CTN Inclusion Exclusion (p1, 2)

DOMAIN: IE

Version# **1**

Approved 10/24/00
Page 1 of 2

ProtocolNumber: STUDYID

SerialNumber:

Form #

3 0 5

16141

Node:	Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
0 6			USUBJID	/ /	

IEDTC

EPOCH

Phase:
- ● Screening
- ○ Active
- ○ Follow-up1
- ○ Follow-up2
- ○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:

○ ○
1 1
○ ○

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day:

0 0 0

Form Completed By:

VISITNUM / VISIT

IECAT

A. INCLUSION CRITERIA

IETEST

ALL ITEMS MUST BE COMPLETED

NOTE: Only exceptions to IE are in the database. That includes "No" responses for inclusion and "Yes" responses for exclusion criteria.

IEORRES

○ Yes ○ No 1. Treatment-seeking males and non-pregnant and non-lactating females, 15 years and older, who fulfill DSM-IV criteria for opiate abuse or dependence, report experiencing symptoms of opiate withdrawal, are currently physically dependent on opioids and are in need of medical assistance for opioid withdrawal.

○ Yes ○ No 2. Systolic blood pressure equal to or greater than 100 mg Hg, and pulse equal to or greater than 56 bpm.

○ Yes ○ No 3. Good general health or, in case of a medical/psychiatric condition needing ongoing treatment, under the care of a physician willing to continue patient's medical management and cooperate with the study physician(s).

○ Yes ○ No 4. Agreeable to and capable of signing the informed consent approved by an institutional review board and, if under the age of 18 (excluding emancipated minors), assent and concurrent consent from a parent or legal guardian.

○ Yes ○ No 5. Use of one of the following acceptable methods of birth control by female patients of childbearing potential:
○ NA
    a. oral contraceptives
    b. barrier (diaphragm or cervical cap) with spermicide or condom
    c. intrauterine progesterone contraceptive system (IUD)
    d. levonorgestrel implant (Norplant ®)
    e. medroxyprogesterone acetate contraceptive injection (Depo-provera)
    f. complete abstinence from sexual intercourse

IECAT

B. EXCLUSION CRITERIA

○ Yes ○ No 1. Medical condition that would make participation, in the opinion of the study physician, medically hazardous (e.g., acute hepatitis, unstable cardiovascular, liver or renal disease).

○ Yes ○ No 2. Clinically significant abnormalities in ECG.

○ Yes ○ No 3. Known allergy or sensitivity to buprenorphine, naloxone, or clonidine.

○ Yes ○ No 4. Receiving beta blockers, calcium channel blockers, tricyclics, digitalis, and/or other medication which may interact adversely with clonidine.

○ Yes ○ No 5. Acute severe psychiatric condition in need of immediate treatment, or imminent suicide risk.

○ Yes ○ No 6. Dependence on alcohol, benzodiazepines or other depressants, or stimulants, and requiring immediate medical attention.

○ Yes ○ No 7. Participation in an investigational drug study, including buprenorphine, within the past 30 days.

○ Yes ○ No 8. Methadone or LAAM maintenance or detoxification within the past 30 days.

○ Yes ○ No 9. Pending legal action that could prohibit or interfere with participation.

○ Yes ○ No 10. Unable to remain in area for duration of active phase of treatment.

○ Yes ○ No 11. Females that are pregnant, lactating, or planning to become pregnant.
○ NA

Please mark bubbles FULLY

Inclusion Exclusion (continued)

16141

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
		USUBJID	/ /	

DS.DSDTC
SC.SCDTC

C.   Study Enrollment

SC.SCTEST

SC.SCORRES

1. Did participant meet all inclusion criteria and none of the exclusion criteria?   ○ Yes   ○ No   *If "No", go to question 3*

2. If randomized/enrolled in the study:

   DM.ARM

   A. Treatment group   ○ Buprenorphine/Naloxone   ○ Clonidine

   B. Date of first "study day" (e.g., first dose of study medication, first therapy session, etc.).

   ☐☐ / ☐☐ / ☐☐☐☐   DM.RFSTDTC

   (mm/dd/yyyy)

3. If NOT randomized/enrolled, reason(s) not randomized/enrolled:

   DS.DSTERM

   DS.DSOCCUR

   A. Failed to return to clinic   ○ Yes   ○ No   DSCAT=SCREEN FAILURE

   B. Declined study participation (specify below)   ○ Yes   ○ No

   C. Moved from area (current or pending)   ○ Yes   ○ No

   D. Incarceration (current or pending)   ○ Yes   ○ No

   E. Death   ○ Yes   ○ No

   F. Failed to meet inclusion criteria or met exclusion criteria as noted above   ○ Yes   ○ No

Comments:

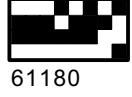THIS DATA NOT ENTERED

CTN Demographics Form

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 5 0

61180

SC.SCTEST=NODE

Node: 0 6

Site:

Name Code:

ID Number: USUBJID

Date of Assessment: (mm/dd/yyyy)

DM.DMDTC / SC.SCDTC

EPOCH

Phase:
○ Screening
○ Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:

CQIComments:
○ Entireform
○ Question#(s):

QA Corrections:
○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day:

Form Completed By

VISITNUM / VISIT

1. Sex: DM.SEX

   ○ Male ○ Female

2. Date of birth: DM.BRTHDTC

   (mm/dd/yyyy)

3. Ethnicity/Race: DM.RACE (if multiple, then = 'MULTIPLE')
   For each of the following, answer **"Yes"** to all that apply to you, and **"No"** to those that do not.

   ○ Yes ○ No White SCTEST
   ○ Yes ○ No Black, African American, or Negro
   ○ Yes ○ No American Indian or Alaskan Native
   ○ Yes ○ No Spanish, Hispanic, or Latino
   (mark all that apply)

   SCORRES
   ○ Mexican, Mexican-American, or Chicano
   ○ Puerto Rican
   ○ Cuban
   ○ Other (specify)

   QNAM=SOTHERS
   QLABEL=SPANISH, HISPANIC, OR LATINO: OTHER TEXT
   IDVAR=SCSEQ

   ○ Yes ○ No Asian
   (mark all that apply)
   ○ Asian-Indian
   ○ Chinese
   ○ Filipino
   ○ Japanese
   ○ Korean
   ○ Vietnamese
   ○ Other (specify)

   QNAM=AOTHERS
   QLABEL=ASIAN: OTHER TEXT
   IDVAR=SCSEQ

   ○ Yes ○ No Native Hawaiian or Pacific Islander
   (mark all that apply)
   ○ Native Hawaiian
   ○ Guamanian or Chamarro
   ○ Samoan
   ○ Other (specify)

   ○ Yes ○ No Other (specify)

   QNAM=OOTHERS
   QLABEL=ETHNICITY/RACE OTHER TEXT
   IDVAR=SCSEQ

   QNAM=NOTHERS
   QLABEL=NATIVE HAWAIIAN OR PACIFIC ISLANDER: OTHER TEXT
   IDVAR=SCSEQ

   ○ Participantchoosesnottoanswer

4. Education completed: SCTEST
   (GED=12 years)
   Years: SCORRES
   SCORRESU

5. Usual employment pattern:

   a. Past 3 years: SCTEST
   ○ Full time (35+ hrs/wk) ○ Service
   ○ Part time (regular hours) ○ Retired/Disability
   ○ Part time (irreg., day-work) ○ Homemaker
   ○ Student ○ Unemployed
   ○ In controlled environment SCORRES

   b. Past 30 days: SCTEST
   ○ Full time (35+ hrs/wk) ○ Service
   ○ Part time (regular hours) ○ Retired/Disability
   ○ Part time (irreg., daywork) ○ Homemaker
   ○ Student ○ Unemployed
   ○ In controlled environment SCORRES

6. Marital status: SCTEST
   ○ LegallyMarried
   ○ Livingwithpartner/Cohabitating
   ○ Widowed
   ○ Separated
   ○ Divorced
   ○ Nevermarried

Please PRINT CLEARLY

Please fill bubbles completely: ○ ● ○ ○

Demographics Form (continued)

61180

STUDYID

SerialNumber: ☐☐☐☐☐

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
☐☐☐☐☐	☐☐☐☐☐	☐☐☐☐ USUBJID	☐☐ / ☐☐ / ☐☐☐☐	

SUDTC

SUCAT=

7. Drug/Alcohol Use:

For the following, please record use information for the past 30 days (days of use), lifetime (years of regular use), and route of administration. For lifetime use, the use of a substance 3 or more times per week is considered regular use. The usual route of administration should be coded. If more than 1 route is frequently used, then choose the most serious. The routes are listed from least severe to most severe. If Past 30 Days and Lifetime Use are zero, route should be coded as "N/A." If substance use is less than 6 months, code Lifetime use as 00 years (6-12 months of use is coded as 1 year) and make a note on the form.

SUEVLINT=-P30   SUDUR

SUBSTANCE:	Past 30 Days	Lifetime Use Years	Most frequent route of administration:		Comment:
SUTRT Alcohol (any use at all)	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection SUROUTE ○ N/A	THIS DATA NOT ENTERED
Alcohol (to intoxication)	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection ○ N/A	
Heroin	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection ○ N/A	
Methadone/LAAM (prescribed)	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection ○ N/A	
Methadone/LAAM (illicit)	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection ○ N/A	
Other Opiates/Analgesics	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection ○ N/A	
Barbiturates	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection ○ N/A	
Other Sedatives/Hypnotics /Tranquilizers including Benzodiazapines	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection ○ N/A	
Cocaine	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection ○ N/A	
Amphetamines/ Methamphetamine	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection ○ N/A	
Cannabis	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection ○ N/A	
Hallucinogens	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IVornon-IVInjection ○ N/A	
Inhalants	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ IV or non-IV Injection ○ N/A	
More than 1 substance per day (including alcohol)	☐☐	☐☐			
Nicotine (tobacco products)	☐☐	☐☐	○ Oral ○ Nasal ○ Smoking	○ N/A	

8. According to the interviewer, which substance is the major problem? Interviewer should determine the major drug of abuse. Code as above. Ask patient when not clear.

○ No problem
○ Alcohol (any)
○ Alcohol (intox.)
○ Heroin
○ Methadone/LAAM (presc)

○ Methadone/LAAM (illicit)
○ Opiates/Analgesics
○ Barbiturates
○ Sed/Hyp/Tranq/Benz
○ Cocaine

○ Amphetamines/Meth
○ Cannabis
○ Hallucinogens
○ Inhalants
○ Nicotine

○ Alcohol and drug (dual addiction)
○ Polydrug

SUTRT

SUCAT=MAJOR DRUG PROBLEM

CTN Medical History (MEDHX)

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 7 0

Node:	Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
0 6			USUBJID	/ /

MHDTC

EPOCH

Phase:
○ Screening
○ Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:
⓪ ⓪
① ①

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day:

Form Completed By:

VISITNUM / VISIT

Notes:

THIS DATA NOT ENTERED

_____ / /

If form completed by someone other than the evaluator, please sign and date

MD signature:

MHTERM   MHOCCUR   MHOCCUR

MEDICAL CONDITION	PAST HISTORY			ACTIVE			NOT ASSESSED	
MHSEQ 1. Dermatological	○ Yes	○ No		○ Yes	○ No		○	
2. Eyes, Ears, Nose, and Throat	○	○		○	○		○	
MHSPID 3. Cardiovascular	○	○		○	○		○	
4. Respiratory	○	○		○	○		○	
5. Skin Test Positive for TB	○	○		○	○		○	
6. X - Ray Positive for TB	○	○		○	○		○	
7. Symptoms of TB	○	○		○	○		○	
8. Musculoskeletal	○	○		○	○		○	
9. Gastrointestinal	○ Yes	○ No		○ Yes	○ No		○	
10. Hepatic	○	○		○	○		○	
11. Genitourinary	○	○		○	○		○	
12. Endocrine	○	○		○	○		○	
13. Psychiatric	○	○		○	○		○	
14. Neurological	○	○		○	○		○	
15. Seizure	○	○		○	○		○	
16. Allergies	○	○		○	○		○	
17. Other _____	○ Yes	○ No		○ Yes	○ No		○	

MHENRF = BEFORE   MHENRF=DURING/AFTER   MHSTAT

Please PRINT CLEARLY 1 2 3 4 5 6 7 8 9 0

A B C D E F G H I J K L M
N O P Q R S T U V W X Y Z

33239

CTN VITAL SIGNS

Version# **1**

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 7 5

33289

Node:	Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
0 6			USUBJID	/ /

VSDTC

EPOCH

Phase:
○ Screening
○ Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:

⓪ ⓪
① ①

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1   ○ QA2   ○ QA3   ○ QA4

Study Day:

Form Completed By:

VISITNUM / VISIT

/ /

Complete after the subject has been seated for 5 minutes. Please complete form each time vital signs are assessed.

If form completed by someone other than the evaluator, please sign and date

Signature of medical personnel:

VSDTC

1.Time(24hour,hh:mm)

:

VSPOS
○ Sitting
○ Standing

VSTEST

VSTEST

VSTEST

VSTEST

VSORRES

VSORRESU

VSORRES

2.Temperature

.

○ (°F)
○ (°C)

VSORRES

VSORRESU

3.BloodPressure(mmHg)

/

VSORRES

4.Pulse(bpm)

VSORRES

5.Respirations(1min)

VSORRESU

NOTES:

THIS DATA NOT ENTERED

Please PRINT CLEARLY

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

| A | B | C | D | E | F | G | H | I | J | K | L | M |
| N | O | P | Q | R | S | T | U | V | W | X | Y | Z |

CTN Physical Examination

30699

ProtocolNumber: STUDYID

☐☐☐☐ - ☐☐☐ - ☐☐☐☐

SerialNumber: ☐☐☐☐

Form # 2 6 5

Node:	Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
0 6			U$UBJID	☐☐ / ☐☐ / ☐☐☐☐	PEDTC / VSDTC

Phase:
○ Screening
○ Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

EPOCH

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI: ☐☐
⓪ ⓪
① ①

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day: ☐☐☐

Form Completed By: ☐☐☐☐

VISITNUM / VISIT

VSTEST
VSORRES
A.Height
☐☐☐

VSORRESU
○ inches
○ centimeters

VSTEST
VSORRES
B.Weight
☐☐☐

VSORRESU
○ pounds
○ kilograms

___ / ___ / ___

If form completed by someone other than the evaluator, please sign and date

MD signature:

Circled items represent recommended minimum physical exam

PETEST

PEORRES

THIS DATA NOT ENTERED

	N	NCS	SIG	NA	Comments:
1. Skin, Hair, and Nails	○	○	○	○	_____
2. Head and Neck	○	○	○	○	_____
3. Ears, Eyes, Nose, and Throat	○	○	○	○	_____
4. Heart	○	○	○	○	_____
5. Chest	○	○	○	○	_____
6. Lungs	○	○	○	○	_____
7. Abdomen	○	○	○	○	_____
8. Rectal	○	○	○	○	_____
9. Genitalia	○	○	○	○	_____
10. Prostate	○	○	○	○	_____
11. Breasts	○	○	○	○	_____
12. Pelvic	○	○	○	○	_____
13. Extremities	○	○	○	○	_____
14. Lymph Nodes	○	○	○	○	_____
15. Musculoskeletal	○	○	○	○	_____
16. Neurological	○	○	○	○	_____
17. Other: _____	○	○	○	○	_____

If NA then PESTAT=NOT DONE and PEREASND=NA

Please PRINT CLEARLY

Normal
Abnormal, **N**ot **C**linically **S**ignificant
Abnormal, clinically **SIG**nificant
Not **A**ssessed

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

CTN Pregnancy Test

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 3 5

8802

Node:	Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
0 6			USUBJID	/ /

EPOCH

Phase:
● Screening
○ Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:
○ 0 ○ 0
○ 1 ○ 1

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1   ○ QA2   ○ QA3   ○ QA4

RPDTC
Study Day:
0 0 0

VISITNUM / VISIT

Form Completed By:

Do not complete nor fax if male.

1. Was a pregnancy test performed? RPTEST

    RPORRES ○ Yes   ○ No(skiptoquestion3andmakeanote)

2. What was the result?
    ○ Positive   ○ Negative

3. Is the participant lactating?
    ○ Yes   ○ No

4. Does participant agree to use an acceptable form of birth control?
    ○ Yes   ○ No

    Acceptable forms of birth control:

    a. oral contraceptives
    b. barrier (diaphragm or cervical cap) with spermicide or condom
    c. intrauterine progesterone contraceptive system (IUD)
    d. levonorgestrel implant (Norplant ®)
    e. medroxyprogesterone acetate contraceptive injection (Depo-provera)
    f. complete abstinence from sexual intercourse
    g. not of child-bearing potential

Comments:

THIS DATA NOT ENTERED

Please mark bubbles FULLY

Correct ●   Incorrect ◉ ⊗ ●

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 9 5

39180

Node:	Site:	Name Code:	ID Number:	Date of BASELINE Interview: (mm/dd/yyyy)
0 6			USUBJID	/ /

QNAM = BASEDT
QLABEL= DATE OF BASELINE INTERVIEW
IDVAR = EXSEQ

EPOCH

Phase:
○ Screening
● Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1 ○ QA2 ○ QA3 ○ QA4

NOTE: For protocol 002 only, take-home dose can only be given for weekends or holidays.

EXDOSFRM=TABLET EXDOSU

EXROUTE

EXDOSE

VISITNUM / VISIT

Studyday: 0 1	Today'sdate: / /	EXDTC	Time(24hour): :	Total mg. ingested:
StaffID:	Datedosagetaken: / /	EXSTDTC / EXENDTC		Amount sent home:

QNAM=MGGIV QLABEL=EXTRA 4MG GIVEN IDVAR=EXSEQ

○ Extra4mggiven(includeintotalmgingested)

QNAM=NOMEDGIV QLABEL=NO STUDY MEDICATION IDVAR=EXSEQ

Comments: THIS DATA NOT ENTERED

Initials

○ Nostudymedicationingested

Studyday: 0 2	Today'sdate: / /	Time(24hour): :	Total mg. ingested:
StaffID:	Datedosagetaken: / /		Amount sent home:

QNAM=DOSRET
QLABEL=AMOUNT RETURNED
IDVAR=EXSEQ

Amount returned:

Initials ○ No study medication ingested

Comments:

QNAM=DOSHOM
QLABEL=AMOUNT SENT HOME
IDVAR=EXSEQ

Studyday: 0 3	Today'sdate: / /	Time(24hour): :	Total mg. ingested:
StaffID:	Datedosagetaken: / /		Amount sent home:

Amount returned:

Initials ○ No study medication ingested

Comments:

Please print within the boxes.

Correct 9   Incorrect 9

Bup/Naloxone Dosage Log (continued)

39180

SerialNumber:

Site:

Name Code:

ID Number:

Studyday: 0 4

Today'sdate: / /

Time(24hour): :

Total mg. ingested:

StaffID:

Datedosagetaken: / /

Amount sent home:

Amount returned:

Initials ○ No study medication ingested

Comments:

Studyday: 0 5

Today'sdate: / /

Time(24hour): :

Total mg. ingested:

StaffID:

Datedosagetaken: / /

Amount sent home:

Amount returned:

Initials ○ No study medication ingested

Comments:

Studyday: 0 6

Today'sdate: / /

Time(24hour): :

Total mg. ingested:

StaffID:

Datedosagetaken: / /

Amount sent home:

Amount returned:

Initials ○ No study medication ingested

Comments:

Studyday: 0 7

Today'sdate: / /

Time(24hour): :

Total mg. ingested:

StaffID:

Datedosagetaken: / /

Amount sent home:

Amount returned:

Initials ○ No study medication ingested

Comments:

Please PRINT CLEARLY 1 2 3 4 5 6 7 8 9 0

| A | B | C | D | E | F | G | H | I | J | K | L | M |
| N | O | P | Q | R | S | T | U | V | W | X | Y | Z |

39180

Site:

Name Code:

ID Number:

SerialNumber:

Studyday: **0 8**

Today'sdate: ☐☐ / ☐☐ / ☐☐☐☐

Time(24hour): ☐☐ : ☐☐

Total mg. ingested:

StaffID: ☐☐☐

Datedosagetaken: ☐☐ / ☐☐ / ☐☐☐☐

Amount sent home:

Amount returned:

Initials ☐ ○ No study medication ingested

Comments:

Studyday: **0 9**

Today'sdate: ☐☐ / ☐☐ / ☐☐☐☐

Time(24hour): ☐☐ : ☐☐

Total mg. ingested:

StaffID: ☐☐☐

Datedosagetaken: ☐☐ / ☐☐ / ☐☐☐☐

Amount sent home:

Amount returned:

Initials ☐ ○ No study medication ingested

Comments:

Studyday: **1 0**

Today'sdate: ☐☐ / ☐☐ / ☐☐☐☐

Time(24hour): ☐☐ : ☐☐

Total mg. ingested:

StaffID: ☐☐☐

Datedosagetaken: ☐☐ / ☐☐ / ☐☐☐☐

Amount sent home:

Amount returned:

Initials ☐ ○ No study medication ingested

Comments:

Studyday: **1 1**

Today'sdate: ☐☐ / ☐☐ / ☐☐☐☐

Time(24hour): ☐☐ : ☐☐

Total mg. ingested:

StaffID: ☐☐☐

Datedosagetaken: ☐☐ / ☐☐ / ☐☐☐☐

Amount sent home:

Amount returned:

Initials ☐ ○ No study medication ingested

Comments:

**SERIAL number on this page
should match number on page 1**

39180

Site:

Name Code:

ID Number:

SerialNumber:

Studyday: **1 2**

Today'sdate: ___ / ___ / _____

Time(24hour): ___ : ___

Total mg. ingested:

StaffID:

Datedosagetaken: ___ / ___ / _____

Amount sent home:

Amount returned:

Initials

○ No study medication ingested

Comments:

Studyday: **1 3**

Today'sdate: ___ / ___ / _____

Time(24hour): ___ : ___

Total mg. ingested:

StaffID:

Datedosagetaken: ___ / ___ / _____

Amount sent home:

Total mg returned:

Initials

○ No study medication ingested

Comments:

No medication is to be given on Day 14.

Studyday: **1 4**

Today'sdate: ___ / ___ / _____

Time(24hour): ___ : ___

Total mg returned:

StaffID:

Comments:

Initials

Additional comments:

THIS DATA NOT ENTERED

CTN Clonidine Dosage Log

EXCAT

43366

DOMAIN: EX

Version# **1**

Approved 10/24/00
Page 1 of 4

Form #

ProtocolNumber: STUDYID

SerialNumber:

3 0 0

Node:	Site:	Name Code:	ID Number:	Date of BASELINE Interview: (mm/dd/yyyy)
0 6			USUBJID	/ /

EPOCH

Phase:
- ○ Screening
- ● Active
- ○ Follow-up1
- ○ Follow-up2
- ○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:

○ 0 ○ 0
○ 1 ○ 1

CQIComments:
- ○ Entireform
- ○ Question#(s):

QA Corrections:
- ○ QA1 ○ QA2 ○ QA3 ○ QA4

QNAM = BASEDT
QLABEL= DATE OF BASELINE INTERVIEW
IDVAR=EXSEQ

QNAM=NOMEDGIV   IDVAR=EXSEQ
QLABEL=NO STUDY MEDICATION

○ No oral clonidine given (leave oral dosage **BLANK**)

VISITNUM / VISIT

Studyday:	Today'sdate:	EXDTC	Time(24hour):
0 1	/ /		:

EXDOSU
EXROUTE=INGESTED

EXDOSE

StaffID:	Datedosagetaken:	EXSTDTC EXENDTC
	/ /	

Total mg. ingested: _ . _

EXDOSFRM=TABLET

Amount sent home: _ . _

EXDOSE
EXROUTE=TRANSDERMAL

EXDOSFRM=PATCH

Numberofpatchesapplied:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6

Number of patches removed:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6

QNAM = NUMREMOV
QLABEL = NUMBER OF PATCHES REMOVED
IDVAR = EXSEQ

QNAM=DOSHOM
QLABEL=AMOUNT SENT HOME
IDVAR=EXSEQ

Comments: THIS DATA NOT ENTERED

Initials

Studyday:	Today'sdate:	Time(24hour):
0 2	/ /	:

○ Nooralclonidinegiven (leave oral dosage **BLANK**)

StaffID:	Datedosagetaken:
	/ /

Total mg. ingested: _ . _

Amount sent home: _ . _

Amount returned: _ . _

Numberofpatchesapplied:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6

Number of patches removed:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6

Comments:

QNAM=DOSRET   IDVAR=EXSEQ
QLABEL=AMOUNT RETURNED

Initials

Studyday:	Today'sdate:	Time(24hour):
0 3	/ /	:

○ Nooralclonidinegiven (leave oral dosage **BLANK**)

StaffID:	Datedosagetaken:
	/ /

Total mg. ingested: _ . _

Amount sent home: _ . _

Amount returned: _ . _

Numberofpatchesapplied:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6

Number of patches removed:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6

Comment

Initials

Please print within the boxes.

Correct **9**   Incorrect **9**

43366

Site:

Name Code:

ID Number:

SerialNumber:

Studyday: 0 4

Today'sdate: / /

Time(24hour): :

○ Nooralclonidinegiven (leave oral dosage **BLANK**)

StaffID:

Datedosagetaken: / /

Total mg. ingested: .

Amount sent home: .

Amount returned: .

Numberofpatchesapplied: ⓪ ① ② ③ ④ ⑤ ⑥

Number of patches removed: ⓪ ① ② ③ ④ ⑤ ⑥

Initials

Comments:

Studyday: 0 5

Today'sdate: / /

Time(24hour): :

○ Nooralclonidinegiven (leave oral dosage **BLANK**)

StaffID:

Datedosagetaken: / /

Total mg. ingested: .

Amount sent home: .

Amount returned: .

Numberofpatchesapplied: ⓪ ① ② ③ ④ ⑤ ⑥

Number of patches removed: ⓪ ① ② ③ ④ ⑤ ⑥

Initials

Comments:

Studyday: 0 6

Today'sdate: / /

Time(24hour): :

○ Nooralclonidinegiven (leave oral dosage **BLANK**)

StaffID:

Datedosagetaken: / /

Total mg. ingested: .

Amount sent home: .

Amount returned: .

Numberofpatchesapplied: ⓪ ① ② ③ ④ ⑤ ⑥

Number of patches removed: ⓪ ① ② ③ ④ ⑤ ⑥

Initials

Comments:

Studyday: 0 7

Today'sdate: / /

Time(24hour): :

○ Nooralclonidinegiven (leave oral dosage **BLANK**)

StaffID:

Datedosagetaken: / /

Total mg. ingested: .

Amount sent home: .

Amount returned: .

Numberofpatchesapplied: ⓪ ① ② ③ ④ ⑤ ⑥

Number of patches removed: ⓪ ① ② ③ ④ ⑤ ⑥

Initials

Comments:

Please PRINT CLEARLY

1 2 3 4 5 6 7 8 9 0

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

43366

Site:

Name Code:

ID Number:

SerialNumber:

Studyday: | 0 8

Today'sdate: ___ / ___ / ____

Time(24hour): __ : __

○ Nooralclonidinegiven (leave oral dosage **BLANK**)

StaffID:

Datedosagetaken: ___ / ___ / ____

Total mg. ingested: __ . __ __

Amount sent home: __ . __ __

Amount returned: __ . __ __

Numberofpatchesapplied: ⓪ ① ② ③ ④ ⑤ ⑥

Number of patches removed: ⓪ ① ② ③ ④ ⑤ ⑥

Initials

Comments:

Studyday: | 0 9

Today'sdate: ___ / ___ / ____

Time(24hour): __ : __

○ Nooralclonidinegiven (leave oral dosage **BLANK**)

StaffID:

Datedosagetaken: ___ / ___ / ____

Total mg. ingested: __ . __ __

Amount sent home: __ . __ __

Amount returned: __ . __ __

Numberofpatchesapplied: ⓪ ① ② ③ ④ ⑤ ⑥

Number of patches removed: ⓪ ① ② ③ ④ ⑤ ⑥

Initials

Comments:

Studyday: | 1 0

Today'sdate: ___ / ___ / ____

Time(24hour): __ : __

○ Nooralclonidinegiven (leave oral dosage **BLANK**)

StaffID:

Datedosagetaken: ___ / ___ / ____

Total mg. ingested: __ . __ __

Amount sent home: __ . __ __

Amount returned: __ . __ __

Numberofpatchesapplied: ⓪ ① ② ③ ④ ⑤ ⑥

Number of patches removed: ⓪ ① ② ③ ④ ⑤ ⑥

Initials

Comments:

Studyday: | 1 1

Today'sdate: ___ / ___ / ____

Time(24hour): __ : __

○ Nooralclonidinegiven (leave oral dosage **BLANK**)

StaffID:

Datedosagetaken: ___ / ___ / ____

Total mg. ingested: __ . __ __

Amount sent home: __ . __ __

Amount returned: __ . __ __

Numberofpatchesapplied: ⓪ ① ② ③ ④ ⑤ ⑥

Number of patches removed: ⓪ ① ② ③ ④ ⑤ ⑥

Initials

Comments:

SERIAL number on this page should match number on page 1

Clonidine Dosage Log (continued)

Approved 10/24/00

43366

SerialNumber:

Site:	Name Code:	ID Number:

Study day: 1 2

Today's date: ___ / ___ / ____

Time (24 hour): __ : __

○ No oral clonidine given (leave oral dosage **BLANK**)

Total mg. ingested: __ . __

Amount sent home: __ . __

Amount returned: __ . __

Staff ID: ___

Date dosage taken: ___ / ___ / ____

Number of patches applied: ⓪ ① ② ③ ④ ⑤ ⑥

Number of patches removed: ⓪ ① ② ③ ④ ⑤ ⑥

Initials

Comments:

Study day: 1 3

Today's date: ___ / ___ / ____

Time (24 hour): __ : __

○ No oral clonidine given (leave oral dosage **BLANK**)

Total mg. ingested: __ . __

Amount sent home: __ . __

Amount returned: __ . __

Staff ID: ___

Date dosage taken: ___ / ___ / ____

Number of patches applied: ⓪ ① ② ③ ④ ⑤ ⑥

Number of patches removed: ⓪ ① ② ③ ④ ⑤ ⑥

Initials

Comments:

No medication is to be given on Day 14.

Study day: 1 4

Today's date: ___ / ___ / ____

Time (24 hour): __ : __

Amount returned: __ . __

Staff ID: ___

Number of patches removed: ⓪ ① ② ③ ④ ⑤ ⑥

Initials

Comments:

Additional comments:

THIS DATA NOT ENTERED

CTN Intake Urine Log
Buprenorphine protocols 1, 2

Version # **1**
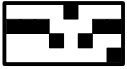
58132

Protocol Number: STUDYID

- -

Serial Number:

Form #
2 0 5

Node:	Site:	Name Code:	ID Number:
0 6		USUBJID	

EPOCH

Phase:
- ● Screening
- ○ Active
- ○ Follow-up 1
- ○ Follow-up 2
- ○ Follow-up 3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to
answer

CQI:

○ 0 ○ 0
○ 1 ○ 1

CQI Comments:
○ Entire form
○ Question #(s):
QA Corrections:
○ QA1   ○ QA2   ○ QA3   ○ QA4

---

1. AccuTest

LBMETHOD = ACCUTEST

Side 1 of AccuTest Screen:

LBORRES

LBTEST	Amphetamines	○ Positive ○ Negative
	Barbiturates	○ Positive ○ Negative
	Benzodiazepines	○ Positive ○ Negative
	Cocaine	○ Positive ○ Negative
	Methamphetamine	○ Positive ○ Negative

Side 2 of AccuTest Screen:

LBORRES

	Methadone	○ Positive ○ Negative
	Morphine	○ Positive ○ Negative
LBTEST	PCP	○ Positive ○ Negative
	TCA	○ Positive ○ Negative
	THC	○ Positive ○ Negative

Result read by:

QNAM = LBREADYBY
QLABEL = RESULT READ BY
IDVAR = VISITNUM

LBMETHOD=CENTRAL LAB

2. Study day:

VISITNUM / VISIT

0 0

Date urine collected: LBDTC

/ /

Collected by:

QNAM = LBCOLBY
QLABEL = COLLECTED BY
IDVAR = VISITNUM

Date urine shipped:

/ /

Shipped by:

QNAM = LBSHIPBY
QLABEL = SHIPPED BY
IDVAR = VISITNUM

QNAM = SHIPDTC
QLABEL = DATE URINE SHIPPED
IDVAR = VISITNUM

Comments:

THIS DATA NOT ENTERED

CTN Active Urine Log
Buprenorphine protocols 1, 2

DOMAIN: LB

Version# **1**

Approved 10/24/00
Page 1 of 1

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 0 6

57613

Node: **0 6**   Site: ___   Name Code: USUBJID   ID Number: ___

EPOCH

Phase:
○ Screening
● Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI: [ ] [ ]
⓪ ⓪
① ①

CQIComments:
○ Entireform
○ Question#(s):

QA Corrections:
○ QA1   ○ QA2   ○ QA3   ○ QA4

QNAM = LBCOLBY
QLABEL = COLLECTED BY
IDVAR = VISITNUM

LBMETHOD=CENTRAL LAB

1. Study day: ___   Date urine collected: LBDTC ___ / ___ / ___   Collectedby: ___

VISITNUM / VISIT

LBREASND/LBSTAT
○ Pt.didNOTattend
○ Sampleinvalid
○ Refused
○ UrineNOTcollected(specifyincomments)

Dateurineshipped: ___ / ___ / ___   Shippedby: ___

QNAM = SHIPDTC
QLABEL = DATE URINE SHIPPED
IDVAR = VISITNUM

QNAM = LBSHIPBY
QLABEL = SHIPPED BY
IDVAR = VISITNUM

2. Study day: ___   Date urine collected: ___ / ___ / ___   Collectedby: ___

○ Pt. did NOT attend
○ Sample invalid
○ Refused
○ Urine NOT collected (specify in comments)

Dateurineshipped: ___ / ___ / ___   Shippedby: ___

3. Study day: ___   Date urine collected: ___ / ___ / ___   Collectedby: ___

○ Pt. did NOT attend
○ Sample invalid
○ Refused
○ Urine NOT collected (specify in comments)

Dateurineshipped: ___ / ___ / ___   Shippedby: ___

4. Study day: ___   Date urine collected: ___ / ___ / ___   Collectedby: ___

○ Pt. did NOT attend
○ Sample invalid
○ Refused
○ Urine NOT collected (specify in comments)

Dateurineshipped: ___ / ___ / ___   Shippedby: ___

5. Final study visit test result:

Side 1 of AccuTest Screen:

LBMETHOD = ACCUTEST

Amphetamines	○ Positive	○ Negative
Barbiturates	○ Positive	○ Negative
Benzodiazepines	○ Positive	○ Negative
Cocaine	○ Positive	○ Negative
Methamphetamine	○ Positive	○ Negative

QNAM = LBREADYBY
QLABEL = RESULT READ BY
IDVAR= EPOCH

Resultreadby: ___

LBREASND/LBSTAT
○ Pt. did NOT attend
○ Sample invalid
○ Refused
○ Urine NOT collected (specify in comments)

Side 2 of AccuTest Screen:

Methadone	○ Positive	○ Negative
Morphine	○ Positive	○ Negative
PCP	○ Positive	○ Negative
TCA	○ Positive	○ Negative
THC	○ Positive	○ Negative

Comments:

THIS DATA NOT ENTERED

CTN Follow-up Urine Log
Buprenorphine protocols 1, 2

DOMAIN: LB

Version# **1**

Approved 10/24/00
Page 1 of 1

58064

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 0 7

Node:	Site:	Name Code:	ID Number:
0 6		USUBJID	

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:

⓪ ⓪
① ①

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1   ○ QA2   ○ QA3   ○ QA4

QNAM = LBCOLBY
QLABEL = COLLECTED BY
IDVAR = VISITNUM

LBMETHOD=CENTRAL LAB

EPOCH / VISITNUM

1. Follow-up: 0 1

Date urine collected: LBDTC

☐ / ☐ / ☐

Collectedby: ☐

LBREASND/LBSTAT
○ Pt. did NOT attend
○ Sample invalid
○ Refused
○ Urine NOT collected (specify in comments)

Dateurineshipped:

☐ / ☐ / ☐

Shippedby: ☐

QNAM = SHIPDTC
QLABEL = DATE URINE SHIPPED
IDVAR = VISITNUM

QNAM = LBSHIPBY
QLABEL = SHIPPED BY
IDVAR = VISITNUM

2. Follow-up: 0 2

Date urine collected:

☐ / ☐ / ☐

Collectedby: ☐

○ Pt. did NOT attend
○ Sample invalid
○ Refused
○ Urine NOT collected (specify in comments)

Dateurineshipped:

☐ / ☐ / ☐

Shippedby: ☐

3. Follow-up: 0 3

Date urine collected:

☐ / ☐ / ☐

Collectedby: ☐

○ Pt. did NOT attend
○ Sample invalid
○ Refused
○ Urine NOT collected (specify in comments)

Dateurineshipped:

☐ / ☐ / ☐

Shippedby: ☐

Comments:

THIS DATA NOT ENTERED

QSCAT **CTN Visual Analog Scale**

DOMAIN: QS

Form #
2 6 0

Version# **1**

Approved 10/24/00
Page 1 of 1

ProtocolNumber: STUDYID

SerialNumber:

Node: **0 6**

Site:

Name Code:

ID Number: USUBJID

Date of Assessment: (mm/dd/yyyy) QSDTC

Study Day:

Form Completed By: QSEVAL

VISITNUM / VISIT

Phase:
○ Screening   ○ Active   ○ Follow-up1   ○ Follow-up2   ○ Follow-up3

EPOCH

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
CQI:
○ QA1   □
○ QA2   □
○ QA3   ☺ ☹
○ QA4   ☺ ☹

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

Indicate how you feel RIGHT NOW by drawing a vertical black line.

QSTEST 1. How much do you currently crave opiates?

QSORRES   QSORRESU='0-100 POINT ANALOG SCALE'

Not at all |_____| *Extremely*

QSTEST 2. How much does the medication that you are receiving help to manage withdrawal sickness?   ○ **NA**

QSORRES   QSORRESU='0-100 POINT ANALOG SCALE'

Not at all |_____| *Extremely*

Please mark scale with a **BOLD BLACK** pen (|)

Substance Dependence

ProtocolNumber: STUDYID	SerialNumber:	**Form #** 2 5 5

39017

Node:	Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
0 6			USUBJID	/ /	QSDTC

EPOCH

Phase:
- ● Screening
- ○ Active
- ○ Follow-up1
- ○ Follow-up2
- ○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:
○ 0 ○ 0
○ 1 ○ 1

CQIComments:
○ Entireform
○ Question#(s):

QA Corrections:
○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day: 0 0 0
VISITNUM / VISIT

Form Completed By QSEVAL

Code only for substances used
IN PAST 12 MONTHS

QSEVLINT= -P12M

QSTEST

Substance columns (left to right): Alcohol, Amphetamines, Cannabis, Cocaine, Hallucinogens, Inhalants, Nicotine, Opiates, PCP, Sedatives/Benzodiazapines

A1. Have you found that you needed to use a lot more (drug) in order to get high than you did when you first started using it? *IF YES, how much more? IF NO, what about finding that when you used the same amount, it had much less effect than before?*

Tolerance, as defined by either a need for markedly increased amounts of the substance in order to achieve intoxication or desired effect, or markedly diminished effect with continued use of the same amount of substance

Alcohol	Amphetamines	Cannabis	Cocaine	Hallucinogens	Inhalants	Nicotine	Opiates	PCP	Sed./Benzo.	
○	○	○	○	○	○	○	○	○	○	Present
○	○	○	○	○	○	○	○	○	○	Absent
○	○	○	○	○	○	○	○	○	○	Uncertain

QSORRES

A2. Have you ever had withdrawal symptoms, that is felt sick when you cut down or stopped using (drug)? *IF YES, what symptoms did you have? [Need to refer to withdrawal symptoms associated with each drug:]* Have you used (drug) to keep yourself from getting sick with (specific withdrawal symptom[s])?

Withdrawal, as manifested by either the characteristic withdrawal syndrome for the substance (see special criteria sets for withdrawal in p. 185 of DSM-IV manual) or the same (or closely related) substance is taken to relieve or avoid withdrawal symptoms

Alcohol	Amphetamines	Cannabis	Cocaine	Hallucinogens	Inhalants	Nicotine	Opiates	PCP	Sed./Benzo.	
○	○	○	○	○	○	○	○	○	○	Present
○	○	○	○	○	○	○	○	○	○	Absent
○	○	○	○	○	○	○	○	○	○	Uncertain

A3. Have you often found that when you started using (drug), you ended up using more of it than you were planning to? *IF NO, what about using it over a much longer period of time than you were planning to?*

Substance often taken in larger amounts or over a longer period than subject intended

Alcohol	Amphetamines	Cannabis	Cocaine	Hallucinogens	Inhalants	Nicotine	Opiates	PCP	Sed./Benzo.	
○	○	○	○	○	○	○	○	○	○	Present
○	○	○	○	○	○	○	○	○	○	Absent
○	○	○	○	○	○	○	○	○	○	Uncertain

Please mark bubbles FULLY   Correct ●   Incorrect ⊙ ⊗ ◗

Dependence

39017

SerialNumber: [ ][ ][ ][ ][ ]

Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
[ ][ ][ ][ ]	[ ][ ][ ][ ][ ]	[ ][ ][ ][ ][ ][ ]	[ ][ ] / [ ][ ] / [ ][ ][ ][ ]

Columns: Alcohol, Amphetamines, Cannabis, Cocaine, Hallucinogens, Inhalants, Nicotine, Opiates, PCP, Sedatives/Benzodiazapines

A4. Have you tried to cut down or stop using (drug)? *IF YES, have you ever actually stopped using (drug) altogether? (How many times did you try to cut down or stop altogether?) IF UNCLEAR, did you want to stop or cut down? IF NO, is this something you kept worrying about?*

Persistent desire or one or more unsuccessful efforts to cut down or control substance use.
— Present / Absent / Uncertain

A5. Have you spent a lot of time using (drug) or doing whatever you had to do to get it? Did it take you a long time to get back to normal? (How much time?)

A great deal of time spent in activities necessary to get the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain smoking) or recover from its effects.
— Present / Absent / Uncertain

A6. Have you had times when you would use (drug) so often that you used (drug) instead of working or spending time in hobbies with your family or friends?

Important social, occupational, or recreational activities given up or reduced because of substance abuse.
— Present / Absent / Uncertain

A7. *IF NOT ALREADY KNOWN*, has (drug) caused psychological problems, like making you depressed? *IF NOT ALREADY KNOWN*, has (drug) ever caused physical problems or made a physical problem worse? *IF YES TO EITHER OF THE ABOVE*, did you keep on using (drug) anyway?

Continued substance use despite knowledge of having persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the use of the substance (e.g., continued drinking despite worsening ulcer).
— Present / Absent / Uncertain

QSTEST

Number of "Present" responses for each column. Dependence is indicated by a total of 3 or more.
[ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

QSORRES

Substance Abuse
Complete this page only if participant does not meet substance dependence criteria on pages 1 & 2.

39017

SerialNumber: ☐☐☐☐☐

Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
☐☐☐☐	☐☐☐☐☐	☐☐☐☐☐	☐☐ / ☐☐ / ☐☐☐☐

Now I'd like to ask you a few more questions about your use of (drug not coded as meeting criteria for dependence).

QSEVLINT= -P12M

A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one (or more) of the following occurring within a 12-month period.

Columns: Alcohol, Amphetamines, Cannabis, Cocaine, Hallucinogens, Inhalants, Nicotine, Opiates, PCP, Sedatives/Benzodiazepines

B1. Have you often been intoxicated or high while very hungover with (drug) while you were doing something important like being at school or work, or taking care of children? *IF NO, what about missing something important, like staying away from school or work or missing an appointment because you were intoxicated, high, or very hungover? IF YES AND UNKNOWN, how often? (Over what period of time?)*

Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school, neglect of children or household).

Alcohol	Amphet.	Cannabis	Cocaine	Halluc.	Inhalants	Nicotine	Opiates	PCP	Sed./Benzo.	
O	O	O	O	O	O	O	O	O	O	Present
O	O	O	O	O	O	O	O	O	O	Absent
O	O	O	O	O	O	O	O	O	O	Uncertain

B2. Have you ever used (drug) in a situation in which it might have been dangerous to use (drug) at all? (Have you ever driven while you were really too high to drive?) *IF YES AND UNKNOWN, how often? (Over what period of time?)*

Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use).

Alcohol	Amphet.	Cannabis	Cocaine	Halluc.	Inhalants	Nicotine	Opiates	PCP	Sed./Benzo.	
O	O	O	O	O	O	O	O	O	O	Present
O	O	O	O	O	O	O	O	O	O	Absent
O	O	O	O	O	O	O	O	O	O	Uncertain

B3. Has your use of (drug) ever gotten you into trouble with the law? *IF YES AND UNKNOWN, how often? (Over what period of time?)*

Recurrent substance-related legal problems (e.g., arrests for substance-related disorderly conduct).

Alcohol	Amphet.	Cannabis	Cocaine	Halluc.	Inhalants	Nicotine	Opiates	PCP	Sed./Benzo.	
O	O	O	O	O	O	O	O	O	O	Present
O	O	O	O	O	O	O	O	O	O	Absent
O	O	O	O	O	O	O	O	O	O	Uncertain

B4. Has your use of (drug) caused problems with other people, such as with family members, friends, or people at work? (Did you ever get into physical fights or bad arguments about your drug use?) *IF YES, did you keep on using (drug) anyway? (Over what period of time?)*

Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights).

Alcohol	Amphet.	Cannabis	Cocaine	Halluc.	Inhalants	Nicotine	Opiates	PCP	Sed./Benzo.	
O	O	O	O	O	O	O	O	O	O	Present
O	O	O	O	O	O	O	O	O	O	Absent
O	O	O	O	O	O	O	O	O	O	Uncertain

QSTEST

Number of "Present" responses for each column. Abuse is indicated by a total of 1 or more.

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

QSORRES

39017

STUDYID

SerialNumber:

Site:	**Name Code:**	**ID Number:**	**Date of Assessment:**	(mm/dd/yyyy)
		USUBJID	/ /	

QSTEST

QSORRES

1. Is participant currently opioid dependent? ○ Yes ○ No

2. Is participant currently dependent on any other substance (e.g., alcohol, benzodiazapines) which requires medical attention? ○ Yes ○ No

3. Is participant currently in need of medical assistance for opioid withdrawal? ○ Yes ○ No

Signature of physician:

THIS DATA NOT ENTERED

Datesigned:

	/		/		

Comments:

THIS DATA NOT ENTERED

SERIAL number on this page should match number on page 1

ProtocolNumber: STUDYID   SerialNumber:

32993

- -

Node: **06**   Site: Name Code: ID Number: USUBJID   Date of Assessment: (mm/dd/yyyy) / / QSDTC

EPOCH

Phase:
- ○ Screening
- ○ Active
- ○ Follow-up1
- ○ Follow-up2
- ○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:
○ 0   ○ 0
○ 1   ○ 1

CQIComments:
○ Entireform
○ Question#(s):

QA   Corrections:
○ QA1   ○ QA2   ○ QA3   ○ QA4

Study Day:

VISITNUM / VISIT

Form Completed By:

QSEVAL

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking the appropriate bubble. If you are unsure about how to answer a question, please give the best answer you can.

QSTEST 1. In general, would you say your health is: QSORRES
- ○ Excellent
- ○ Verygood
- ○ Good
- ○ Fair
- ○ Poor

2. Compared to one year ago, how would you rate your health in general now?
- ○ Muchbetternowthanoneyearago
- ○ Somewhatbetternowthanoneyearago
- ○ Aboutthesameasoneyearago
- ○ Somewhatworsenowthanoneyearago
- ○ Muchworsenowthanoneyearago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Mark **one** bubble on each line.)

QSORRES

QSTEST

	QSORRES		
a. Vigorous activities such as running, lifting heavy objects, participating in strenuous sports	○ Yes,limitedalot	○ Yes,limitedalittle	○ No,notlimitedatall
b. Moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	○ Yes,limitedalot	○ Yes,limitedalittle	○ No,notlimitedatall
c. Lifting or carrying groceries	○ Yes,limitedalot	○ Yes,limitedalittle	○ No,notlimitedatall
d. Climbing several flights of stairs	○ Yes,limitedalot	○ Yes,limitedalittle	○ No,notlimitedatall
e. Climbing one flight of stairs	○ Yes,limitedalot	○ Yes,limitedalittle	○ No,notlimitedatall
f. Bending, kneeling, or stooping	○ Yes,limitedalot	○ Yes,limitedalittle	○ No,notlimitedatall
g. Walking more than a mile	○ Yes,limitedalot	○ Yes,limitedalittle	○ No,notlimitedatall
h. Walking several blocks	○ Yes,limitedalot	○ Yes,limitedalittle	○ No,notlimitedatall
i. Walking one block	○ Yes,limitedalot	○ Yes,limitedalittle	○ No,notlimitedatall
j. Bathing or dressing yourself	○ Yes,limitedalot	○ Yes,limitedalittle	○ No,notlimitedatall

1 2 3 4 5 6 7 8 9 0

A B C D E F G H I J K L M
N O P Q R S T U V W X Y Z

32993

SerialNumber:

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)

/   /

This is page 2 of the questionnaire. Make sure you complete page 1 first.

QSEVLINT = -P4W

4. During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?** (Mark **one** bubble on each line.)

    a.   Cut down the <u>amount of time</u> you spent on work or other activities ○ Yes ○ No

    b.   <u>Accomplished less</u> than you would like ○ Yes ○ No

    c.   Were limited in the <u>kind</u> of work or other activities ○ Yes ○ No

    d.   Had <u>difficulty</u> performing the work or other activities (for example, ○ Yes ○ No
        it took extra effort)

5. During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)? (Mark **one** bubble on each line.)

    a.   Cut down the <u>amount of time</u> you spent on work or other activities ○ Yes ○ No

    b.   <u>Accomplished less</u> than you would like ○ Yes ○ No

    c.   Didn't do work or other activities as <u>carefully</u> as usual ○ Yes ○ No

6. During the **past 4 weeks,** to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Mark **one** bubble.)

    ○ Notatall   ○ Slightly   ○ Moderately   ○ Quiteabit   ○ Extremely

7. How much **bodily** pain have you had during the **past 4 weeks?** (Mark **one** bubble.)

    ○ None   ○ Verymild   ○ Mild   ○ Moderate   ○ Severe   ○ Verysevere

8. During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)? (Mark **one** bubble.)

    ○ Notatall   ○ Alittlebit   ○ Moderately   ○ Quiteabit   ○ Extremely

Please mark bubbles FULLY   Correct ●   Incorrect ◉ ⊗ ●

SF - 36 ™
(continued)

32993

SerialNumber:

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
			/ /	

This is page 3 of the questionnaire. Make sure you complete pages 1 & 2 first.

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9. These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks…** (Mark **one** bubble on each line.)

   QSEVLINT = -P4W

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. did you feel full of pep?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
b. have you been a very nervous person?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
c. have you felt so down in the dumps that nothing could cheer you up?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
d. have you felt calm and peaceful?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
e. did you have a lot of energy?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
f. have you felt downhearted and blue?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
g. did you feel worn out?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
h. have you been a happy person?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6
i. did you feel tired?	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6

10. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)? (Mark **one** bubble.)

   ○ Allofthetime   ○ Mostofthetime   ○ Someofthetime   ○ Alittleofthetime   ○ Noneofthetime

11. How **true** or **false** is **each** of the following statements for you? (Mark **one** bubble on each line.)

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people.	○ 1	○ 2	○ 3	○ 4	○ 5
b. I am as healthy as anybody I know.	○ 1	○ 2	○ 3	○ 4	○ 5
c. I expect my health to get worse.	○ 1	○ 2	○ 3	○ 4	○ 5
d. My health is excellent.	○ 1	○ 2	○ 3	○ 4	○ 5

12 a. Which are you? ○ Male   ○ Female

   b. How old were you on your last birthday?
      ○ Lessthan35   ○ 35-44   ○ 45-54   ○ 55-64   ○ 65-74   ○ 75-84   ○ 85andolder

13. Have you ever filled out this form before?   ○ Yes   ○ No   ○ Don'tremember

Thank you for your time.

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 8 5

5417

Node:	Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
0 6			USUBJID	/ /	

QSDTC

EPOCH

Phase:
○ Screening
○ Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:
⓪ ⓪
① ①

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day:

Form Completed By:

VISITNUM / VISIT

QSEVAL

Please fill in the circle which best describes how you have been feeling in the last 24 hours.

QSEVLINT = -PT24H

		NONE		QSORRES		**MODERATE**					**SEVERE**
QSTEST		**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
1.	Muscle cramps	○	○	○	○	○	○	○	○	○	○
2.	Depressed or sad	○	○	○	○	○	○	○	○	○	○
3.	Painful joints	○	○	○	○	○	○	○	○	○	○
4.	Excessive yawning	○	○	○	○	○	○	○	○	○	○
5.	Hot or cold flashes	○	○	○	○	○	○	○	○	○	○
6.	Trouble getting to sleep	○	○	○	○	○	○	○	○	○	○
7.	Sick to stomach	○	○	○	○	○	○	○	○	○	○
8.	Irritable	○	○	○	○	○	○	○	○	○	○
9.	Runny nose	○	○	○	○	○	○	○	○	○	○
10.	Poor appetite	○	○	○	○	○	○	○	○	○	○
11.	Weak knees	○	○	○	○	○	○	○	○	○	○
12.	Excessive sneezing	○	○	○	○	○	○	○	○	○	○
13.	Tense, jittery	○	○	○	○	○	○	○	○	○	○
14.	Watery eyes	○	○	○	○	○	○	○	○	○	○
15.	Abdominal cramps	○	○	○	○	○	○	○	○	○	○
16.	Fitful sleep	○	○	○	○	○	○	○	○	○	○
		0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**

Please mark bubbles FULLY

Correct ● Incorrect ⊙ ⓧ ◖

28148

ProtocolNumber: STUDYID

SerialNumber:

DOMAIN: QS
Form #
2 4 0

Node:	Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
0 6			USUBJID	/ /

QSDTC

EPOCH

Phase:
○ Screening
○ Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:

○ 0 ○ 0
○ 1 ○ 1

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day:

VISITNUM / VISIT

Form Completed By

QSEVAL

Please help us improve our program by answering some questions about the services you have received. We are interested in your honest opinions, whether they are positive or negative. Please answer all of the questions. We also welcome your comments and suggestions. Thank you very much; we really appreciate your help.

QSTEST 1. When you first came to our program, were you seen as promptly as you felt necessary?

QSORRES ○ Yes,verypromptly
○ Yes,promptly
○ No,therewassomedelay
○ No,itseemedtotakeforever

2. In general, how satisfied are you with the comfort and attractiveness of our facility?
○ Quitedissatisfied
○ Indifferentormildlydissatisfied
○ Mostlysatisfied
○ VerySatisfied

3. Did the characteristics of our building detract from the services you have received?
○ Yes,theydetractedverymuch
○ Yes,theydetractedsomewhat
○ No,theydidnotdetractmuch
○ No,theydidnotdetractatall

4. How satisfied are you with the amount of help you have received?
○ Quitedissatisfied
○ Indifferent
○ Mostlysatisfied
○ VerySatisfied

5. Considering your particular needs, how appropriate are the services you have received?
○ Highlyappropriate
○ Generallyappropriate
○ Generallyinappropriate
○ Highlyinappropriate

28148

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
			/ /	

6. Have the services you received helped you to deal more effectively with your problems?
    - ○ Yes, they helped a great deal
    - ○ Yes, they helped somewhat
    - ○ No, they really didn't help
    - ○ No, they seemed to make things worse

7. When you talked to the person with whom you have worked most closely, how closely did he or she listen to you?
    - ○ Not at all closely
    - ○ Not too closely
    - ○ Fairly closely
    - ○ Very closely

8. Did you get the kind of service you wanted?
    - ○ No, definitely not
    - ○ No, not really
    - ○ Yes, generally
    - ○ Yes, definitely

9. Are there other services you need, but have not received?
    - ○ Yes, there definitely were
    - ○ Yes, I think there were
    - ○ No, I don't think there were
    - ○ No, there definitely were not

10. How clearly did the person with whom you worked most closely understand your problem and how you felt about it?
    - ○ Very clearly
    - ○ Clearly
    - ○ Somewhat unclearly
    - ○ Very unclearly

11. How competent and knowledgeable was the person with whom you have worked closely?
    - ○ Poor abilities at best
    - ○ Only of average ability
    - ○ Competent and knowledgeable
    - ○ Highly competent and knowledgeable

12. How would you rate the quality of service you have received?
    - ○ Excellent
    - ○ Good
    - ○ Fair
    - ○ Poor

Only one answer per question, please.

SerialNumber:

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
			/ /	

13. In an overall general sense, how satisfied are you with the service you have received?

○ Verysatisfied
○ Mostlysatisfied
○ Indifferentormildlydissatisfied
○ Quitedissatisfied

14. If a friend were in need of similar help, would you recommend our program to him or her?

○ No,definitelynot
○ No,Idon'tthinkso
○ Yes,Ithinkso
○ Yes,definitely

15. Have the people in our program generally understood the kind of help you wanted?

○ No,theymisunderstoodalmostcompletely
○ No,theyseemedtomisunderstand
○ Yes,theyseemedtogenerallyunderstand
○ Yes,theyunderstoodalmostperfectly

16. To what extent has our program met your needs?

○ Almostallofmyneedshavebeenmet
○ Mostofmyneedshavebeenmet
○ Onlyafewofmyneedshavebeenmet
○ Noneofmyneedshavebeenmet

17. Have your rights as an individual been respected?

○ No,almostneverrespected
○ No,sometimesnotrespected
○ Yes,generallyrespected
○ Yes,almostalwaysrespected

18. If you were to seek help again, would you come back to our program?

○ No,definitelynot
○ No,Idon'tthinkso
○ Yes,Ithinkso
○ Yes,definitely

Please fill bubbles completely: ○ ● ○ ○

CTN Clinical Opiate Withdrawal Scale (COWS)

Revised 11/09/00
Page 1 of 2

Version # **2** DOMAIN: QS, VS

Protocol Number: STUDYID

Serial Number:

Form #

2 8 0

46946

Node:	Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
0 6			USUBJID	/ /

QSDTC

EPOCH

Phase:
- ○ Screening
- ○ Active
- ○ Follow-up 1
- ○ Follow-up 2
- ○ Follow-up 3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:

⓪ ⓪
① ①

CQI Comments:
- ○ Entire form
- ○ Question #(s):

QA Corrections:
- ○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day:

VISITNUM / VISIT

Form Completed By

QSEVAL

For each item, mark the choice that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

QSTEST 1. **Resting pulse rate:** *measured after patient is sitting or lying for one minute*

QSORRES
- ○ 0 - pulse rate 80 or below
- ○ 1 - pulse rate 81-100
- ○ 2 - pulse rate 101-120
- ○ 4 - pulse rate greater than 120

Beats/minute

VS.VSTEST=PULSE RATE

VS.VSORRES

VS.VSORRESU

2. **GI upset:** *over last 1/2 hour*

- ○ 0 - no GI symptoms
- ○ 1 - stomach cramps
- ○ 2 - nausea or loose stool
- ○ 3 - vomiting or diarrhea
- ○ 5 - multiple episodes of diarrhea or vomiting

QSEVLINT = -PT30M

3. **Sweating:** *over past 1/2 hour not accounted for by room temperature or patient activity*

- ○ 0 - no report of chills or flushing
- ○ 1 - subjective report of chills or flushing
- ○ 2 - flushed or observable moistness on face
- ○ 3 - beads of sweat on brow or face
- ○ 4 - sweat streaming off face

QSEVLINT = -PT30M

4. **Tremor:** *observation of outstretched hands*

- ○ 0 - no tremor
- ○ 1 - tremor can be felt, but not observed
- ○ 2 - slight tremor observable
- ○ 4 - gross tremor or muscle twitching

5. **Restlessness:** *observation during assessment*

- ○ 0 - able to sit still
- ○ 1 - reports difficulty sitting still, but is able to do so
- ○ 3 - frequent shifting or extraneous movements of legs/arms
- ○ 5 - unable to sit still for more than a few seconds

Please PRINT CLEARLY

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

| A | B | C | D | E | F | G | H | I | J | K | L | M |
| N | O | P | Q | R | S | T | U | V | W | X | Y | Z |

**COWS
(continued)**

46946

Serial Number:

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)

6. **Yawning:** *observation during assessment*

   ○ 0 - no yawning
   ○ 1 - yawning once or twice during assessment
   ○ 2 - yawning three or more times during assessment
   ○ 4 - yawning several times/minute

7. **Pupil size:**

   ○ 0 - pupils pinned or normal size for room light
   ○ 1 - pupils possibly larger than normal for room light
   ○ 2 - pupils moderately dilated
   ○ 5 - pupils so dilated that only the rim of the iris is visible

8. **Anxiety or irritability:**

   ○ 0 - none
   ○ 1 - patient reports increasing irritability or anxiousness
   ○ 2 - patient obviously irritable or anxious
   ○ 4 - patient so irritable or anxious that participation in the assessment is difficult

9. **Bone or joint aches:** *if patient was having pain previously, only the additional component attributed to opiate withdrawal is scored*

   ○ 0 - not present
   ○ 1 - mild diffuse discomfort
   ○ 2 - patient reports severe diffuse aching of joints/muscle
   ○ 4 - patient is rubbing joints or muscles and is unable to sit still because of discomfort

10. **Gooseflesh skin:**

    ○ 0 - skin is smooth
    ○ 3 - piloerection of skin can be felt or hairs standing up on arms
    ○ 5 - prominent piloerection

11. **Runny nose or tearing:** *not accounted for by cold symptoms or allergies*

    ○ 0 - not present
    ○ 1 - nasal stuffiness or unusually moist eyes
    ○ 4 - nose constantly running or tears streaming down cheeks

QSTEST

Total score:
QSORRES

The total score is the sum of all 11 items.

Initials of evaluator and date scored:

Score: 5-12=mild; 13-24=moderate; 25-36=moderately severe; more than 36=severe withdrawal

Please fill bubbles completely: ○ ● ○ ○

CTN HIV Risk Behavior Scale (HRBS)

Version# | 1 |

Page 1 of 2

38157

ProtocolNumber: STUDYID **SerialNumber:**

DOMAIN: QS

Form #

3 1 5

| Node: | Site: | Name Code: | ID Number: | Date of Assessment: | (mm/dd/yyyy) |

0 6

USUBJID

QSDTC

EPOCH

Phase:
○ Screening
○ Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:

○ 0 ○ 0
○ 1 ○ 1

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day:

VISITNUM / VISIT

Form Completed By

QSEVAL

Please select only <u>one</u> answer per question.

QSSCAT= <u>Injected Drug Use</u>

QSEVLINT = -P1M

QSTEST

1. How many **times** have you hit up (i.e., injected yourself with any drugs or were injected by someone else) in the last <u>month</u>?

QSORRES
○ Notimes
○ Once
○ Morethanonce
○ Onceaday
○ 2-3timesaday
○ Morethanthreetimesaday

If no needle use in the last month, skip to question 7.

2. How many **times** in the last <u>month</u> have you used a needle **after** someone else had already used it? Please include the number of times you used a needle after your partner in addition to the number of times you used a needle after others.
○ Notimes
○ Onetime
○ Twotimes
○ 3-5times
○ 6-10times
○ Morethan10times

3. How many **different** people (including your partner) have used a needle **before** you in the last <u>month</u>?
○ None
○ Oneperson
○ Twopeople
○ 3-5people
○ 6-10people
○ Morethan10people

4. How many **times** in the last <u>month</u> has **someone else** used a needle **after** you used it?
○ Notimes
○ Onetime
○ Twotimes
○ 3-5times
○ 6-10times
○ Morethan10times

5. How **often**, in the last <u>month</u> have you cleaned needles before re-using them?
○ Doesnotre-use
○ Everytime
○ Often
○ Sometimes
○ Rarely
○ Never

6. Before using needles again, how **often** in the last <u>month</u> did you use bleach to clean them?
○ Doesnotre-use
○ Everytime
○ Often
○ Sometimes
○ Rarely
○ Never

Please PRINT CLEARLY

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

| A | B | C | D | E | F | G | H | I | J | K | L | M |
| N | O | P | Q | R | S | T | U | V | W | X | Y | Z |

38157

SerialNumber:

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)

QSSCAT=

QSTEST

Sexual Behavior

QSEVLINT = -P1M

7. How many **people**, including any regular partners, casual acquaintances and clients, have you had sex with in the last <u>month</u>?

QSORRES

- ○ None
- ○ Oneperson
- ○ Twopeople
- ○ 3-5people
- ○ 6-10people
- ○ Morethan10people

> If no sex in the last 30 days, you have completed this questionnaire. **THANK YOU FOR YOUR TIME.**

8. How **often**, in the last <u>month</u>, have you used condoms when having sex with your regular partner(s)?

- ○ Noregularpartner/Nopenetrativesex
- ○ Everytime
- ○ Often
- ○ Sometimes
- ○ Rarely
- ○ Never

9. How **often**, in the last <u>month</u>, have you used condoms when you had sex with casual partners (acquaintances)?

- ○ Nocasualpartners/Nopenetrativesex
- ○ Everytime
- ○ Often
- ○ Sometimes
- ○ Rarely
- ○ Never

10. How **often**, in the last <u>month</u>, have you used condoms when you **have been paid** for sex with money or drugs or when you **have paid** for sex with money or drugs?

- ○ Nopaidsex/Nopenetrativesex
- ○ Everytime
- ○ Often
- ○ Sometimes
- ○ Rarely
- ○ Never

11. How many **times** have you had anal sex in the last <u>month</u>?

- ○ Notimes
- ○ Onetime
- ○ Twotimes
- ○ 3-5times
- ○ 6-10times
- ○ Morethan10times

12. How often have you used condoms during anal sex in the last <u>month</u>?

- ○ Noregularpartner/nopenetrativesex
- ○ Everytime
- ○ Often
- ○ Sometimes
- ○ Rarely
- ○ Never

Please mark bubbles FULLY

Correct

Incorrect

22325

ProtocolNumber: STUDYID

SerialNumber:

Form #

2 9 1

Node:	Site: (G3)	Name Code:	ID Number: (G1)	Date of Assessment: (mm/dd/yyyy) (G5)
0 6			USUBJID	/ /

EPOCH

Phase:
○ Screening
○ Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:
[ ] [ ]
⓪ ⓪
① ①

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day:

Form Completed By:

(G11)

VISITNUM / VISIT QSEVAL
✚

Note: See page 16 for instructions and codes

Circled items asked at follow-up
✱ Starred items rephrased at follow-up as "Since the last ASI interview,..."

Comments:

THIS DATA NOT ENTERED

QSSCAT=**GENERAL INFORMATION**

QSTEST

QSORRES

G4. Date of admission:

/ /

(MM) (DD) (YYYY)

G8. Class:
○ 1-Intake
○ 2-Follow-up

G9. Contact code:
○ 1-InPerson
○ 2-Telephone(IntakeASImustbeinperson)
○ 3-Mail

G10. Gender:
○ 1-Male
○ 2-Female

G12. Special:
○ 1-Patientterminated
○ 2-Patientrefused
○ 3-Patientunabletorespond

Please PRINT CLEARLY
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

| A | B | C | D | E | F | G | H | I | J | K | L | M |
| N | O | P | Q | R | S | T | U | V | W | X | Y | Z |

22325

SerialNumber: [ ][ ][ ][ ][ ]

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
[ ][ ][ ][ ]	[ ][ ][ ][ ]	USUBJID [ ][ ][ ]	[ ][ ] / [ ][ ] / [ ][ ][ ][ ]

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

[ ][ ] / [ ][ ]

A-Yrs.　　B-Mos.

QSORRESU='YEAR'　　QSORRESU='MONTH'

Comments: THIS DATA NOT ENTERED

G16. Date of birth:

[ ][ ] / [ ][ ] / [ ][ ][ ][ ]

(MM)　　(DD)　　(YYYY)

G17. Of what race do you consider yourself?

- ○ 1-White(NotHispanic)
- ○ 2-Black(NotHispanic)
- ○ 3-AmericanIndian
- ○ 4-AlaskanNative
- ○ 5-Asian/Pacific
- ○ 6-Hispanic-Mexican
- ○ 7-Hispanic-PuertoRican
- ○ 8-Hispanic-Cuban
- ○ 9-OtherHispanic

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-AlcoholorDrugTreat.
- ○ 4-MedicalTreatment
- ○ 5-PsychiatricTreatment
- ○ 6-Other: _____

QSEVLINT = -P30D

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

G20. How many days?

[ ][ ]

QSEVLINT = -P30D

QSORRESU = 'DAY'

- • "NN" if question G19 is "No". Refers to total number of days detained in the past 30 days.

Please PRINT CLEARLY

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

22325

SerialNumber: ☐☐☐☐☐

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
☐☐☐☐	☐☐☐☐☐	USUBJID	☐☐ / ☐☐ / ☐☐☐☐	

QSTEST

QSORRES

Comments:

THIS DATA NOT ENTERED

* **M1.** How many times in your life have you been hospitalized for medical problems? ☐☐
- Include O.D.'s & 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? ○ 1-Yes ○ 0-No
- *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? ○ 1-Yes ○ 0-No
- *If "Yes", specify in comments.*
- Medication prescribed by a M.D. 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? ○ 1-Yes ○ 0-No
- *If "Yes", specify in comments.*
- Include Worker's 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 the liver, abscesses from needles, etc.).

QSEVLINT = -P30D

QSORRESU = 'DAY'

For questions M7 & M8, please ask patient to use the Patient's Rating Scale.

M7. How troubled or bothered have you been by these medical problems in the past 30 days? ⓪ ① ② ③ ④
- Restrict response to problem days of question M6.

QSEVLINT = -P30D

M8. How important to you *now* is treatment for these medical problems? ⓪ ① ② ③ ④
- Refers to the need for *new* or *additional* medical treatment by the patient.

CONFIDENCE RATINGS
Is the above information significantly distorted by:

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

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

Please PRINT CLEARLY

1	2	3	4	5	6	7	8	9	0

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

QSSCAT= **EMPLOYMENT/SUPPORT STATUS**

22325

SerialNumber:

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
		USUBJID	/ /	

QSTEST

QSORRES

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

A-Yrs.   B-Mos.
QSORRESU='MONTH'   THIS DATA NOT ENTERED
QSORRESU='YEAR'

* 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.

Mos.
QSORRESU='MONTH'

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

E5. Do you have an ○ 1-Yes ○ 0-No
automobile available for use?
- If answer to E4 is "No", then E5 must be
"No". Does not require ownership, only
requires availability on a regular basis.
QSORRESU='YEAR'   QSORRESU='MONTH'

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

A-Yrs.   B-Mos.

E7. Usual (or last)
occupation ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨
See Hollingshead categories on page 16

(Specify in detail)

E9. Does someone contribute ○ 1-Yes ○ 0-No
the majority of your support?

E10. Usual employment pattern, past three years:
○ 1-Full time (35+ hours) ○ 5-Military Service
○ 2-Part time (reg. hrs) ○ 6-Retired/disablility
○ 3-Part time (irreg. hrs) ○ 7-Unemployed
○ 4-Student ○ 8-In controlled
environment

QSEVLINT = -P3Y

- 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 the more current situation.

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

QSEVLINT = -P30D

QSORRESU = 'DAY'

- Include "under the table" work,
paid sick days, and vacations.

Comments:

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

EMPLOYMENT/SUPPORT STATUS (continued)

22325

SerialNumber: ☐☐☐☐☐

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
☐☐☐☐	☐☐☐☐	USUBJID	☐☐ / ☐☐ / ☐☐☐☐

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

E12. Employment:
- <u>Net</u> 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 E20-21, please ask patient to use the Patient's Rating Scale.

E20. How troubled or bothered have you been by these employment problems in the past 30 days?
- If the patient has been incarcerated or detained during the past 30 days, they cannot have employment problems.

⓪ ① ② ③ ④

E21. How important to you *now* is counseling for these employment problems?
- The patients rating in question E20-21 refer to question E19.
- Stress help in finding or preparing for a job, not giving them a job.

⓪ ① ② ③ ④

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

E23. Patient's misrepresentation? ○ 1-Yes ○ 0-No

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

Comments: THIS DATA NOT ENTERED

QSEVLINT = -P30D

QSORRESU='DOLLAR'

QSEVLINT = -P30D

QSORRESU = 'DAY'

QSEVLINT = -P30D

QSEVLINT = -P30D

QSSCAT= **ALCOHOL/DRUGS**

22325

SerialNumber: ☐☐☐☐☐

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
☐☐☐☐	☐☐☐☐	USUBJID	☐☐ / ☐☐ / ☐☐☐☐	

QSEVLINT= -P30D

Comments: THIS DATA NOT ENTERED

Route of administration:
1-Oral
2-Nasal
3-Smoking
4-Non IV injection
5-IV injection

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.

QSTEST QSORRES

Past 30   Lifetime use
QSORRESU='YEAR'

A-Days   B-Years

D1. Alcohol - (any use at all)   ☐☐ ☐☐

QSORRESU = 'DAY'

D2. Alcohol - (to intoxication)   ☐☐ ☐☐

D3. Heroin   ☐☐ ☐☐   ○ Oral ○ Non IV ○ Nasal ○ IV ○ Smoke

D4. Methadone   ☐☐ ☐☐   ○ Oral ○ Non IV ○ Nasal ○ IV ○ Smoke

D5. Other opiates/ analgesics   ☐☐ ☐☐   ○ Oral ○ Non IV ○ Nasal ○ IV ○ Smoke

D6. Barbiturates   ☐☐ ☐☐   ○ Oral ○ Non IV ○ Nasal ○ IV ○ Smoke

D7. Other sed/ hyp/tranq.   ☐☐ ☐☐   ○ Oral ○ Non IV ○ Nasal ○ IV ○ Smoke

D8. Cocaine   ☐☐ ☐☐   ○ Oral ○ Non IV ○ Nasal ○ IV ○ Smoke

D9. Amphetamines   ☐☐ ☐☐   ○ Oral ○ Non IV ○ Nasal ○ IV ○ Smoke

D10. Cannabis   ☐☐ ☐☐   ○ Oral ○ Non IV ○ IV ○ Smoke

D11. Hallucinogens   ☐☐ ☐☐   ○ Oral ○ Non IV ○ Nasal ○ IV ○ Smoke

D12. Inhalants   ☐☐ ☐☐   ○ Nasal

D13. More than one substance per day (including alcohol).   ☐☐ ☐☐

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

Alcohol/Drugs
(continued)

22325

STUDYID

SerialNumber:

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
		U$UBJID	/ /	

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. Characterized by shaking, severe disorientation, fever, hallucinations, they usually require medical attention.

Comments: THIS DATA NOT ENTERED

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 $ QSEVLINT = -P30D   QSORRESU='DOLLAR'

D24. Drugs
- Only count actual **money** spent. What is the financial burden caused by drugs/alcohol? $ QSEVLINT = -P30D   QSORRESU='DOLLAR'

D25. How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days?
- *Include AA/NA*   QSEVLINT = -P30D

For questions D28-31, please ask patient to use the Patient's Rating Scale. The patient is rating the need for additional substance abuse treatment.

D26. How many days in the past 30 have you experienced alcohol problems?   QSEVLINT = -P30D

D28. How troubled or bothered have you been the past 30 days by these alcohol problems?   ⓪ ① ② ③ ④   QSEVLINT = -P30D

D30. How important to you *now* is treatment for these alcohol problems?   ⓪ ① ② ③ ④

D27. How many days in the past 30 have you experienced drug problems?
- Include only: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.   QSEVLINT = -P30D

D29. How troubled or bothered have you been in the past 30 days by these drug problems?   ⓪ ① ② ③ ④   QSEVLINT = -P30D

D31. How important to you *now* is treatment for these drug problems?   ⓪ ① ② ③ ④

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

D34. Patient's misrepresentation?   ○ 1-Yes   ○ 0-No
D35. Patient's inability to understand?   ○ 1-Yes   ○ 0-No

QSSCAT= **LEGAL STATUS**

22325

SerialNumber:

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
		USUBJID	/ /	

QSTEST

QSORRES

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

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

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

* L3. Shoplifting/vandalism

* L4. Parole/probation violations

* L5. Drug charges

* L6. Forgery

* L7. Weapons offense

* L8. Burglary/larceny/B&E

* L9. Robbery

* L10. Assault

* L11. Arson

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.

Comments: THIS DATA NOT ENTERED

Please PRINT CLEARLY

1 2 3 4 5 6 7 8 9 0

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

LEGAL STATUS
(continued)
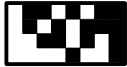
22325

STUDYID

SerialNumber:

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
		USUBJID	/ /	

* (L12.) Rape

* (L13.) Homicide/manslaughter

* (L14.) Prostitution

* (L15.) Contempt of court

* (L16.) Other: _____

* (L17) How many of these charges resulted in convictions?
- If L3-16="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? Mos.

- If incarcerated 2 weeks or more, round this up to 1 month. List total number of months incarcerated.

Comments: THIS DATA NOT ENTERED

QSORRESU='MONTH'

Please PRINT CLEARLY

1	2	3	4	5	6	7	8	9	0

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

**LEGAL STATUS
(continued)**

22325

SerialNumber:

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
		USUBJID	/ /	

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

Comments: THIS DATA NOT ENTERED

L25 What for? (If multiple charges, use most severe.)
- Refers to question L24. If more than one, choose most severe.
- Don't include civil cases, unless a criminal offense is involved.

○ 03-Shoplift ○ 08-Burglary ○ 13-Homicide ○ 19-DWI

○ 04-Prob. viol. ○ 09-Robbery ○ 14-Prostitution ○ 20-Major driving violation

○ 05-Drug ○ 10-Assault ○ 15-Contempt

○ 06-Forgery ○ 11-Arson ○ 16-Other

○ 07-Weapons ○ 12-Rape ○ 18-Disorderly conduct

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

QSEVLINT = -P30D

QSORRESU = 'DAY'

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.

QSEVLINT = -P30D

QSORRESU = 'DAY'

For questions L28 & 29, please ask patient to use the Patient's Rating Scale

L28 How serious do you feel your present legal problems are? ⓪ ① ② ③ ④
- Exclude civil problems.

L29 How important to you *now* is counseling or referral for these legal problems? ⓪ ① ② ③ ④
- Patient is rating a need for additional referral to legal counsel for defense against criminal charges.

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

L31 Patient's misrepresentation? ○ 1-Yes ○ 0-No

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

Please PRINT CLEARLY 1 2 3 4 5 6 7 8 9 0

| A | B | C | D | E | F | G | H | I | J | K | L | M |
| N | O | P | Q | R | S | T | U | V | W | X | Y | Z |

41616

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 9 2

Node:	Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
0 6			USUBJID	/ /	

EPOCH

Phase:
○ Screening
○ Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:
☐ ☐
⓪ ⓪
① ①

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1   ○ QA2   ○ QA3   ○ QA4

Study Day:

Form Completed By:

VISITNUM / VISIT   QSEVAL

QSTEST

QSORRES

Comments: THIS DATA NOT ENTERED

F1. Marital Status:
○ 1-Married   ○ 4-Separated
○ 2-Remarried ○ 5-Divorced
○ 3-Widowed   ○ 6-Never Married

Common-law marriage=1. Specify in comments.

F3. Are you satisfied with this situation?
Satisfied=generally liking the situation. Refers to question F1.
○ 2-Yes   ○ 0-No   ○ 1-Indifferent

* **F4.** Usual living arrangements (past 3 yrs.):
○ 1-With sexual partner and children   ○ 6-With friends
○ 2-With sexual partner alone   ○ 7-Alone
○ 3-With children alone   ○ 8-Controlled environment
○ 4-With parents   ○ 9-No stable arrangements
○ 5-With family

QSEVLINT = -P3Y

Choose arrangements most representative of the past 3 years. If there is an even split in time between these arrangements, choose the most recent arrangements.

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

Do you live with anyone who:

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

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

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

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

Please PRINT CLEARLY   1 2 3 4 5 6 7 8 9 0

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

41616

SerialNumber: ☐☐☐☐☐

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
☐☐☐☐	☐☐☐☐	USUBJID	☐☐ / ☐☐ / ☐☐☐☐

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

QSEVLINT = -P30D

A. Past 30 days

B. In your life

(F18.) Mother   ○ 1-Yes ○ 0-No   ○ 1-Yes ○ 0-No

(F19.) Father   ○ 1-Yes ○ 0-No   ○ 1-Yes ○ 0-No

(F20.) Brothers/sisters   ○ 1-Yes ○ 0-No   ○ 1-Yes ○ 0-No

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

(F21.) Sexual partner/spouse   ○ 1-Yes ○ 0-No   ○ 1-Yes ○ 0-No

(F22.) Children   ○ 1-Yes ○ 0-No   ○ 1-Yes ○ 0-No

(F23.) Other significant family: ○ 1-Yes ○ 0-No   ○ 1-Yes ○ 0-No

(specify) ☐☐☐☐☐☐☐☐☐

(F24.) Close friends   ○ 1-Yes ○ 0-No   ○ 1-Yes ○ 0-No

(F25.) Neighbors   ○ 1-Yes ○ 0-No   ○ 1-Yes ○ 0-No

(F26.) Co-workers   ○ 1-Yes ○ 0-No   ○ 1-Yes ○ 0-No

Did anyone abuse you: A. Past 30 days   B. In your life

F28. Physically (cause you physical harm)?   ○ 1-Yes ○ 0-No   ○ 1-Yes ○ 0-No

F29. Sexually (force sexual advances/acts)?   ○ 1-Yes ○ 0-No   ○ 1-Yes ○ 0-No

---

Comments: THIS DATA NOT ENTERED

Please PRINT CLEARLY

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 |

| A | B | C | D | E | F | G | H | I | J | K | L | M |
| N | O | P | Q | R | S | T | U | V | W | X | Y | Z |

41616

SerialNumber: [ ][ ][ ][ ][ ]

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
[ ][ ][ ][ ]	[ ][ ][ ][ ][ ]	USUBJID [ ][ ][ ][ ]	[ ][ ] / [ ][ ] / [ ][ ][ ][ ]	

QSORRESU = 'DAY'

F30. How many days in the past 30 have you had serious conflicts with your family? [ ][ ]

Comments: THIS DATA NOT ENTERED

QSEVLINT = -P30D

For questions F32-34, please ask patient to use the Patient's Rating Scale

F32. How troubled or bothered have you been in the past 30 days by these family problems? ⓪ ① ② ③ ④

QSEVLINT = -P30D

F34. How important to you *now* is treatment or counseling for these family problems? ⓪ ① ② ③ ④

F31. How many days in the past 30 have you had serious conflicts with other people (excluding family)? [ ][ ]

QSORRESU = 'DAY'

QSEVLINT = -P30D

For questions F33-35, ask the patient to use the patient's rating scale

F33. How troubled or bothered have you been in the past 30 days by social problems? ⓪ ① ② ③ ④

QSEVLINT = -P30D

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

F35. How important to you *now* is treatment or counseling for these social problems? ⓪ ① ② ③ ④

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

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

F38. Patient's inability to understand? ◯ 1-Yes ◯ 0-No

Please PRINT CLEARLY   1 2 3 4 5 6 7 8 9 0

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

PSYCHIATRIC STATUS

QSSCAT=

41616

SerialNumber:

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
		USUBJID	/ /	

QSTEST/QSORRES

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

* (P1.) In a hospital or inpatient setting?

* (P2.) As an outpatient or private patient

(P3.) Do you receive a pension for a psychiatric disability? ○ 1-Yes ○ 0-No

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.

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

QSEVLINT = -P30D

A. Past 30 days   B. In your life

	A. Past 30 days	B. In your life
(P4.) Experienced serious depression- sadness, hopelessness, loss of interest, difficulty with daily function?	○ 1-Yes ○ 0-No	○ 1-Yes ○ 0-No
(P5.) Experienced serious anxiety/tension- uptight, unreasonably worried, inability to feel relaxed?	○ 1-Yes ○ 0-No	○ 1-Yes ○ 0-No
(P6.) Experienced hallucinations- saw things or heard voices that were not there?	○ 1-Yes ○ 0-No	○ 1-Yes ○ 0-No
(P7.) Experienced trouble understanding, concentrating, or remembering?	○ 1-Yes ○ 0-No	○ 1-Yes ○ 0-No
(P8.) Experienced trouble controlling violent behavior including episodes of rage, or violence?	○ 1-Yes ○ 0-No	○ 1-Yes ○ 0-No
(P9.) Experienced serious thoughts of suicide? • Patient seriously considered a plan for taking his/her life.	○ 1-Yes ○ 0-No	○ 1-Yes ○ 0-No
(P10.) Attempted suicide? • Include actual suicidal gestures or attempts	○ 1-Yes ○ 0-No	○ 1-Yes ○ 0-No
(P11.) Been prescribed medication for any psychological/emotional problem? • Prescribed for the patient by MD. Record "Yes" if a medication was prescribed *even if* the patient is not taking it.	○ 1-Yes ○ 0-No	○ 1-Yes ○ 0-No

For questions P8-10, patient could have been under the influence of alcohol/drugs.

Comments:

THIS DATA NOT ENTERED

Please PRINT CLEARLY

1	2	3	4	5	6	7	8	9	0

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

PSYCHIATRIC STATUS
(continued)
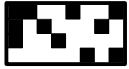
41616

SerialNumber:

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
		USUBJID	/ /	

Comments: THIS DATA NOT ENTERED

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

QSEVLINT = -P30D

QSORRESU = 'DAY'

- This refers to problems noted in question P4-10

**For questions P13 & 14, please ask patient to use
the Patient's Rating Scale**

(P13) How much have you been troubled or ⓪ ① ② ③ ④
bothered by these psychological or emotional
problems in the past 30 days?

QSEVLINT = -P30D

- Patient should be rating the problem days
from question P12

(P14) How important to you *now* is treatment ⓪ ① ② ③ ④
for these psychological or emotional problems?

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

(P22) Patient's misrepresentation?   ○ 1-Yes   ○ 0-No

(P23) Patient's inability to understand?   ○ 1-Yes   ○ 0-No

**Please
PRINT CLEARLY**   1 2 3 4 5 6 7 8 9 0

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

CODES
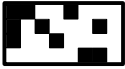
41616

SerialNumber:

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)

/   /

Patient Rating Scale

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

Hollingshead Categories

1. Higher executive, major professional, owner of large business.

2. Business manager if medium sized business, lesser professionals, i.e., nurses, opticians, pharmacists, social workers, teachers.

3. Administrative personnel, manager, minor professionals, owner/Proprietor of small business, 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 (barber, brakeman, chef, electrician, fireman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, police, 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, include unemployed).

8. Homemaker.

9. Student, disabled, no occupation.

Comments (include question number)

Please PRINT CLEARLY

1 2 3 4 5 6 7 8 9 0

A B C D E F G H I J K L M
N O P Q R S T U V W X Y Z

CTN Ancillary Medication Dispensed

Version# | 1

ProtocolNumber: STUDYID   SerialNumber:

2908

Form #
2 1 0

Node:	Site:	Name Code:	ID Number:	Date of BASELINE Interview: (mm/dd/yyyy)
0 6			USUBJID	/ /

CMDTC

EPOCH

Phase:
○ Screening
● Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:
⓪ ⓪
① ①

CQIComments:
○ Entireform
○ Question#(s):

QA Corrections:
○ QA1   ○ QA2   ○ QA3   ○ QA4

CMCAT = ANCILLARY MEDICATIONS

All participants have the option to receive ancillary medications during days 1-13. Use of ancillary medications are **LIMITED TO THOSE MEDICATIONS LISTED BELOW.** Use of ancillary medications will be closely monitored for the duration of the study interventions.

VISITNUM / VISIT

CMINDIC
A. FOR ANXIETY AND RESTLESSNESS:

CMTRT   CMDOSETXT

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13
1. Oxazepam (Serax) 15-30 mg. po q6 hours prn; NTE 120 mg. per 24 hours **OR**	○	○	○	○	○	○	○						
2. Phenobarbitol (Arco-lase plus Donnatal) 15-30 mg. po q6 hours prn; NTE 120 mg. per 24 hours **OR**	○	○	○	○	○	○	○						
3. Hydroxyzene hydrochloride (Atarax, Marax, Vistaril) 50 mg. po q6 hours prn; NTE 200 mg. per 24 hours **OR**	○	○	○	○	○	○	○	○	○	○	○	○	○
4. Lorazepam (Ativan) 1-2 mg. q6 hours prn; NTE 8 mg. per 24 hours **OR**	○	○	○	○	○	○	○	○	○	○	○	○	○
5. Oxazepam (Serax) 15-30 mg. po q6 hours prn; NTE 60 mg. per 24 hours **OR**								○	○	○	○	○	○
6. Phenobarbitol (Arco-lase plus Donnatal) 15-30 mg. po q6 hours prn; NTE 60 mg. per 24 hours								○	○	○	○	○	○

CMOCCUR

| Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 | Day 7 | Day 8 | Day 9 | Day 10 | Day 11 | Day 12 | Day 13 |

Please mark bubbles FULLY

Correct ●
Incorrect ◉ ⊗ ●

2908

SerialNumber: ☐ ☐ ☐ ☐ ☐ ☐

Site: ☐ ☐ ☐ ☐   **Name Code:** ☐ ☐ ☐ ☐   **ID Number:** ☐ ☐ ☐ ☐

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13
B. FOR BONE PAIN AND ARTHRALGIAS:													
7. Non-steroidal anti-inflammatory agent, such as ibuprofen (Advil, Motrin, and others) 800 mg. po q8 hours with food; NTE 3200 mg. per 24 hours **OR**	○	○	○	○	○	○	○	○	○	○	○	○	○
8. Acetaminophen (Tylenol) 650 mg. q4-6 hours; NTE 3900 mg. per 24 hours **OR**	○	○	○	○	○	○	○	○	○	○	○	○	○
9. Methocarbamol (Robaxin and others) 500-1000 mg. po q6 hours prn; NTE 2000 mg. per 24 hours	○	○	○	○	○	○	○	○	○	○	○	○	○
C. FOR NAUSEA:													
10. Trimethobenzamide (Tigan) 250 mg. po q8 hours prn; NTE 750 mg. per 24 hours **OR**	○	○	○	○	○	○	○	○	○	○	○	○	○
11. Trimethobenzamide (Tigan) 100-200 mg. suppositories; NTE 750 mg. per 24 hours	○	○	○	○	○	○	○	○	○	○	○	○	○
D. FOR DIARRHEA:													
12. Loperamide (Imodium) 2 mg., 2 caps followed by 1 cap after each unformed stool; NTE 8 mg. per 24 hours **OR**	○	○	○	○	○	○	○	○	○	○	○	○	○
13. Donnatal 1-2 tablets po q6-8 hours prn; NTE 8 tablets per day	○	○	○	○	○	○	○	○	○	○	○	○	○
E. FOR INSOMNIA:													
14. Zolpidem tartrate (Ambien) 10 mg. 1-3 tabs po qhs prn **OR**	○	○	○	○	○	○	○	○	○	○	○	○	○
15. Trazadone hydrochloride (Desyrel) 50 mg. 1-3 tabs po qhs prn **OR**	○	○	○	○	○	○	○	○	○	○	○	○	○
16. Doxepin hydrochloride (Sinequan, Zonalon) 50 mg. 1-3 tabs po qhs prn **OR**	○	○	○	○	○	○	○	○	○	○	○	○	○
17. Diphenhydramine HCL (Benadryl) 25-50 mg. q 4-6 hrs prn; NTE 300 mg. q 24 hrs	○	○	○	○	○	○	○	○	○	○	○	○	○

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13
F. IF NO ANCILLARY MEDICATIONS GIVEN, PLEASE MARK HERE:	○	○	○	○	○	○	○	○	○	○	○	○	○

Signature of physician at final review:

DateSigned: ☐ ☐ / ☐ ☐ / ☐ ☐ ☐ ☐

QNAM=ANCSDTC
QLABEL=NO ANCILLARY MEDICATIONS GIVEN FOR DAY x
IDVAR=USUBJID

QNAM=ANCSDTC
QLABEL=DATE PHYSICIAN SIGNATURE ANCILLARY MEDS
IDVAR = USUBJID

CTN Prior and Concomitant Medications

Version# **1**

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 2 0

53909

CMCAT = PRIOR AND CONCOMITANT MEDICATIONS

Node: **0 6**

Site:

Name Code:

ID Number: USUBJID

Date of BASELINE Interview: (mm/dd/yyyy)

CMDTC

QNAM = NOCON1-16
QLABEL = NO LISTED CONMEDS WERE TAKEN FOR DAY x
IDVAR = USUBJID

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1   ○ QA2   ○ QA3   ○ QA4

QNAM=INTERACT
QLABEL=POSSIBLE INTERACTION WITH STUDY MED
IDVAR=CMSEQ

☞ **IF NO LISTED CONMEDS WERE TAKEN, PLEASE MARK HERE:**

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU1

ROUTE CODES
1=oral
2=subcutaneous
3=intramuscular
4=intravenous
5=topical
6=rectal
7=nasal
8=inhaled
9=other

Fill in the bubble below if the medication has the potential to interact negatively with the study medications.

Drug type	CMTRT A. Medication (generic)	CMINDC B. Purpose/Indication	CMROUTE C. Route code	CMDOSTOT D. Total daily dosage in grams:	CMDOSU

CMSCAT

1. Beta blockers

E. Last use within last 30 days: / CMENDTC /

○ **Possible interaction with study medication**

VISITNUM / VISIT

F.Studydayshavingtakenthismedication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU1

2. Calcium channel blockers

E. Last use within last 30 days: / /

○ **Possible interaction with study medication**

F. Study days having taken this medication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU 1

3. Digitalis

E. Last use within last 30 days: / /

○ **Possible interaction with study medication**

F. Study days having taken this medication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU 1

4. Tricyclics

E. Last use within last 30 days: / /

○ **Possible interaction with study medication**

F. Study days having taken this medication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU 1

Please PRINT CLEARLY

1	2	3	4	5	6	7	8	9	0

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

53909

SerialNumber: ☐☐☐☐☐

Site: ☐☐☐☐☐ **Name Code:** ☐☐☐☐ **ID Number:** ☐☐☐☐☐

| | A. Medication (generic) | B. Purpose/Indication | C. Route code | D. Total daily dosage in grams: |

5. Buprenorphine/ Clonidine (non-study)

E. Last use within last 30 days: ☐☐ / ☐☐ / ☐☐☐☐

○ **Possible interaction with study medication**

F. Study days having taken this medication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU 1

6. Methadone

E. Last use within last 30 days: ☐☐ / ☐☐ / ☐☐☐☐

○ **Possible interaction with study medication**

F. Study days having taken this medication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU 1

7. LAAM

E. Last use within last 30 days: ☐☐ / ☐☐ / ☐☐☐☐

○ **Possible interaction with study medication**

F. Study days having taken this medication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU 1

○ No medication recorded above could interact with the study medications in a dangerous or undesirable manner.

Signature of physician at **BASELINE:**

QNAM = NOINTB
QLABEL=AT BASELINE, NO INTERACTING MEDS
IDVAR = USUBJID

DateSigned: ☐☐ / ☐☐ / ☐☐☐☐

QNAM = NOINTBD
QLABEL=PHYSICIAN SIGNATURE BASELINE
IDVAR = USUBJID

○ No medication recorded above could interact with the study medications in a dangerous or undesirable manner.

Signature of physician at **END OF ACTIVE PARTICIPATION:**

QNAM = NOINTEA
QLABEL=AT END OF ACTIVE, NO INTERACTING MEDS
IDVAR = USUBJID

DateSigned: ☐☐ / ☐☐ / ☐☐☐☐

QNAM = NOINTEAD
QLABEL=PHYSICIAN SIGNATURE, END OF ACTIVE   IDVAR = USUBJID

○ No medication recorded above could interact with the study medications in a dangerous or undesirable manner.

Signature of physician at **FOLLOW-UP 1:**

QNAM = "NOINTFU"
QLABEL=AT END OF FUP 1, NO INTERACTING MEDS
IDVAR = USUBJID

DateSigned: ☐☐ / ☐☐ / ☐☐☐☐

QNAM = NOINTFUD
QLABEL=PHYSICIAN SIGNATURE, END OF FUP 1   IDVAR = USUBJID

Please use form 221 - Prior and ConMed Addendum to record additional medications

CTN Prior and ConMed Addendum

Version# **1**

Approved 10/24/00
Page 1 of 1

ProtocolNumber: *STUDYID*

SerialNumber:

Form #
2 2 1

31296

Node:	Site:	Name Code:	ID Number: *USUBJID*	Date of BASELINE Interview: (mm/dd/yyyy) *CMDTC*
0 6				/ /

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:

CQIComments:
○ Entireform
○ Question#(s):

QA   Corrections:
○ QA1   ○ QA2   ○ QA3   ○ QA4

0 0
1 1

QNAM=INTERACT
QLABEL=POSSIBLE INTERACTION WITH STUDY MED
IDVAR=CMSEQ

CMCAT = PRIOR AND CONCOMITANT MEDICATIONS

CMSCAT

CMTRT
A. Medication (generic)

CMINDC
B. Purpose/Indication

CMROUTE
C. Route code

CMDOSTOT   *CMDOSU*
D. Total daily dosage in grams:

1. Other

CMENDTC E. Last use within last 30 days: ___ / ___ / ___

○ Possible interaction with study medication

F. Study days having taken this medication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU 1

VISITNUM / VISIT

2. Other

E. Last use within last 30 days: ___ / ___ / ___

○ Possible interaction with study medication

F. Study days having taken this medication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU 1

3. Other

E. Last use within last 30 days: ___ / ___ / ___

○ Possible interaction with study medication

F. Study days having taken this medication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU 1

CMSPID

4. Other

E. Last use within last 30 days: ___ / ___ / ___

○ Possible interaction with study medication

F. Study days having taken this medication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU 1

5. Other

E. Last use within last 30 days: ___ / ___ / ___

○ Possible interaction with study medication

F. Study days having taken this medication:
○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11 ○ 12 ○ 13 ○ 14 ○ FU 1

Please PRINT CLEARLY   1 2 3 4 5 6 7 8 9 0

A B C D E F G H I J K L M
N O P Q R S T U V W X Y Z

CTN Adverse Events

Form # **2 2 5** Version# **1**

32771

Node: 0 6

Protocol Number: _____ - STUDYID

Site: _____

Name Code: _____

ID Number: _____ - _____ USUBJID

Serial#: _____

Date of Assessment: ___/___/___ (mm/dd/yyyy) AEDTC

Phase: EPOCH
○ Screening ○ Active ○ Follow-up 1 ○ Follow-up 2 ○ Follow-up 3

Study Day: _____ VISITNUM / VISIT

Form Completed By: _____

☞ IF NO AE OCCURRED, PLEASE MARK HERE: ○

CQI Comments:
○ Entire form
○ Question#(s): _____
QA Corrections: _____
CQI: _____

○ QA1
○ QA2
○ QA3
○ QA4

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

Page _____ **of** _____

C. TYPE OF REPORT
1=Anticipated
2=Unanticipated
3=Intercurrent illness
4=Withdrawal
AEREL

D. STUDY DRUG RELATED
1=Definitely
2=Probably
3=Possibly
4=Remotely
5=Definitely not
9=Unknown
AEREL

E. SEVERITY
1=Mild
2=Moderate
3=Severe
4=Life threatening
AESEV

F. ACTION TAKEN REGARDING STUDY DRUG
1=None
2=Discontinued permanently
3=Discontinued temporarily
4=Reduced dose
5=Increased dose
6=Delayed dose
AEACN

G. OTHER ACTION TAKEN (May code up to 3)
1=None
2=Therapy pharm. (OTC or Rx) **
3=Therapy non-pharm. *
4=Hospitalization *

H. OUTCOME
1=Resolved, no sequelae
2=Not yet resolved, but improving
3=Not yet resolved, no change
4=Not yet resolved, worsening
5=Resulted in chronic condition, severe and/or permanent *
6=Deceased *
7=Unknown
AEOUT

I. SERIOUS? If YES, complete SAE from
AESER

AESPID

A. Adverse event description (One item per line. List syndrome components separately.) AETERM

B. Date and time of onset/change in severity ___/___/___ AESTDTC

C: ① ② ③ ④ **D.** ① ② ③ ④ ⑤ ⑨ **E.** ① ② ③ ④ **F:** ① ② ③ ④ ⑤ ⑥ **G.** ① ② ③ ④ **H:** ① ② ③ ④ ⑤ ⑥ ⑦ (Use 24 hour clock) + **I.** ○ Yes* ○ No

J. Date and time of resolution/change in severity + ___:___ (Use 24 hour clock) + AEENTC

A. Adverse event description

B. Date and time of onset/change in severity + ___/___/___

C: ① ② ③ ④ **D:** ① ② ③ ④ ⑤ ⑨ **E:** ① ② ③ ④ **F:** ① ② ③ ④ ⑤ ⑥ **G.** ① ② ③ ④ **H:** ① ② ③ ④ ⑤ ⑥ ⑦ (Use 24 hour clock) + **I.** ○ Yes* ○ No

J. Date and time of resolution/change in severity ___:___ (Use 24 hour clock) +

A. Adverse event description

B. Date and time of onset/change in severity + ___/___/___

C: ① ② ③ ④ **D:** ① ② ③ ④ ⑤ ⑨ **E:** ① ② ③ ④ **F:** ① ② ③ ④ ⑤ ⑥ **G.** ① ② ③ ④ **H:** ① ② ③ ④ ⑤ ⑥ ⑦ (Use 24 hour clock) + **I.** ○ Yes* ○ No

J. Date and time of resolution/change in severity ___:___ (Use 24 hour clock) +

Physician's signature _____

Datesigned: ___/___/___

* Complete SERIOUS Adverse Event form
** Complete Conmed form
+ Estimate time to the best of your ability (e.g., if the subject awoke with a headache, enter time the subject awoke.) If time is unknown, enter 55:55

QVAL   QNAM=RPTTYP   QLABEL=TYPE OF REPORT   IDVAR=AESEQ

AEACNOTH   AECONTRT

60796

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 3 0

Node:	Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
0 6			USUBJID	/ / AEDTC

EPOCH

Phase:
○ Screening
○ Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:
[ ] [ ]
⓪ ⓪
① ①

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1   ○ QA2   ○ QA3   ○ QA4

Study Day:
VISITNUM / VISIT

Form Completed By

DEMOGRAPHIC INFORMATION

1. Randomization date: [ ] / [ ] / [ ]

QNAM = AERANDDT
QLABEL= RANDOMIZATION DATE (SAE PAGE)
IDVAR= AESEQ

2. Sex: ○ Male   ○ Female

QNAM=AESEX   QLABEL=SEX (SAE PAGE)   IDVAR=AESEQ

3. Date of birth: [ ] / [ ] / [ ]

QNAM=AEDOB   IDVAR = AESEQ
QLABEL=DATE OF BIRTH (SAE PAGE)

4. Race/Ethnicity:
○ White,notofHispanicorigin
○ HispanicorLatino
○ AfricanAmericanorBlack not of Hispanic origin.
○ AsianorPacificIslander
○ NativeAmericanorNativeAlaskan
○ Unknown
○ Other   specify:

QNAM=AEETHNIC
QLABEL=RACE/ETHNICITY (SAE PAGE)
IDVAR = AESEQ

QNAM=AEETHOTH
QLABEL=RACE/ETHNICITY (SAE PAGE)
IDVAR=AESEQ

5. Height: [ ] [ ]   ○ inches   ○ centimeters

QNAM=AEHGT
QLABEL=HEIGHT (SAE PAGE)
IDVAR=AESEQ

QNAM=AEHGTU   IDVAR=AESEQ
QLABEL=HEIGHT UNITS (SAE PAGE)

6. Weight: [ ] [ ]   ○ pounds   ○ kilograms

QNAM=AEWGT
QLABEL=WEIGHT (SAE PAGE)
IDVAR=AESEQ

QNAM=AEHGTU   IDVAR=AESEQ
QLABEL=WEIGHT UNITS (SAE PAGE)

SERIOUS ADVERSE EVENT   AESER=Y

7. Serious adverse event description:

AETERM

8. Onset date: [ ] / [ ] / [ ]   AESTDTC

9. Severity grade: ○ Severe   ○ Life-threatening   ○ Lethal   AESEV

10. Was SAE related to Investigational Agent?
○ Definitely   ○ Probably   ○ Possibly   ○ Remotely   ○ Definitelynot   ○ Unknown   AEREL

Please use the final page of the form for additional notes.

Please PRINT CLEARLY   1 2 3 4 5 6 7 8 9 0

A B C D E F G H I J K L M
N O P Q R S T U V W X Y Z

SAE
(continued)

60796

SerialNumber:

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
		USUBJID	/ /	

11. Action taken regarding Investigational Agent:

AEACN

- ○ None
- ○ Discontinuedpermanently
- ○ Discontinuedtemporarily
- ○ Reduceddose
- ○ Increaseddose
- ○ Delayeddose

12. Other action(s) taken: AEACNOTH

- ○ None
- ○ Remedialtherapy-pharmacologic
- ○ Remedialtherapy-nonpharmacologic
- ○ Hospitalization(neworprolonged)

13. Outcome: AEOUT

AESDEATH
AESLIFE
AESHOSP

- ○ Death
- ○ Life-threateningevent
- ○ Hospitalization

- ○ Disability
- ○ Congenitalanomaly
- ○ Other

AEDISAB
AESCONG
AESMIE

specify:

QNAM=AESOUTOT

QLABEL=OUTCOME - OTHER, SPECIFY

IDVAR=AESEQ

14. Relevant tests/laboratory data, including dates:

QNAM = RELTEST1 - RELTEST3
QLABEL = SAE - RELEVANT TESTS/LAB DATA, LINE 1   (2,3)
IDVAR = AESEQ

15. Relevant history, including pre-existing medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):

QNAM = RELHIST1 - RELHIST3
QLABEL = RELEVANT HISTORY, PRE-EXIST COND, LINE 1   (2,3)
IDVAR = AESEQ

16. SAE resolution date:

/ / AEENDTC

(mm/dd/yyyy)

○ Continuing

If Continuing then
AEENRF=DURING/AFTER

Please use the final page of the form for additional notes.

Please PRINT CLEARLY

1	2	3	4	5	6	7	8	9	0

A	B	C	D	E	F	G	H	I	J	K	L	M
N	O	P	Q	R	S	T	U	V	W	X	Y	Z

SAE (continued)

60796

STUDYID

SerialNumber: ☐☐☐☐☐

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
☐☐☐☐	☐☐☐☐	USUBJID	☐☐ / ☐☐ / ☐☐☐☐	

17. Is Investigational Agent information known? ○ Yes ○ No

QNAM=IAKNOWN QLABEL=IS INVEST. AGENT INFORMATION KNOWN? IDVAR=AESEQ

18. If yes, Investigational Agent name:

QNAM=IANAME QLABEL=INV AGENT NAME IDVAR=AESEQ

19. Lot number:

QNAM=IALOT QLABEL=INV AGENT LOT NUMBER IDVAR=AESEQ

20. Expiration date: ☐☐ / ☐☐ / ☐☐

QNAM=IAEXPDT QLABEL=INV AGENT EXPIRATION DATE IDVAR=AESEQ

21. Route of administration:
○ auricular   ○ intravenous   ○ sublingual
○ inhaled   ○ nasal   ○ transdermal
○ intra-articular   ○ oral   ○ vaginal
○ intramuscular   ○ rectal   ○ unknown
○ intraocular   ○ subcutaneous   ○ other

QNAM = IAROUTE QLABEL = INV AGENT ROUTE IDVAR = AESEQ

QNAM = IAROTH QLABEL=INV AGENT ROUTE - OTHER, SPECIFY IDVAR = AESEQ

specify:

22. Frequency:
○ single dose   ○ twice daily   ○ as needed
○ every other day   ○ three times a day   ○ other
○ once daily   ○ four times a day

QNAM = IAFREQ QLABEL=INV AGENT FREQUENCY IDVAR = AESEQ

specify:

QNAM = IAFRQOTH QLABEL=INV AGENT FREQUENCY - OTHER, SPECIFY IDVAR=AESEQ

23. Quantity:

QNAM = IAQUANT QLABEL = INV AGENT QUANTITY IDVAR = AESEQ

24. Unit code:
○ capsule   ○ microliter   ○ puff   ○ teaspoon
○ drop   ○ milligram   ○ spray/squirt   ○ unknown
○ grain   ○ milliliter   ○ suppository   ○ other
○ gram   ○ ounce   ○ tablespoon
○ microgram   ○ patch   ○ tablet

QNAM = IAUNIT QLABEL = INV AGENT UNIT IDVAR = AESEQ

specify:

QNAM=IAUNTOTH QLABEL=INV AGENT UNIT - OTHER, SPECIFY IDVAR=AESEQ

25. Start date: ☐☐ / ☐☐ / ☐☐

QNAM=IASTDTC QLABEL=INV AGENT START DATE IDVAR=AESEQ

26. Stop date: ☐☐ / ☐☐ / ☐☐

QNAM=IAENDTC QLABEL=INV AGENT END DATE IDVAR=AESEQ

27. Name of investigator:

QNAM=INVNAME QLABEL=INVESTIGATOR NAME IDVAR=AESEQ

Investigator's signature: _____

Datesigned: ☐☐ / ☐☐ / ☐☐

QNAM=INVSIGDT QLABEL=INV AGENT DATE INVESTIGATOR SIGNED IDVAR=AESEQ

28. Name of physician:

QNAM=DRNAME QLABEL=PHYSICIAN'S NAME IDVAR = AESEQ

Physician's signature: _____

Datesigned: ☐☐ / ☐☐ / ☐☐

QNAM=DRSIGDT QLABEL=INV AGENT DATE PHYSICIAN SIGNED IDVAR=AESEQ

If there is more than one Investigational Agent, please use form 231 - SAE Addendum

Please PRINT CLEARLY 1 2 3 4 5 6 7 8 9 0

A B C D E F G H I J K L M
N O P Q R S T U V W X Y Z

**SAE
(continued)**

60796

STUDYID

SerialNumber:

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
		USUBJID	/ /	

29. Additional comments (specify question number):

COVAL1 - COVAL16   IDVAR=AESEQ

Please print in UPPERCASE letters only.

38819

ProtocolNumber: STUDYID

SerialNumber:

Form #
2 3 1

Node:	Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
0 6			USUBJID	/ /

EPOCH

Phase:
- ○ Screening
- ○ Active
- ○ Follow-up1
- ○ Follow-up2
- ○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI:
0 0
1 1

CQIComments:
- ○ Entireform
- ○ Question#(s):

QA Corrections:
- ○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day:

Form Completed By:

1. Is secondary Investigational Agent information known?   ○ Yes   ○ No

2. If yes, secondary Investigational Agent name:

3. Lot number:

4. Expiration date: [ ] / [ ] / [ ]

5. Route of administration:
   - ○ auricular
   - ○ inhaled
   - ○ intra-articular
   - ○ intramuscular
   - ○ intraocular
   - ○ intravenous
   - ○ nasal
   - ○ oral
   - ○ rectal
   - ○ subcutaneous
   - ○ sublingual
   - ○ transdermal
   - ○ vaginal
   - ○ unknown
   - ○ other

   specify:

6. Frequency:
   - ○ single dose
   - ○ every other day
   - ○ once daily
   - ○ twice daily
   - ○ three times a day
   - ○ four times a day
   - ○ as needed
   - ○ other

   specify:

7. Quantity:

8. Unit code:
   - ○ capsule
   - ○ drop
   - ○ grain
   - ○ gram
   - ○ microgram
   - ○ microliter
   - ○ milligram
   - ○ milliliter
   - ○ ounce
   - ○ patch
   - ○ puff
   - ○ spray/squirt
   - ○ suppository
   - ○ tablespoon
   - ○ tablet
   - ○ teaspoon
   - ○ unknown
   - ○ other

   specify:

9. Start date: [ ] / [ ] / [ ]

10. Stop date: [ ] / [ ] / [ ]

DOMAIN: SUPPAE

11. Nameofinvestigator:

QNAM=SAINVNM QLABEL=SECONDARY INV INVESTIGATOR NAME   IDVAR=AESEQ

Investigator's signature:

Datesigned: [ ] / [ ] / [ ]

QNAM=SAIVSGDT
QLABEL=SECONDARY
INV AGENT INVEST.
SIGNED
IDVAR=AESEQ

12. Nameofphysician:

QNAM=SADRNM QLABEL=SECONDARY INV PHYSICIAN NAME   IDVAR=AESEQ

Physician's signature:

Datesigned: [ ] / [ ] / [ ]

QNAM=SADRSGDT
QLABEL=SECONDARY
INV AGENT PHYSIC.
SIGNED
IDVAR=AESEQ

NOTE: This page will have a different serial number than the full SAE form.

CTN Study Discharge Report

ProtocolNumber: STUDYID

☐☐☐☐☐ - ☐☐☐ - ☐☐☐☐☐

SerialNumber: ☐☐☐☐☐

Form #
2 1 5

63799

Node:	Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
0 6	☐☐☐☐	☐☐☐☐	USUBJID	☐☐ / ☐☐ / ☐☐☐☐	DSDTC

EPOCH

Phase:
● Screening
● Active
○ Follow-up1
○ Follow-up2
○ Follow-up3

CQI Codes:
Blank-No errors
01-Pt unavailable
10-Data collector error
11-Pt unable/unwilling to answer

CQI: ☐☐
⓪ ⓪
① ①

CQIComments:
○ Entireform
○ Question#(s):
QA Corrections:
○ QA1 ○ QA2 ○ QA3 ○ QA4

Study Day: ☐☐☐

Form Completed By: ☐☐☐

VISITNUM / VISIT

DSCAT = DISPOSITION EVENT

1. Reason(s) for discharge (mark all that apply).

DSTERM/DSDECOD

Please clarify all reasons for discharge:

THIS DATA NOT ENTERED

○ Participant completed active phase of study

○ Participant withdrew from study

○ Administratively withdrawn (SPECIFY)

○ Hospitalized or developed acute medical condition which would make further treatment hazardous

○ Transferred to another treatment program (indicate type)

  ○ Methadone

  ○ LAAM

  ○ Drug Free

  ○ Therapeutic Community

  ○ Inpatient Detox or Treatment

  ○ Other (SPECIFY)

○ Participant is pregnant

○ Participant has developed sensitivity or allergy to buprenorphine/naloxone or clonidine

○ Participant has moved from the area

○ Participant is in a controlled environment

○ Participant can no longer attend clinic

○ Participant no longer attends clinic

○ Death

2. Date of final visit to the clinic: ☐☐ / ☐☐ / ☐☐☐☐ DSSTDTC

3. Study day corresponding to date of final visit: ☐☐

QNAM = LSTVISDY
QLABEL = STUDY DAY CORRESPONDING TO FINAL VISIT

Please PRINT CLEARLY

Please fill bubbles completely: ○ ● ○ ○