CSP/NIDA #1033 – Lorcaserin
Variable Reference Guide

Listing of Forms:

01 – Serious Adverse Event
02 – Adverse Event
03 – ASI Medical
04 – ASI Employment
05 – ASI Alcohol/Drugs
06 – ASI Legal
07 – ASI Family
08 – ASI Psychiatric
09 – Beck Depression Inventory II
10 – Blood/Plasma
11 – BSCS
12 – CBT (Cognitive Behavioral Therapy)
13 – Alcohol Intervention
14 – Concomitant Medications
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16 – C-SSRS (Since Last Visit)
17 – Demographics
18 –Early Termination
19 – ECG
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21 – Enrollment
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23 – Physical Exam
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26 – Study Day 8
27 – SUR Pre-Screening
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31 – SUR Week 3
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33 – SUR Week 5
34 – SUR Week 6
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39 – SUR Week 11
40 – SUR Week 12
41 – SUR Week 13
42 – SUR Week 14
43 – SUR Week 16
44 – Urine Screening
45 – Urine Treatment
46 – Visit Date
47 – Vitals

VRG Created: 11/29/2017

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

1. Log # on AE Form SAEAENUM

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

2. Name of Event: SAEEVENT

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	SAEDEATH	1
Life-threatening	SAETHRET	1
Hospitalization (initial or prolonged)	SAEHOSP	1
Persistent or significant disability/incapacity	SAEDISAB	1
Congenital anomaly / birth defect	SAECONGT	1
Other serious (important medical event)	SAEOTHER	1

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

SAESPECO

4. Severity SAESEVER 1 Mild 2 Moderate 3 Severe

5. Expected? SAEEXPEC 1 Expected 2 Unexpected

6. Relatedness SAERELAT 1 Not Related 2 Possibly 3 Definitely

7. Description of event (include treatment):

SAEDESCR

8. Relevant medical & psychiatric history:

SAEMHX ____

____

____

9. Relevant test results & laboratory data:

SAERESLT ____

____

____

10. Date of onset: SAEONDAT / ______ / ________ *(mm/dd/yyyy)*

11. Date reported to site: SAERPDAT / ______ / ________ *(mm/dd/yyyy)*

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

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

14. Action taken: SAEACTON

- [1] Dose unchanged
- [2] Drug interrupted
- [3] Drug permanently discontinued
- [4] Other alteration to study procedures
- [5] Unknown / lost to follow-up

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

14b. If interrupted and restarted, enter date drug restarted: SAESTART / ______ / ________

14c. If study drug was withdrawn, did the subject improve? SAEIMPRV [1] Yes [2] No

15. Was study blind broken? BLINDBRK [1] Yes [2] No

IF YES:

15a. Date of unblinding BLINDDAT / ______ / ________ *(mm/dd/yyyy)*

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

15c. Reason for unblinding:

BLINDRES ____

____

16. Outcome: SAEOUTCM

- [1] Recovered / Resolved
- [2] Recovering / Resolving
- [3] Not Recovered / Not Resolved
- [4] Fatal
- [5] Unknown

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

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

SAE Reviewed By ________________________ Date __________
(Investigator)

Entered into eDC on __________
date

NIDA/VA CS #1033, ADVERSE EVENTS LOG

____ ____ ____ ____ - ____ ____ ____ ____

SUBJECT ID# ALPHA

Severity	**Relationship**	**Action Taken**	**Outcome**
1 Mild 2 Moderate 3 Severe *If severity increases, enter a stop date for the current AE & begin a new AE.*	1 Not related 2 Possibly related 3 Definitely related	1 Dose Unchanged 2 Drug Interrupted 3 Drug Permanently Discontinued 4 Other Alteration to Study Procedures 5 Unknown/Lost to follow-up	1 Recovered/resolved 2 Recovering/resolving 3 Not recovered/not resolved 4 Fatal 5 Unknown/Lost to follow-up

Name of Adverse Event	Start Date	Ongoing? AEONGO	Stop Date	Severity	Relationship	Action Taken	Outcome	Is this an SAE? AESERIS	Assessed By *(initials)*	Log Line # *in Medidata*
AETERM	AESTART	YES 1 NO 2	AEEND	AESEVER	AERELATE	AEACTION	AEOUTCOM	YES 1 NO 2		
		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 ☐		

Addiction Severity Index *Lite* - CF

Clinical/Training Version

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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: 1 = Baseline 2 = Follow-up
(circle one)

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? ☐ RELGPREF

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? ☐ ENVIRO

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? ☐☐ NUMDAYS

•"NN" if Question G19 is No. Refers to total 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? XHOSP

- 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 MEDPROB

- ***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 RXMED

- ***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 PENSION

- ***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? MEDDAYS

- 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.

TROUBDAY

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

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

CONFIDENCE RATINGS

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

M10. Patient's misrepresentation? 0 - No 1 - Yes CONFRAT1

M11. Patient's inability to understand? 0 - No 1 - Yes CONFRAT2

MEDICAL COMMENTS

(Include question number with your notes)

EMPLOYMENT/SUPPORT STATUS

E1.* Education completed: EDYEARS MONTHED
- 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
TECHED

E4. Do you have a valid driver's license?
- Valid license; not suspended/revoked. 0 - No 1 - Yes

DRIVELIC

E5. Do you have an automobile available?
- If answer to **E4** is "**No**", then **E5** must be "**No**". 0 - No 1 - Yes
Does not require ownership, only requires availability on a regular basis.

AUTO

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

FTJOBY Yrs / Mos

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

E9 Does someone contribute the majority of your support? 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

EMPLPATT

- 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? WORKDAYS
- 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? NETPAY
- Net or "take home" pay, include any "under the table" money.

E13. Unemployment Compensation? UNEMPLOY

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

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

E16. Mate, family, or friends? FAMFRIEN
- 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? 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.? DEPENDNT
- 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 ? EMPPROBS
- 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 EMPTROUB
- If the patient has been incarcerated or detained during the

E21. How important to you *now* is counseling for EMPLTX
- 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 significantly distorted by:

E23. Patient's misrepresentation CONFRAT3

E24. Patient's inability to understand? 0-No 1-Yes CONFRAT4

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)	ALC30	ALCLIFE	
D2	Alcohol (to intoxication)	INTOX30	INTOXLIF	
D3	Heroin	HERO30	HEROLIFE	HEROROUT
D4	Methadone	METH30	METHLIFE	METHROUT
D5	Other Opiates/Analgesics	OPI30	OPILIFE	OPIROUT
D6	Barbiturates	BARBS30	BARBSLIF	BARBROUT
D7	Sedatives/Hypnotics/ Tranquilizers	SEDS30	SEDSLIFE	SEDSROUT
D8	Cocaine	COC30	COCLIFE	COCROUT
D9	Amphetamines	AMP30	AMPLIFE	AMPROUT
D10	Cannabis	CAN30	CANLIFE	CANROUT
D11	Hallucinogens	HALL30	HALLIFE	HALROUT
D12	Inhalants	INHAL30	INHALIFE	INHAROUT
D13	More than 1 substance per day (including alcohol)	MULT30	MULTLIFE	

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

• ***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? ALCABUSE [ ][ ]

D20*. Drug abuse? DRUGABUSE [ ][ ]

- 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? ALCDETOX [ ][ ]

D22. Drugs? DRGDETOX [ ][ ]

- 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? ALCMONEY [ ][ ][ ][ ][ ]

D24. Drugs? DRGMONEY [ ][ ][ ][ ][ ]

- 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 OUTPTDAY [ ][ ]

For Questions D28-D31, ask the patient to use the Patient Rating scale. The patient is rating the need for additional substance abuse treatment.

How many days in the past 30 have you experienced:

D26. Alcohol problems? ALC30PRB [ ][ ]

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

D28. Alcohol problems? ALC30TRB [ ]

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

D30. Alcohol problems? ALCIMPTX [ ]

How many days in the past 30 have you experienced:

D27. Drug problems? DRG30P [ ][ ]

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

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

D29. Drug problems? DRG30TRB [ ]

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

D31. Drug problems? [ ]

CONFIDENCE RATINGS

Is the above information significantly distorted by:

D34. Patient's misrepresentation? 0-No 1-Yes ALCCONF1 [ ]

D35. Patient's inability to understand? ALCCONF2 [ ]

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.
LEGADMIT

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

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

L3 * Shoplift/Vandal SHOPLIFT	☐☐	L10* Assault ASSAULT	☐☐
L4 * Parole/Probation PAROLE	☐☐	L11* ARSON	☐☐
L5 * Drug Charges DRUGCHRG	☐☐	L12* Rape RAPE	☐☐
L6 * Forgery FORGERY	☐☐	L13* HOMICIDE	☐☐
L7* Weapons Offense WEAPONS	☐☐	L14* Prostitution PROSTUTE	☐☐
L8* Burglary/Larceny/B&E BURGLARY	☐☐	L15* CONTEMPT	☐☐
L9 * Robbery ROBBERY	☐☐	L16* Other LEGOTHER	☐☐

• 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? CONVICT ☐☐
• 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? DISORDER ☐☐

L19* Driving while intoxicated? ☐☐ DRIVING

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

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.
INCARCX

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

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.
AWAITFOR
• Don't include civil cases, unless a criminal offense is involved.

L26 How many days in the past 30, were you detained or incarcerated? INCARC30 ☐☐
• Include being arrested and released on the same day.

LEGAL COMMENTS

(Include question number with your notes)

LEGSPECF

LEGAL STATUS (cont.)

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.

PROFIT30

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

SERLEGAL

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.

LEGALTX

CONFIDENCE RATINGS

Is the above information significantly distorted by:

L31. Patient's misrepresentation?

LEGCONF1

L32. Patient's inability to understand?

LEGCONF2

LEGAL COMMENTS

(Include question number with your notes)

FAMILY/SOCIAL RELATIONSHIPS

F1. Marital Status: MARITAL
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? SATMAR
0-No 1-Indifferent 2-Yes
• Satisfied = generally liking the situation. - Refers to Questions F1 & F2.

F4.* Usual living arrangements (past 3 years): LIVING
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? SATLIV
0-No 1-Indifferent 2-Yes

Do you live with anyone who:

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

F8. Uses non-prescribed drugs? 0-No 1-Yes FAMDRUG

F9. With whom do you spend most of your free time? FAMTIME
1-Family 2-Friends 3-Alone
• If a girlfriend/boyfriend is considered as family by patient, then they must refer to them as family throughout this section, not a friend.

F10. Are you satisfied with spending your free time this way? 0-No 1-Indifferent 2-Yes SATTIME
• 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	MOTH30	MOTHLIFE
F19. Father	FATH30	FATHLIFE
F20. Brother/Sister	SIB30	SIBLIFE
F21. Sexual Partner/Spouse	SPOUSE30	SPOUSLIF
F22. Children	CHILD30	CHILDLIF
F23. Other Significant Family (specify) SPECFAM	OTHFAM30	OTHFAMLF
F24. Close Friends	FRIEND30	FRNDLIF
F25. Neighbors	NEIGH30	NEIGHLIF
F26. Co-workers	COWRK30	COWRKLIF

• "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.	PHYSABUS	PHYSLIFE
F29. Sexually? • Forced sexual advances/acts.	SEXABUSE	SXABLIFE

FAMILY/SOCIAL COMMENTS
(Include question number with your notes)

FAMILY/SOCIAL (cont.)

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

FAMCONF

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:

FAMTROUB

F32. Family problems ?

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

FAMCOUNS

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:

OTHCONF

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:

SOCTROUB

F33. Social problems?

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

SOCCOUNS

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? 0-No 1-Yes

FAMILY/SOCIAL COMMENTS
(Include question number with your notes)

FAMCONF1

FAMCONF2

PSYCHIATRIC STATUS

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

INPATTX

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.

OUTPTTX

- Enter diagnosis in comments if known.

P3. Do you receive a pension for a psychiatric disability? 0-No 1-Yes PENSION ☐

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?	DEPRES30 ☐	DEPRSLIF ☐
P5. Experienced serious anxiety/ tension, uptight, unreasonably worried, inability to feel relaxed?	ANX30	ANXLIF
P6. Experienced hallucinations-saw things or heard voices that were not there?	HALLU30 ☐	HALLULIF ☐
P7. Experienced trouble understanding, concentrating, or remembering?	COGNIT30	COGNILIF

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

	Past 30 Days	Lifetime
P8. Experienced trouble controlling violent behavior including episodes of rage, or violence?	VIOLEN30 ☐	VIOLLIF ☐
P9. Experienced serious thoughts of suicide? • Patient seriously considered a plan for taking his/her life.	SUICID30	SUICDLIF
P10. Attempted suicide? • Include actual suicidal gestures or attempts.	ATTMP30 ☐	ATTMPLIF ☐
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.	RXMED30	RXMEDLIF

P12. How many days in the past 30 have you experienced these psychological or emotional problems? PSYCH30 ☐☐

- 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 significantly distorted by:

P22. Patient's misrepresentation? 0-No 1-Yes ☐ PSYCONF1

P23. Patient's inability to understand? 0-No 1-Yes ☐ PSYCONF2

PSYCHIATRIC STATUS COMMENTS

(Include question number with your comments)

PSYTROUB

PSYCHTX

NIDA/VA CS #1033
BECK DEPRESSION INVENTORY II

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

Was the BDI completed at this visit? [1] Yes [2] No

TODAY'S DATE: BDIDAT / ______ / __________

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 BDISAD

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 BDIPESS

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 BDIPF

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 BDILOP

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.

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

5. Guilty Feelings BDIGF

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 BDIPUNF

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 BDISD

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 BDISC

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 BDISTW

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.

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10. Crying BDICRY

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 BDIAGIT

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 BDILOI

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 BDIIND

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 BDIWOR

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.

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

15. Loss of Energy BDILOE

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 BDICSP

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 BDIIRR

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 BDICA

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.

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19. Concentration Difficulty BDICD

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 BDITIR

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 BDILOIS

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

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NIDA/VA CS # 1033
BLOOD/PLASMA SAMPLES

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

Were any blood and/or plasma samples drawn at today's visit? 1 YES 2 NO
Q2SAMPYN

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

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

1. Plasma (*Xenobiotics*) 1
   XENOSAMP
2. Blood Chemistry (*Q2*) 1
   Q2CHEM
3. Hematology (*Q2*) 1
   Q2HEMA

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)

NIDA/VA CS #1033
BRIEF SUBSTANCE CRAVING SCALE

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

BSCSYN

Was the BSCS completed at this visit? [1] Yes [2] No

TODAY'S DATE: BSCSDAT/ ______ / __________

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:** INTCRAVE

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:** FREQCRAV

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:** LENGTH

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:**

NUMBER Times

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

Enter time as hours & minutes: _____ Hours _____ Minutes
TIMEHR TIMEMIN

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

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: DATE / ______ / 2 0 1 ____

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

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
COGNITIVE BEHAVIORAL THERAPY

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

Progress Notes may also serve as source documentation.

1. Did the subject attend Cognitive Behavioral Therapy (CBT) session?
   ATTENDYN
   [1] Yes
   [2] No

2. If Yes, date of session CBTDATE / ______ / ___________

3. Length of session (minutes) NUMBMINS mins

4. Other behavioral method used to reduce cocaine use?
   SESSOTH
   [1] Motivational Books
   [2] Audio Tapes / CDs
   [3] Hypnosis
   [4] Acupuncture
   [5] Other, Specify ___SESSOTH_STR___________________________________

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? ATTNDALC

   [1] Yes
   [2] 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: ALCMOD / ______ / ___________
   [1] Study Day 1 [2] Study Day 8 [3] Week 3 [4] Week 8

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

NIDA/VA CS #1033, CONCOMITANT MEDICATIONS

____ ____ ____ ____ - ____ ____ ____ ____
SUBJECT ID# ALPHA

UNITS:		ROUTE:		FREQUENCY:
Caplet/Tablet 1	Puff 5	Oral 1	Topical/Transdermal 5	QD 1
Drop 2	Spray/Squirt 6	Nasal 2	Intramuscular 6	BID 2
Milligram 3	Tablespoon 7	Intravenous 3	Sublingual 7	TID 3
Milliliter 4	Teaspoon 8	Inhalation 4	Subcutaneous 8	QID 4
	Unknown/Other 9		Other 9	Other, MUST SPECIFY BELOW 5 CMFREQ_STR

Medication Name	Start Date	Stop Date	Mark X if Continuing	Indication	Dose	Units	Route	Frequency	Recorded by	Log Line # *(from Medidata)*
CMNAME	CMSTART	CMEND	☐ 1 CMONGO	CMINDICT	CMDOSE	CMUNITS	CMFORM	CMFREQ		
			☐							
			☐							
			☐							
			☐							
			☐							
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			☐							

NIDA/VA CS # 1033
CONSENT CONFIRMATION

___SUBJNUM___ ___ - ___ALPHCODE___
SUBJECT ID# ALPHA
SUBJID

The subject (referenced by Subject ID# and ALPHA Code above) has been asked to participate in CS #1033, "Phase 2, Multi-Center Trial of Lorcaserin in the Treatment of Cocaine Use Disorder". The study has been discussed with the subject, and all questions were answered.

The Consent Form, version: ICFVERDT /___ ___ /___ ___ ___ ___, was signed by the subject
(ICF version date)

on ICFSIGDT /___ ___ /___ ___ ___ ___ at________________ prior to the performance of
(Subject Signature date) (time)

any study-related procedures.

The subject has been provided with a copy of the signed Informed Consent form.

Name of Person obtaining consent______________________POCSIGDT__________

Form Completed By ________________________________ Date ______________

*Date Entered into eDC:*____________

COLUMBIA-SUICIDE SEVERITY RATING SCALE (C-SSRS)

Since Last Visit

Version 1/14/09

Posner, K.; Brent, D.; Lucas, C.; Gould, M.; Stanley, B.; Brown, G.; Fisher, P.; Zelazny, J.; Burke, A.; Oquendo, M.; Mann, J.

Disclaimer:

This scale is intended to be used by individuals who have received training in its administration. The questions contained in the Columbia-Suicide Severity Rating Scale are suggested probes. Ultimately, the determination of the presence of suicidal ideation or behavior depends on the judgment of the individual administering the scale.

Definitions of behavioral suicidal events in this scale are based on those used in **The Columbia Suicide History Form**, *developed by John Mann, MD and Maria Oquendo, MD, Conte Center for the Neuroscience of Mental Disorders (CCNMD), New York State Psychiatric Institute, 1051 Riverside Drive, New York, NY, 10032. (Oquendo M. A., Halberstam B. & Mann J. J., Risk factors for suicidal behavior: utility and limitations of research instruments. In M.B. First [Ed.]* Standardized Evaluation in Clinical Practice, *pp. 103 -130, 2003.)*

For reprints of the C-SSRS contact Kelly Posner, Ph.D., New York State Psychiatric Institute, 1051 Riverside Drive, New York, New York, 10032; inquiries and training requirements contact posnerk@nyspi.columbia.edu

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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 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:	**Yes** ☐ **No** ☐
2. Non-Specific Active Suicidal Thoughts 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:	**Yes** ☐ **No** ☐
3. Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act 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:	**Yes** ☐ **No** ☐
4. Active Suicidal Ideation with Some Intent to Act, without Specific Plan 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:	**Yes** ☐ **No** ☐
5. Active Suicidal Ideation with Specific Plan and Intent 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:	**Yes** ☐ **No** ☐

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 Ideation:*** _____ ________________________________ ***Type # (1-5)*** ***Description of Ideation***	Most Severe
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	____

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:**___________

Was the C-SSRS conducted at this study visit? CSSRSYN [1] Yes [2] No

Did the subject's responses on the C-SSRS indicate any of the following:

1. Acute suicidality, as evidenced by a YES response to Question 4 or 5 on the C-SSRS, indicating active suicidal ideation with intent to act? SUICIDAL [1] Yes [2] No

2. Suicidal behavior such that a determination of YES is made on the Suicidal Behavior section of the C-SSRS for "Actual Attempt," "Interrupted Attempt," or "Aborted Attempt"? ATTEMPT [1] Yes [2] No

If the response to Question 1 or 2 was YES, record as an AE and discontinue from study drug and study.

NIDA/VA CS # 1033
DEMOGRAPHICS

____ ____ ____ ____ - ____ ____ ____ ____
SUBJECT ID# ALPHA

1. Date of Birth _____ / _____ / _________
DOB

2. Age (*automatically calculated*)
AGE

3. Gender
SEX

[1] Male [2] Female

4. Marital Status
MARRIED

[1] Legally Married
[2] Living with partner / cohabitating
[3] Widowed
[4] Separated
[5] Divorced
[6] Never Married
[7] Unknown/Declined to Answer

5. Ethnicity
ETHNICTY

[1] Hispanic or Latino [2] Not Hispanic or Latino [9] Declined to answer

6. Race (please specify if "Other")
RACE

[1] American Indian or Alaskan Native
[2] Asian
[3] Black or African American
[4] Native Hawaiian or Pacific Islander
[5] White
[99] Other (specify) ___RACE_STR_____________
[9] Declined to answer

7. Years of Formal Education (GED=12 years) ______________________
EDUCATN

8. Usual Employment Pattern in the last 30 days:
EMPLOYMT

[1] Full time, 35+ hours / week
[2] Part time, regular hours
[3] Part time, irregular hours
[4] Student
[5] Military Service
[6] Retired /Disabled
[7] Homemaker
[8] Unemployed
[9] In a controlled environment
[10] Unknown

STATUS

Form Completed By ___________________________________ Date Entered into eDC _____________
(Print Name)

NIDA/VA CS # 1033
EARLY TERMINATION

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

1. Choose the **PRIMARY** reason subject was terminated early from the study: TERMREASON

- [1] Serious or unexpected adverse event [*complete SAE form, notify NIDA*] (Specify):
  TERMREASON_STR ____________________
- [2] Medical or psychiatric concern [*record on AE log*] (Specify):
  TERMREASON_STR ____________________
- [3] Pregnancy [*record as an AE, notify NIDA*]
- [4] Exclusion criterion emerged after subject was enrolled in study (Specify):
  TERMREASON_STR ____________________
- [5] Protocol noncompliance (Specify):
  TERMREASON_STR ____________________
- [6] Incarceration
- [7] Subject requested withdrawal from the study (Specify):
  TERMREASON_STR ____________________
- [8] Could not tolerate study drug [*record on AE log*]
- [9] Other reason (Specify):
  TERMREASON_STR ____________________
- [10] Subject failed to return on study Day 8
- [11] Subject went 14 days without study meds

2. Was the subject referred to another treatment program? REFERTX [1] Yes [2] No

Investigator's Signature ____________________ Date ____________________
(Print Name)

Date entered into eDC ____________

NIDA/VA CS # 1033
ECG

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

ECG PAPER STRIP WILL ALSO SERVE AS SOURCE

1. Was an ECG performed? [1] Yes [2] No ECGYN

IF YES, please record the results below:

2. Date of ECG ECGDAT _______ / _______ / _________

3. Ventricular Rate ECGVENT __________ bpm

4. PR ECGPR __________ ms

5. QRS ECGQRS __________ ms

6. QTc ECGQTC __________ ms

7. ECG overall results were: [1] Normal [2] Abnormal ECGRESULT

IF ABNORMAL, MARK ALL ABNORMALITIES NOTED BELOW:

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

	Abnormal Condition	Mark with an (X)
19.	Right ventricular hypertrophy	ABNORMLD
20.	Sinus tachycardia	ABNORMLL
21.	Sinus bradycardia	ABNORMLM
22.	Subacute infarction	ABNORMLF
23.	Supraventricular premature beat	ABNORMLN
24.	Supraventricular tachycardia	ABNORMLP
25.	Symmetrical t-wave inversions	ABNORMLI
26.	Ventricular premature beat	ABNORMLO
27.	Ventricular tachycardia	ABNORMLQ
28.	Other, specify SPECIFYU ____________	ABNORMLU
29.	Other, specify SPECIFYV ____________	ABNORMLV

Form Completed By ____________________________________ Date Entered into eDC ____________
(Print Name)

NIDA/VA CS # 1033
ELIGIBILITY SUMMARY

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

1. Did subject meet all inclusion criteria and no exclusion criteria? ELIGINCL 1 Yes 2 No
*IF NO, SKIP TO Q3.

2. Is subject willing to be enrolled into the study? WILENROL 1 Yes* 2 No
*IF YES, FORM IS COMPLETE.

Select the primary reason the subject is excluded from the study from the summary below:
ELIGEXCL

1 AGE not within range
2 ALCOHOL USE DISORDER requiring medical detox
3 ALLERGY to Lorcaserin or sulfonamides
4 BIRTH CONTROL: no acceptable form used
5 COCAINE USE DAYS: no use days in 30 days prior to screening
6 COCAINE USE DISORDER not diagnosed
7 CONSENT: unable to understand/provide
8 DEPRESSION: evidenced by BDI-II score of ≥ 20 at screening.
9 DIABETES
10 HEALTH revealed at screening to be unstable or unsafe
11 LORCASERIN within 30 days prior to screening
12 MANDATED DRUG TESTING by court/government agency
13 METHADONE / BUPRENORPHINE maintenance treatment within 1 year
14 NOT SEEKING TREATMENT for cocaine use disorder
15 OTHER CLINICAL TRIAL PARTICIPATION within 6 months
16 PREGNANT / LACTATING
17 PSYCHOTIC DISORDER as diagnosed by SCID
18 UNLIKELY TO COMPLETE STUDY, attend visits or complete assessments
19 URINE DRUG SCREEN negative for BE in screening
20 URINE DRUG SCREEN positive for prohibited substance
21 SCREENING INCOMPLETE
22 SUBSTANCE USE DISORDER other than cocaine, benzos, alcohol, nicotine
23 SUICIDAL BEHAVIOR / SUICIDALITY as reported on C-SSRS
24 VCT AUTHORIZATION refused
25 WEIGHT ≤ 110 pounds, or BMI ≤ 20

INVESTIGATOR'S STATEMENT: *I have reviewed all screening assessments and determined that this subject meets all inclusion criteria, does not meet any exclusion criteria, and is eligible for enrollment into CS #1033, "Lorcaserin for Cocaine Use Disorder".*

Principal Investigator's Signature ____ Date ________________

Date Entered into eDC:_____________

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

1. Is the subject willing to be enrolled in the study?
   If no, please specify a reason if subject is not willing to be enrolled in the study
   ENROLLED

   [1] Yes

   [2] No (Specify) ENROLLED_STR

SAVE THIS FORM and USE THIS **LINK** if you need access to the IWRS system

NIDA/VA CS # 1033
MEDICAL HISTORY

____ ____ ____ ____ - ____ ____ ____ ____
SUBJECT ID# ALPHA

Indicate here if the Medical History was taken: 1 Yes 2 No MHXYN

1 Date medical history was taken _______ / _______ / _______ MHXDAT

	Medical Condition	Yes	No	If Yes, Explain
2	Allergies, Drug MHXDRUG	1	2	MHXDRUG_ST
3	Allergies, Other MHXOTHAL	1	2	MHXOTHAL_STR
4	Cardiovascular Disorder MHXCARDI	1	2	MHXCARDI_STR
5	Dermatologic Disorder MHXDERMA	1	2	MHXDERMA_ST
6	Endocrine Disorder MHXENDO	1	2	MHXENDO_STR
7	Gastrointestinal Disorder MHXGASTO	1	2	MHXGASTO_ST
8	Genitourinary Disorder MHXGENIT	1	2	MHXGENIT_STR
9	HEENT Disorder MHXHEENT	1	2	MHXHEENT_STR
10	Hematologic Disorder MHXHEMAT	1	2	MHXHEMAT_ST
11	Hepatic Disorder MXHHEPAT	1	2	MXHHEPAT_STR
12	Infectious Disease Disorder MHXINFEX	1	2	MHXINFEX_STR
13	Metabolic Disorder MHXMETAB	1	2	MHXMETAB_STR
14	Musculoskeletal Disorder MHXMUSCLO	1	2	MHXMUSCLO_ST
15	Neurologic Disorder MHXNEURO	1	2	MHXNEURO_ST
16	Psychiatric Disorder MHXPSYCH	1	2	MHXPSYCH_STR
17	Pulmonary Disorder, Asthma MHXASTHM	1	2	MHXASTHM_ST
18	Pulmonary Disorder, Other MHXPULMO	1	2	MHXPULMO_ST
19	Renal Disorder MXHRENAL	1	2	MXHRENAL_STR
20	Reproductive System Disorder MHXREPRO	1	2	MHXREPRO_ST
21	Other Medical Condition MHXOTH1	1	2	MHXOTH1_STR
22	Other Medical Condition MHXOTH2	1	2	MHXOTH2_STR

Medical Hx Performed By: ______________________________ Date: ____________ Date Entered into eDC ___________

NIDA/VA CS # 1033
PHYSICAL EXAM

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

Indicate here if the Physical Exam was conducted: [1] Yes [2] No
PHYSYN

1. Date of Physical Exam PHYSDAT ______ / ______ / ______

2. Height (inches) PHYSHGT ___ ___ ___ . ___

	EXAMINATION	FINDINGS		DESCRIPTION
		NORMAL	ABNORMAL	Items marked "ABNORMAL" require a DESCRIPTION *Please Print Clearly*
3.	General Appearance PHYSAPP	1	2	PHYSAPP_STR
4.	Skin PHYSSKIN	1	2	PHYSSKIN_STR
5.	HEENT (incl. thyroid, neck) PHYSHENT	1	2	PHYSHENT_STR
6.	Lymph Nodes PHYSLYMP	1	2	PHYSLYMP_STR
7.	Lungs PHYSLUNG	1	2	PHYSLUNG_STR
8.	Cardiovascular PHYSCARD	1	2	PHYSCARD_STR
9.	Abdomen (incl. liver, spleen) PHYSABDO	1	2	PHYSABDO_STR
10.	Extremities/Musculoskeletal PHYSEXTR	1	2	PHYSEXTR_STR
11.	Neuropsychiatric: Mental Status PHYSNEUR	1	2	PHYSNEUR_STR
12.	Neuropsychiatric: Sensory/Motor PHYSSENS	1	2	PHYSSENS_STR

Physical Performed By (Signature) ____ Date________________________

Entered into eDC System By _____________________________________ Date Entered into eDC _______________

NIDA/VA CS #1033
PREGNANCY TEST

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

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

   1 YES
   2 NO, specify reason

   PREGYN_STR ______________________

2. Date Urine Pregnancy Test Performed PREGDAT

   _____ / _____ / _____
   mm dd yy

3. Pregnancy Test Result PREGRESLT

   1 Positive
   2 Negative

Urine Results Recorded By____
(Print Name)

Entered into eDC on____________
(Date)

NIDA/VA CS #1033
SMOKING / ALCOHOL HISTORY

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

THIS FORM IS TO BE COMPLETED VIA INTERVIEW BY A STAFF MEMBER AT SCREENING.

☐ CHECK HERE IF THE SMOKING/ALCOHOL HISTORY WAS NOT DONE

1. Date Collected SHXDAT _____ / _____ / _______ *(mm/dd/yyyy)*

2. Do you smoke? SHXQUIT Yes [1] No [2]

   If YES, complete Smoking History

   If NO, skip to the Alcohol History

SMOKING HISTORY

3. How old were you when you first smoked a cigarette? SHXFIRST (years)

4. How old were you when you first started regular daily cigarette smoking? SHXDAILY (years)

5. Over the past 30 days, on average, how many cigarettes have you smoked per day? SHX30DAY

6. Over the past year, on average, how many cigarettes did you smoke per day? SHXYEAR

7. Over the past 5 years, on average, how many cigarettes did you smoke per day? SHX5YRS

8. How many times have you quit smoking in the past for more than 24 hours at a time? SHXQUITX

9. Have you ever used the prescription medication Chantix (varenicline) to quit smoking? SHXCHANT Yes [1] No [2]

   9a. If YES, specify the longest period of time (# of days) that you were able to quit smoking with Chantix? SHXATMP1 (Days)

10. Have you ever used the prescription medication Zyban/Wellbutrin (Bupropion) to quit smoking? SHXZYBAN Yes [1] No [2]

    10a. If YES, specify the longest period of time (# of days) that you were able to quit smoking with Zyban/Wellbutrin SHXATMP2(Days)

11. Have you ever used Nicotine Replacement Therapy (NRT) to quit smoking? SHXREPLC Yes [1] No [2]

    11a. If YES, specify the longest period of time (# days) that you were able to quit smoking with NRT SHXATMP3 (Days)

    11b. Record the type of NRT used (e.g., gum, patch, spray) __________SHXNRUSE__________

12. What other methods have you used to attempt to quit smoking? (Mark all that apply)

SHXNEVER ☐ 1 No other methods used
SHXASIST ☐ 1 Stopped without assistance
SHXCOUNS ☐ 1 Counseling
SHXHYPNO ☐ 1 Hypnosis / Hypnotherapy
SHXACCUP ☐ 1 Acupuncture
SHXECIG ☐ 1 E-cigarette
SHXOTHER ☐ 1 Other method

12a. If **OTHER METHOD** checked, specify method used: SHXOTHSP ______________________________

13. Over the past 30 days, have you used any tobacco products aside from cigarettes? SHXTOBAC ☐ 1 Yes ☐ 2 No
If YES (mark all that apply)

SHXCIGAR ☐ 1 Cigars
SHXPIPE ☐ 1 Pipe
SHXBIDIS ☐ 1 Bidis (tobacco wrapped in temburni leaf)
SHXSMKLS ☐ 1 Smokeless tobacco (pan, chewing tobacco, snuff)
SHXECIG2 ☐ 1 E-cigarettes
SHXOTH2 ☐ 1 Other tobacco product

13a. If **OTHER TOBACCO PRODUCT** used, specify type used: SHXSPEC2 ______________________________

ALCOHOL HISTORY

14. Over the past 30 days, how many days did you drink alcohol? SHXALC30 (Days)

If the subject consumed alcohol over the past 30 days:

15. How many standard drinks were consumed per day (on average)
for the days on which you drank? SHXALCAV (Drinks/day)

Standard Drink Chart – One standard drink is equal to:
12 oz. beer
4 oz. wine
2.5 oz. of fortified wine
1 oz. of hard liquor

16. What is the maximum number of drinks consumed on any given day over the last 30 days? SHXALCMX (Drinks)

Interview Conducted By ______________________________ Date Entered into eDC ______________
(Print Name)

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

   COKEDAYRANG ☐ 1 <8 Days ☐ 2 >=8 Days ☐☐ days

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

   ALCMOD2 ☐ 1 Yes ☐ 2 No (opted out in writing)

3. Does the subject have current Alcohol Use Disorder and/or Sedative, Hypnotic, or Anxiolytic Use Disorder?

   ALCBENZ ☐ 1 Yes ☐ 2 No

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

   WILLRAND ☐ 1 Yes ☐ 2 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 ___________

NIDA/VA CS #1033

SUBSTANCE USE REPORT, PRE-SCREENING (SURPS)

___ ___ ___ ___ - ___ ___ ___ ___

SUBJECT ID# ALPHA

Begin this record 30 days prior to the day the subject signed the Informed Consent. Maintain a **continuous record of substance use** for every day from 30 days prior to screening up until the day before the IC was signed.

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

Date SURDATEPS	Benzo-diazepines SURBENZPS	Meth-amphetamines SURMETHPS	Amphetamines SURAMPPS	Opiates SUROPIATPS	Marijuana SURMARIJPS	# Cigarettes Smoked SURCIGPS	Cocaine SURCOKEPS	# Standard Drinks
	☐ 1	☐ 1	☐ 1	☐ 1	☐ 1		YES 1 NO 2	SURALCPS 0-50
	☐	☐	☐	☐	☐		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
SUBSTANCE USE REPORT, PRE-SCREENING (SURPS)

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

Date	Benzo-diazepines	Meth-amphetamines	Amphetamines	Opiates	Marijuana	# Cigarettes Smoked	Cocaine	# Standard Drinks
	☐	☐	☐	☐	☐		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	
END DATE = DAY BEFORE ICF SIGNED	☐	☐	☐	☐	☐		YES NO	

Form Completed By____________________________________ Date______________

*Date Entered into eDC*___________________

NIDA/VA CS #1033,
SUBSTANCE USE REPORT (SUR), SCREENING

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

Begin this record on the day the subject signed the Informed Consent. Maintain a **continuous record of substance use** for every day from the date of IC through the last day of screening (the day prior to enrollment. Leave unused days blank. Document substance use beginning on Study Day 1 on the WEEKLY SUR.

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

Date SURDATES	Benzo-diazepines SURBENZS	Meth-amphetamines SURMETHS	Amphetamines SURAMPS	Opiates SUROPIATS	Marijuana SURMARIJS	# Cigarettes Smoked SURCIGS	Cocaine SURCOKES	# Standard Drinks
DATE ICF SIGNED	1	1	1	1	1		YES1 NO2	SURALCS 0-50
							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

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

END ON LAST DAY OF SCREENING. LEAVE UNUSED DAYS BLANK.

Form Completed By ___________________________________ Date ____________
(Print Name)

Date Entered into eDC ____________

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 SURDATE1	Benzo-diazepines SURBENZ1	Meth-amphetamines SURMETH1	Amphetamines SURAMP1	Opiates SUROPIAT1	Marijuana SURMARIJ1	# Cigarettes Smoked SURCIG1	Cocaine SURCOKE1	# Standard Drinks SURALC1 0-50
STUDY DAY 1 →		☐ 1	☐ 1	☐ 1	☐ 1	☐ 1		YES 1 NO 2	
		☐	☐	☐	☐	☐			
		☐	☐	☐	☐	☐		YES NO	
		☐	☐	☐	☐	☐		YES NO	
		☐	☐	☐	☐	☐		YES NO	
		☐	☐	☐	☐	☐		YES NO	
		☐	☐	☐	☐	☐		YES NO	

SURALC1_STR 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.

Variables are ________2 to ________14 and ________16

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

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.

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

Date SURDATE2	Benzo-diazepines SURBENZ2	Meth-amphetamines SURMETH2	Amphetamines SURAMP2	Opiates SUROPIAT2	Marijuana SURMARIJ2	# Cigarettes Smoked SURCIG2	Cocaine SURCOKE2	Check here for indiv. days recorded in AiView	# Standard Drinks SURALC2	Check here for indiv. days recorded in AiView
	☐ 1	☐ 1	☐ 1	☐ 1	☐ 1		YES 1 NO 2	☐ 3	0-50	☐ 999
	☐	☐	☐	☐	☐					
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐
	☐	☐	☐	☐	☐		YES NO	☐		☐

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

NIDA/VA CS # 1033
ON-SITE URINE TOXICOLOGY - SCREENING

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

1. Was a urine sample collected? SAMPYN [1] Yes [2] No

   1a. **If NO**, specify reason:____

   1b. **If YES,** date collected: _____ / _____ / ________ (mm/dd/yyyy) URINEDAT

2. What was the overall result for the on-site urine toxicology screen? LOCALTOX [1] Positive [2] Negative

   2a. Mark ALL substances that returned a positive result below:

   - COCRESLT [1] Cocaine (BE)
   - THCRESLT [1] Marijuana (THC)
   - METRESLT [1] Methamphetamine
   - AMPRESLT [1] Amphetamines
   - ECSRESLT [1] Ecstasy
   - PHNRESLT [1] Phencyclidine
   - PRORESLT [1] Propoxyphene
   - BENZRSLT [1] Benzodiazepines
   - BARBRSLT [1] Barbiturates
   - TRICRSLT [1] Tricyclic Antidepressants
   - MTHDRSLT [1] Methadone
   - BUPRESLT [1] Buprenorphine
   - OXYRESLT [1] Oxycodone
   - OPIARESLT [1] Opiates

3. Fentanyl Result FENTRESLT [1] Positive [2] Negative

4. Cotinine Result COTRESLT [1] Positive [2] Negative

5. EtG Result ETGRESLT [1] Positive [2] Negative

6. [1] Check here to indicate the sample was prepared for shipment to Q2 Solutions for medical urinalysis. Q2SAMP1

Was another urine tox screen performed for this subject during screening? URINEANOTH

Results Recorded By ___________________________________ Date Entered into eDC _______________
(Print Name)

NIDA/VA CS #1033
URINE TOXICOLOGY – TREATMENT

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

1. Was a weekly Urine Sample Collected? URSAMPYN [1] YES [2] NO

2. Date Urine Sample Collected TXURNDAT _____ / _____ / _____
   mm dd yy

3. Cotinine Test Result COTRSLT [1] Positive [2] Negative

4. EtG Test Result ETGRSLT [1] Positive [2] Negative

5. Was a Urine BE sample prepared for **LABCORP** for Toxicology? BESAMP
   [1] Yes
   Specify a reason if a sample was not prepared. [2] No (Specify) BESAMP_STR________

6. Was a back-up sample frozen? FROZEN [1] Yes
   Specify a reason if a back-up was not frozen. [2] No (Specify) FROZEN_STR________

7. Was the sample prepared for **Q2** for medical urinalysis? Q2SAMPTX
   [1] Yes
   Please specify if the sample was not prepared. [2] No (Specify) Q2SAMPTX_STR______
   [3] Not Required
   (required only in weeks 7 & 16)

Urine Results Recorded By_______________________________________
(Print Name)

Entered into eDC on____________
(Date)

NIDA/VA CS #1033
VISIT DATE

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

Please check if subject did not attend this visit NOSHOW ☐

Visit Date VISITDAT ______ / ______ / ______

NIDA/VA CS # 1033
VITAL SIGNS

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

1. Were vital signs recorded at this visit? VITALYN

   1 Yes
   2 No

2. Date Evaluated VITALDAT/ ______ / ______

3. Temperature VITALTEMP °F

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

4. Systolic Blood Pressure, Sitting VITALSYS mm Hg

5. Diastolic Blood Pressure, Sitting VITALDIA mm Hg

6. Pulse Rate VITALPLS bpm

7. Respiratory Rate VITALRES breaths / min

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

9. BMI VITALBMI . ___ ___ *(Round to the nearest whole number in Medidata)*
   (use approved calculator at https://www.mcw.edu/calculators/body-mass-index.htm)

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