Never	Several Times	Regularly	Almost Constantly

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

0	1	2	3	4
None at all	Very short	Short	Somewhat long	Very long

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

_____ Times

5. **Write in the total TIME you spent craving cocaine during the past 24 hours:**

Enter time as hours & minutes: ____ Hours ____ Minutes

6. **WORST day: During the past week, my most intense craving occurred on the following day:**

0	1	2	3	4	5	6	7
All days the same* (go to Q.8)	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

7. **The DATE for that day was:** (*If all days the same, skip to question #8.)

Enter date as month/day/year: _____ / _____ / 2 0 1 ____

8. **The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was:**

0	1	2	3	4
None at all	Slight	Moderate	Considerable	Extreme

THANK YOU. THIS FORM IS COMPLETE. Please give your responses to the research staff.

Date Entered into eDC System _____ Entered by (Staff Initials) _____

NIDA/VA CS #1033
BECK DEPRESSION INVENTORY II

___ ___ ___ ___ - ___ ___ ___ ___
SUBJECT ID# ALPHA

☐ STAFF: CHECK HERE IF ASSESSMENT WAS REFUSED, FORGOTTEN, OR NOT DONE

TODAY'S DATE: _____ / _____ / _____

This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the one statement in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Patterns) or Item 18 (Changes in Appetite).

1. Sadness

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time and I can't snap out of it.
3 I am so sad or unhappy that I can't stand it.

2. Pessimisim

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

0 I do not feel like a failure.
1 I feel I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

0 I don't cry any more than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

11. Agitation

0 I am no more restless or wound up than usual.
1 I feel more restless or wound up than usual.
2 I am so restless or agitated that it's hard to stay still.
3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.
1 I am less interested in other people or things than before.
2 I have lost most of my interest in other people or things.
3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.
1 I find it more difficult to make decisions than usual.
2 I have much greater difficulty in making decisions than I used to.
3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.
1 I do not consider myself as worthwhile and useful as I used to.
2 I feel more worthless as compared to other people.
3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.
1 I have less energy than I used to have.
2 I don't have enough energy to do very much.
3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.

1a I sleep somewhat more than usual
1b I sleep somewhat less than usual.

2a I sleep a lot more than usual.
2b I sleep a lot less than usual.

3a I sleep most of the day.
3b I wake up 1 – 2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.
1 I am more irritable than usual.
2 I am much more irritable than usual.
3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.
1b My appetite is somewhat greater than usual.

2a My appetite is much less than before.
2b My appetite is much greater than usual.

3a I have no appetite at all.
3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.
1 I can't concentrate as well as usual.
2 It's hard to keep my mind on anything for very long.
3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.
1 I get more tired or fatigued more easily than usual.
2 I am too tired or fatigued to do a lot of the things I used to do.
3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.

THANK YOU.

THIS FORM IS COMPLETE.

STAFF USE ONLY:

Form Reviewed By (staff) _____ Date _____

Total Score: _____

*see Study Operations Manual for instructions on scoring the BDI-II