

16141

ProtocolNumber:STUDYID

SerialNumber:

Form #305

Node:

06

Site:

Name Code:

ID Number:

USUBJID

Date of Assessment:

(mm/dd/yyyy)

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

IEDTC

Study Day:

000

Form Completed By:

VISITNUM / VISIT

ALL ITEMS MUST BE COMPLETED

IECAT

A. INCLUSION CRITERIA

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

IETEST

- 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:

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

Inclusion Exclusion (continued)

DOMAIN: DM, SC, DS
Approved 10/24/00
Page 2 of 2



16141

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
<input type="text"/>	<input type="text"/>	USUBJID	<input type="text"/> / <input type="text"/>	<input type="text"/>

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.).

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
(mm/dd/yyyy)									

DM.RFSTDTC

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

DOMAIN: DM, SC

Approved 10/24/00

Page 1 of 2

Version#

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Form #

250

ProtocolNumber:

STUDYID

SerialNumber:

61180

Node:

06

Site:

Name Code:

ID Number:

USUBJD

Date of Assessment: (mm/dd/yyyy)

DM.DMDTC / SC.SCDTC

Form

Study Day:

Completed By

VISITNUM / VISIT

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

1. Sex: DM.SEX

- ☐ Male ☐ Female

SCTEST

4. Education completed: (GED=12 years)

Years:

SCORES

SCORESU

2. Date of birth: DM.BRTHDTC

(mm/dd/yyyy)

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

SCORES

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

SCORES

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

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

- ☐ Yes ☐ No Asian (mark all that apply)

- ☐ Asian-Indian
☐ Chinese
☐ Filipino
☐ Japanese
☐ Korean
☐ Vietnamese
☐ Other (specify)

- ☐ Yes ☐ No Native Hawaiian or Pacific Islander (mark all that apply)

- ☐ Native Hawaiian
☐ Guamanian or Chamorro
☐ Samoan
☐ Other (specify)

- ☐ Yes ☐ No Other (specify)

- ☐ Participant chooses not to answer

QNA=SOTHERS

QLABEL=SPANISH, HISPANIC, OR LATINO: OTHER TEXT

IDVAR=SCSEQ

QNA=AOTHERS

QLABEL=ASIAN: OTHER TEXT

IDVAR=SCSEQ

6. Marital status: SCTest

- ☐ LegallyMarried
☐ Livingwithpartner/Cohabiting
☐ Widowed
☐ Separated
☐ Divorced
☐ Nevermarried

QNA=NOTHERS

QLABEL=NATIVE HAWAIIAN OR PACIFIC ISLANDER: OTHER TEXT

IDVAR=SCSEQ

QNA=OOTHERS

QLABEL=ETHNICITY/RACE OTHER TEXT

IDVAR=SCSEQ

Please PRINT CLEARLY

Please fill bubbles completely:



Demographics Form (continued)

SerialNumber: Page 2 of 2

61180

STUDYID

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

SUCAT=

7. Drug/Alcohol Use:

SUDTC

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:
Alcohol (any use at all)			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	THIS DATA NOT ENTERED
Alcohol (to intoxication)			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
Heroin			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
Methadone/LAAM (prescribed)			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
Methadone/LAAM (illicit)			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
Other Opiates/Analgesics			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
Barbiturates			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
Other Sedatives/Hypnotics /Tranquilizers including Benzodiazapines			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
Cocaine			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
Amphetamines/ Methamphetamine			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
Cannabis			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
Hallucinogens			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
Inhalants			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> IV or non-IV Injection <input type="radio"/> N/A	
More than 1 substance per day (including alcohol)				
Nicotine (tobacco products)			<input type="radio"/> Oral <input type="radio"/> Nasal <input type="radio"/> Smoking <input type="radio"/> 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.

- | | | | |
|--|--|---|---|
| <input type="radio"/> No problem | <input type="radio"/> Methadone/LAAM (illicit) | <input type="radio"/> Amphetamines/Meth | <input type="radio"/> Alcohol and drug (dual addiction) |
| <input type="radio"/> Alcohol (any) | <input type="radio"/> Opiates/Analgesics | <input type="radio"/> Cannabis | <input type="radio"/> Polydrug |
| <input type="radio"/> Alcohol (intox.) | <input type="radio"/> Barbiturates | <input type="radio"/> Hallucinogens | |
| <input type="radio"/> Heroin | <input type="radio"/> Sed/Hyp/Tranq/Benz | <input type="radio"/> Inhalants | |
| <input type="radio"/> Methadone/LAAM (presc) | <input type="radio"/> Cocaine | <input type="radio"/> Nicotine | |

SUTRT

SUCAT=MAJOR DRUG PROBLEM

CTN Medical History (MEDHX)

DOMAIN: MH

Approved 10/24/00

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Version#

1

SerialNumber:

Form #

270



33239

ProtocolNumber: STUDYID

Node:

Site:

Name Code:

ID Number:

Date of Assessment: (mm/dd/yyyy)

MHDTC

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

Notes:

THIS DATA NOT ENTERED

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

MD signature:

MHTERM

MHOCUR

MHOCUR

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

MHENRF = BEFORE

MHENRF=DURING/AFTER

MHSTAT

Please
PRINT CLEARLY

CTN VITAL SIGNS

DOMAIN: VS

Approved 10/24/00

Page 1 of 1

Version#

1

SerialNumber:

Form #

275



33289

ProtocolNumber: STUDYID

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Node:

0	6
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Site:

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Name Code:

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ID Number:

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

		/			/				
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--	--	--	--

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:

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Form

Completed By:

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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

VSORRES

VSTEST

VSTEST

VSORRES

2.Temperature

			.	
--	--	--	---	--

VSORRESU

- ☐ (°F)
☐ (°C)

3.BloodPressure(mmHg)

			/			
--	--	--	---	--	--	--

VSORRESU

VSORRES

4.Pulse(bpm)

--	--	--

VSORRESU

VSORRES

5.Respirations(1min)

--	--

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

DOMAIN: PE, VS

Version#

1

Approved 10/24/00
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30699

ProtocolNumber: STUDYID

SerialNumber:

Form #

2 6 5

Node:

0 6

Site:

Name Code:

ID Number:

USUBJID

Date of Assessment:

(mm/dd/yyyy)

PEDTC /
VSDTC

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:

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

CQIComments:

- ☐ Entireform
☐ Question#(s):

QA Corrections:

- ☐ QA1 ☐ QA2 ☐ QA3 ☐ QA4

Form

Study Day:

Form Completed By:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>
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VISITNUM / VISIT

EPOCH

VSTEST

VSORRES

A.Height

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

VSORRESU

☐ inches☐ centimeters

VSTEST

VSORRES

B.Weight

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

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

PEORRES

N NCS SIG NA

Comments:

THIS DATA NOT ENTERED

① Skin, Hair, and Nails

☐ ☐ ☐ ☐

② Head and Neck

☐ ☐ ☐ ☐

③ Ears, Eyes, Nose, and Throat

☐ ☐ ☐ ☐

④ Heart

☐ ☐ ☐ ☐

If NA then PESTAT=NOT DONE
and PEREASND=NA

⑤ Chest

☐ ☐ ☐ ☐

⑥ Lungs

☐ ☐ ☐ ☐

⑦ Abdomen

☐ ☐ ☐ ☐

8. Rectal

☐ ☐ ☐ ☐

9. Genitalia

☐ ☐ ☐ ☐

10. Prostate

☐ ☐ ☐ ☐

11. Breasts

☐ ☐ ☐ ☐

12. Pelvic

☐ ☐ ☐ ☐

⑬ Extremities

☐ ☐ ☐ ☐

⑭ Lymph Nodes

☐ ☐ ☐ ☐

15. Musculoskeletal

☐ ☐ ☐ ☐

⑮ Neurological

☐ ☐ ☐ ☐

17. Other:

☐ ☐ ☐ ☐

Please
PRINT CLEARLY

Normal

Abnormal, Not Clinically Significant

Abnormal, clinically Significant

Not Assessed

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

DOMAIN: RP
Version#

1

Approved 10/24/00
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8802

ProtocolNumber: STUDYID

SerialNumber:

Form #

2 3 5

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

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:

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>

CQIComments:

- ☐ Entireform
- ☐ Question#(s):

QA Corrections:

- ☐ QA1
- ☐ QA2
- ☐ QA3
- ☐ QA4

RPDTC

Study Day:

0	0	0
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Form

Completed By:

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VISITNUM / VISIT

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:

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

Comments:

THIS DATA NOT ENTERED

Please mark bubbles FULLY

Correct



Incorrect





39180

ProtocolNumber: STUDYID

SerialNumber:

Form #

2 9 5

Node: 06	Site:	Name Code:	ID Number: USUBJID	Date of BASELINE Interview: (mm/dd/yyyy)
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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:

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

CQIComments:

- ☐ Entireform
☐ Question#(s):

QA Corrections:

- ☐ QA1 ☐ QA2 ☐ QA3 ☐ QA4

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

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

EXDOSFRM=TABLET EXDOSU

VISITNUM /
VISIT

Studyday: 01	Today'sdate: / /	EXDTC	Time(24hour): :	EXROUTE	EXDOSE
StaffID:	Datedosagetaken: / /	EXSTDTC	EXENDTC	Total mg. ingested:	
				Amount sent home:	

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

Extra4mggiven(includeintotalmgingested)

QNA=NOMEDGIV QLABEL=NO STUDY MEDICATION IDVAR=EXSEQ

Comments: THIS DATA NOT ENTERED

Initials

☐ Nostudymedicationingested

Studyday: 02	Today'sdate: / /	Time(24hour): :	Total mg. ingested:
StaffID:	Datedosagetaken: / /	QNA=DOSRET QLABEL=AMOUNT RETURNED IDVAR=EXSEQ	Amount sent home:
			Amount returned:

Initials

☐ No study medication ingested

Comments:

QNA=DOSHOM
 QLABEL=AMOUNT
 SENT HOME
 IDVAR=EXSEQ

Studyday: 03	Today'sdate: / /	Time(24hour): :	Total mg. ingested:
StaffID:	Datedosagetaken: / /		Amount sent home:
			Amount returned:

Initials

☐ No study medication ingested

Comments:

Correct

Incorrect

Please print within the boxes.

9

9

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Site:	Name Code:	ID Number:
<div></div>	<div></div>	<div></div>

0	4
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Comments:

0	5
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Comments:

0	6
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Comments:

0	7
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11/11/2016

Comments:

1	2	3	4	5	6	7	8	9	0
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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

Bup/Naloxone Dosage Log (continued)

Approved 10/24/00
Page 3 of 4



39180

SerialNumber:

Site:	Name Code:	ID Number:
<input type="text"/>	<input type="text"/>	<input type="text"/>

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Studyday:

<input type="text"/>	<input type="text"/>
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Today'sdate:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
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Time(24hour):

Total mg.
ingested:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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StaffID:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Datedosagetaken:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Amount sent
home:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Amount
returned:

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

Initials

<input type="text"/>

☐ No study medication ingested

Comments:

Studyday:

<input type="text"/>	<input type="text"/>
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Today'sdate:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
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Time(24hour):

Total mg.
ingested:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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StaffID:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Datedosagetaken:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Amount sent
home:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Amount
returned:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Initials

<input type="text"/>

☐ No study medication ingested

Comments:

Studyday:

<input type="text"/>	<input type="text"/>
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Today'sdate:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
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Time(24hour):

Total mg.
ingested:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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StaffID:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Datedosagetaken:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Amount sent
home:

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

Amount
returned:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Initials

<input type="text"/>

☐ No study medication ingested

Comments:

Studyday:

<input type="text"/>	<input type="text"/>
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Today'sdate:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
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Time(24hour):

Total mg.
ingested:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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StaffID:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Datedosagetaken:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Amount sent
home:

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

Amount
returned:

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

Initials

<input type="text"/>

☐ No study medication ingested

Comments:

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

Bup/Naloxone Dosage Log (continued)

Approved 10/24/00
Page 4 of 4



39180

SerialNumber:

Site:	Name Code:	ID Number:				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Studyday:

Today'sdate:

 / /

Time(24hour):

 :

Total mg.
ingested:

StaffID:

Datedosagetaken:

 / /

Amount sent
home:

Amount
returned:

Initials

☐ No study medication ingested

Comments:

Studyday:

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:

Today'sdate:

 / /

Time(24hour):

 :

Total mg
returned:

StaffID:

Comments:

Initials

Additional comments:

THIS DATA NOT ENTERED

EXCAT CTN Clonidine Dosage Log

DOMAIN: EX

1

Approved 10/24/00
Page 1 of 4

43366

ProtocolNumber: STUDYID

SerialNumber: Version#

Form #

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:

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

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:

0 1

Today'sdate:

EXDTC

Time(24hour):

EXDOSU

EXROUTE=INGESTED

EXDOSE

StaffID:

Datedosagetaken:

EXSTDTC

EXENDTC

EXDOSFRM=TABLET

Total mg.
ingested:
Amount sent
home:

Numberofpatchesapplied:

0 1 2 3 4 5 6

Number of patches removed:

0 1 2 3 4 5 6

EXDOSE

EXROUTE=TRANSDERMAL

EXDOSFRM=PATCH

Initials

Comments:

THIS DATA NOT ENTERED

QNAM = NUMREMOV

QLABEL = NUMBER OF
PATCHES REMOVED

IDVAR = EXSEQ

QNAM=DOSHOM

QLABEL=AMOUNT
SENT HOME

IDVAR=EXSEQ

Studyday:

0 2

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

Comments:

QNAM=DOSRET

IDVAR=EXSEQ

QLABEL=AMOUNT RETURNED

Initials

Studyday:

0 3

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

Comment

Initials

Correct

Incorrect

Please print within the boxes.

9

9

Clonidine Dosage Log (continued)

Approved 10/24/00

Page 3 of 4



43366

Site:	Name Code:	ID Number:
<input type="text"/>	<input type="text"/>	<input type="text"/>

SerialNumber:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Studyday:

<input type="text"/>	<input type="text"/>
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Today'sdate:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Time(24hour):

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
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☐ Nooralclonidinegiven
(leave oral dosage **BLANK**)

Total mg.
ingested:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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StaffID:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Datedosagetaken:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Amount sent
home:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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Amount
returned:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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Numberofpatchesapplied:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Number of patches removed:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Initials

<input type="text"/>	<input type="text"/>
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Comments:

Studyday:

<input type="text"/>	<input type="text"/>
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Today'sdate:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Time(24hour):

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
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☐ Nooralclonidinegiven
(leave oral dosage **BLANK**)

Total mg.
ingested:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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StaffID:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Datedosagetaken:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Amount sent
home:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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Amount
returned:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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Numberofpatchesapplied:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Number of patches removed:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Initials

<input type="text"/>	<input type="text"/>
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Comments:

Studyday:

<input type="text"/>	<input type="text"/>
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Today'sdate:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Time(24hour):

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
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☐ Nooralclonidinegiven
(leave oral dosage **BLANK**)

Total mg.
ingested:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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StaffID:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Datedosagetaken:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Amount sent
home:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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Amount
returned:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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Numberofpatchesapplied:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Number of patches removed:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Initials

<input type="text"/>	<input type="text"/>
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Comments:

Studyday:

<input type="text"/>	<input type="text"/>
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Today'sdate:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Time(24hour):

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>
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☐ Nooralclonidinegiven
(leave oral dosage **BLANK**)

Total mg.
ingested:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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StaffID:

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Datedosagetaken:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Amount sent
home:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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Amount
returned:

<input type="text"/>	.	<input type="text"/>	<input type="text"/>
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Numberofpatchesapplied:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Number of patches removed:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Initials

<input type="text"/>	<input type="text"/>
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Comments:

SERIAL number on this page
should match number on page 1

Clonidine Dosage Log (continued)

Approved 10/24/00

Page 4 of 4



43366

SerialNumber:

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Site:	Name Code:	ID Number:												
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Studyday:

1	2
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Today'sdate:

		/			/				
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Time(24hour):

		:		
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☐ Nooralclonidinegiven
(leave oral dosage **BLANK**)

StaffID:

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Datedosagetaken:

		/			/				
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Total mg.
ingested:

	.		
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Amount sent
home:

	.		
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Amount
returned:

	.		
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Numberofpatchesapplied:

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Number of patches removed:

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Initials

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Comments:

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Studyday:

1	3
---	---

Today'sdate:

		/			/				
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Time(24hour):

		:		
--	--	---	--	--

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

StaffID:

--	--	--

Datedosagetaken:

		/			/				
--	--	---	--	--	---	--	--	--	--

Total mg.
ingested:

	.		
--	---	--	--

Amount sent
home:

	.		
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Amount
returned:

	.		
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Numberofpatchesapplied:

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Number of patches removed:

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Initials

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Comments:

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No medication is to be given on Day 14.

Studyday:

1	4
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Today'sdate:

		/			/				
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Time(24hour):

		:		
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Amount
returned:

	.		
--	---	--	--

StaffID:

--	--	--

Number of patches removed:

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Initials

--	--

Comments:

--

Additional comments:

THIS DATA NOT ENTERED

CTN Intake Urine Log

Buprenorphine protocols 1, 2

DOMAIN: LB
Approved 10/24/00
Page 1 of 1

Version # **1**



58132

Protocol Number: **STUDYID**

Serial Number:

Form #

205

Node:	Site:	Name Code:	ID Number:
06		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:

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

CQI Comments:

- ☐ Entire form
- ☐ Question #(s):

QA Corrections:

- ☐ QA1
- ☐ QA2
- ☐ QA3
- ☐ QA4

LBMETHOD = ACCUTEST

1. AccuTest

Side 1 of AccuTest Screen:

LBORRES

LBTEST

Amphetamines	<input type="radio"/> Positive	<input type="radio"/> Negative
Barbiturates	<input type="radio"/> Positive	<input type="radio"/> Negative
Benzodiazepines	<input type="radio"/> Positive	<input type="radio"/> Negative
Cocaine	<input type="radio"/> Positive	<input type="radio"/> Negative
Methamphetamine	<input type="radio"/> Positive	<input type="radio"/> Negative

Side 2 of AccuTest Screen:

LBORRES

LBTEST

Methadone	<input type="radio"/> Positive	<input type="radio"/> Negative
Morphine	<input type="radio"/> Positive	<input type="radio"/> Negative
PCP	<input type="radio"/> Positive	<input type="radio"/> Negative
TCA	<input type="radio"/> Positive	<input type="radio"/> Negative
THC	<input type="radio"/> Positive	<input type="radio"/> Negative

Result read by:

--	--	--

QNAM = LBREADYBY

QLABEL = RESULT READ BY

IDVAR = VISITNUM

LBMETHOD=CENTRAL LAB

2. Study day:

VISITNUM / VISIT

00

Date urine collected:

		/			/				
--	--	---	--	--	---	--	--	--	--

LBDMTC

Date urine shipped:

		/			/				
--	--	---	--	--	---	--	--	--	--

Collected by:

--	--	--

QNAM = LBCOLBY

QLABEL = COLLECTED BY

IDVAR = VISITNUM

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

57613

ProtocolNumber: STUDYID

SerialNumber:

Form #

206

Node:

06

Site:

Name Code:

USUBJID

ID Number:

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

QNAM = LBCOLBY
QLABEL = COLLECTED BY
IDVAR = VISITNUM

LBMETHOD=CENTRAL LAB

1. Study day:

Date urine collected:

LB DTC

Collectedby:

VISITNUM /
VISIT

Dateurineshipped:

Shippedby:

LBREASND/LBSTAT

- ☐ Pt.didNOTattend
☐ Sampleinvalid
☐ Refused
☐ UrineNOTcollected(specifyincomments)

QNAM = SHIPDTC
QLABEL = DATE URINE SHIPPED
IDVAR = VISITNUM

2. Study day:

Date urine collected:

Collectedby:

Dateurineshipped:

Shippedby:

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

QNAM = LBSHIPBY
QLABEL = SHIPPED BY
IDVAR = VISITNUM

3. Study day:

Date urine collected:

Collectedby:

Dateurineshipped:

Shippedby:

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

4. Study day:

Date urine collected:

Collectedby:

Dateurineshipped:

Shippedby:

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

5. Final study visit test result:

Side 1 of AccuTest Screen:

LBMETHOD = ACCUTEST

Amphetamines
Barbiturates
Benzodiazepines
Cocaine
Methamphetamine

- ☐ Positive ☐ Negative
☐ Positive ☐ Negative
☐ Positive ☐ Negative
☐ Positive ☐ Negative
☐ 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
Morphine
PCP
TCA
THC

- ☐ Positive ☐ Negative
☐ Positive ☐ Negative
☐ Positive ☐ Negative
☐ Positive ☐ Negative
☐ 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 #

207

Node:

06

Site:

Name Code:

USUBJID

ID Number:

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 = LBCOLBY
QLABEL = COLLECTED BY
IDVAR = VISITNUM

LBREASND/LBSTAT

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

QNAM = LBSHIPBY
QLABEL = SHIPPED BY
IDVAR = VISITNUM

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

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

1. Follow-up:

01

Date urine collected: LB DTC

 / /

Collectedby:

Dateurineshipped:

 / /

Shippedby:

QNAM = SHIPDTC
QLABEL = DATE URINE SHIPPED
IDVAR = VISITNUM

2. Follow-up:

02

Date urine collected:

 / /

Collectedby:

Dateurineshipped:

 / /

Shippedby:

3. Follow-up:

03

Date urine collected:

 / /

Collectedby:

Dateurineshipped:

 / /

Shippedby:

Comments:

THIS DATA NOT ENTERED

DOMAIN: QS

Version#

VISITNUM / VISIT

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

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

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:

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

CQIComments:

- ☐ Entireform
☐ Question#(s):

QA Corrections:

- ☐ QA1 ☐ QA2 ☐ QA3 ☐ QA4

Study Day:

0	0	0
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VISITNUM / VISIT

Form Completed By

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QSEVAL

Code only for substances used
IN PAST 12 MONTHS

QSEVLINT= -P12M

QSTEST

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

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

Please mark bubbles FULLY

Correct



Incorrect



DSM-IV Criteria (continued)

Dependence

Approved 10/24/00

Page 2 of 4

SerialNumber:

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39017

Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>

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.

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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.

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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.

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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).

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

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

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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QSTEST

QSORRES

DSM-IV Criteria (continued)

Approved 10/24/00

Page 3 of 4

Substance Abuse

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

SerialNumber:

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39017

Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)																									
<table border="1"><tr><td></td><td></td><td></td><td></td><td></td></tr></table>						<table border="1"><tr><td></td><td></td><td></td><td></td><td></td></tr></table>						<table border="1"><tr><td></td><td></td><td></td><td></td><td></td></tr></table>						<table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td><td>/</td><td></td><td></td><td></td><td></td></tr></table>			/			/				
		/			/																							

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.

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).

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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).

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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).

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	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).

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Present
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Absent
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Uncertain

QSTEST

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

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QSORRES

DSM-IV Criteria (continued)

Summary

DOMAIN: QS

Approved 10/24/00

Page 4 of 4



39017

STUDYID

SerialNumber:

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Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)																							
<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td>U</td><td>S</td><td>U</td><td>B</td><td>J</td><td>I</td><td>D</td></tr></table>	U	S	U	B	J	I	D	<table border="1"><tr><td></td><td></td></tr></table> / <table border="1"><tr><td></td><td></td></tr></table> / <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>									
U	S	U	B	J	I	D																					

QSTEST

QSORRES

1. Is participant currently opioid dependent? ☐ Yes ☐ No
2. Is participant currently dependent on any other substance (e.g., alcohol, benzodiazepines) 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:

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Comments:

THIS DATA NOT ENTERED

32993

ProtocolNumber: STUDYID

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2 4 5

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

QSDTC

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:

<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>

CQIComments:

- ☐ Entireform
☐ Question#(s):

QA Corrections:

- ☐ QA1 ☐ QA2 ☐ QA3 ☐ QA4

Study Day:

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Form Completed By:

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VISITNUM / VISIT

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



32993

SerialNumber:

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Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>

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 amount of time you spent on work or other activities ☐ Yes ☐ No
- b. Accomplished less than you would like ☐ Yes ☐ No
- c. Were limited in the kind of work or other activities ☐ Yes ☐ No
- d. Had difficulty performing the work or other activities (for example, it took extra effort) ☐ Yes ☐ No

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 amount of time you spent on work or other activities ☐ Yes ☐ No
- b. Accomplished less than you would like ☐ Yes ☐ No
- c. Didn't do work or other activities as carefully 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



SerialNumber:

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32993

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)																				
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This is page 3 of the questionnaire. Make sure you complete pages 1 & 2 first.

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.)

- a. did you feel full of pep? **QSEVLINT = -P4W**
- b. have you been a very nervous person?
- c. have you felt so down in the dumps that nothing could cheer you up?
- d. have you felt calm and peaceful?
- e. did you have a lot of energy?
- f. have you felt downhearted and blue?
- g. did you feel worn out?
- h. have you been a happy person?
- i. did you feel tired?

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
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 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.)

- a. I seem to get sick a little easier than other people.
- b. I am as healthy as anybody I know.
- c. I expect my health to get worse.
- d. My health is excellent.

Definitely true	Mostly true	Don't know	Mostly false	Definitely false
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 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.

QSCAT CTN Adjective Rating Scale for Withdrawal

1

Approved 10/24/00

Page 1 of 1 DOMAIN: QS



5417

Protocol Number: STUDYID

Version#

Serial Number:

Form #

2 8 5

Node:

0 6

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:

☐☐
☐☐
☐☐

CQI Comments:

- ☐ Entire form
☐ Question#(s):

QA Corrections:

- ☐ QA1 ☐ QA2 ☐ QA3 ☐ QA4

Study Day:

VISITNUM /
VISIT

Form

Completed By:

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Depressed or sad	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Painful joints	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Excessive yawning	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Hot or cold flashes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Trouble getting to sleep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Sick to stomach	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Irritable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Runny nose	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Poor appetite	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Weak knees	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Excessive sneezing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Tense, jittery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Watery eyes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Abdominal cramps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Fitful sleep	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2	3	4	5	6	7	8	9

Please mark bubbles FULLY

Correct



Incorrect



CSQ-18B

Protocol Number:

STUDYID

Version#

Serial Number:

DOMAIN: QS

Form #

2 4 0

28148

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:

<input type="checkbox"/>	<input type="checkbox"/>
0 0	1 1

CQIComments:

- ☐ Entire form
☐ Question#(s):

QA Corrections:

- ☐ QA1 ☐ QA2 ☐ QA3 ☐ QA4

Study Day:

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VISITNUM / VISIT

Form Completed By

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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

The *Client Satisfaction Questionnaire (CSQ)* was developed at the University of California San Francisco (UCSF) by Drs. Clifford Attkisson and Daniel Larsen in collaboration with Drs. William A. Hargreaves, Maurice LeVois, Tuan Nguyen, Robert E. Roberts and Bruce Stegner. Every effort has been made to publish information and research on the CSQ for widest possible dissemination. Proceeds from the publication of the CSQ will be used to support postdoctoral training, student academic affairs, and health and human services research activities.

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Clifford Attkisson, Ph.D.

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28148

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

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.



28148

SerialNumber:

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

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:



QSCAT CTN Clinical Opiate Withdrawal Scale (COWS)

Revised 11/09/00

Page 1 of 2

DOMAIN: QS, VS

Form #

280



46946

Protocol Number: STUDYID

Version # 2
Serial Number:

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

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

CQI Comments:

- ☐ Entire form
- ☐ Question #(s):

QA Corrections:

- ☐ QA1
- ☐ QA2
- ☐ QA3
- ☐ QA4

Study Day:

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VISITNUM / VISIT

Form Completed By

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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

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



46946

**COWS
(continued)**Revised 11/09/00
Page 2 of 2

Serial Number:

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

--	--

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:

QSCAT CTN HIV Risk Behavior Scale (HRBS)

Version# 1 Approved 10/24/00
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

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:

<input type="checkbox"/>	<input type="checkbox"/>
<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>

CQIComments:

- ☐ Entireform
- ☐ Question#(s):

QA Corrections:

- ☐ QA1
- ☐ QA2
- ☐ QA3
- ☐ QA4

Study Day:

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VISITNUM / VISIT

Form Completed By

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QSEVAL

Please select only one answer per question.

QSSCAT= **Injected Drug Use**

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 month?

- 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 month 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 month?
- ☐ None
 - ☐ Oneperson
 - ☐ Twopeople
 - ☐ 3-5people
 - ☐ 6-10people
 - ☐ Morethan10people

4. How many **times** in the last month has **someone else** used a needle **after** you used it?

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

5. How **often**, in the last month 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 month did you use bleach to clean them?

- ☐ Doesnotre-use
- ☐ Everytime
- ☐ Often
- ☐ Sometimes
- ☐ Rarely
- ☐ Never

Please PRINT CLEARLY

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A	B	C	D	E	F	G	H	I	J	K	L	M
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38157

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Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
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QSSCAT= **Sexual Behavior**

QSEVLINT = -P1M

QSTEST

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

- ☐ None
☐ One person
☐ Two people
☐ 3-5 people
☐ 6-10 people
☐ More than 10 people

QSORRES

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

10. How **often**, in the last month, 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

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

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

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

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

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

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

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

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

Please mark bubbles FULLY

Correct



Incorrect



QSCAT

CTN Addiction Severity Index Lite CF

DOMAIN: QS
Version#

1

Approved 10/24/00

Page 1 of 16



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ProtocolNumber: STUDYID

SerialNumber:

Form #

291

Node:	Site: (G3)	Name Code:	ID Number: (G1)	Date of Assessment: (mm/dd/yyyy) (G5)
06			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:

<input type="checkbox"/>	<input type="checkbox"/>
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,..."

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(IntakeASI must be in person)
☐ 3-Mail

G10.

Gender:

- ☐ 1-Male
☐ 2-Female

G12.

Special:

- ☐ 1-Patient terminated
☐ 2-Patient refused
☐ 3-Patient unable to respond

Comments:

THIS DATA NOT ENTERED

Please
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GENERAL INFORMATION (continued)

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USUBJID

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

		/		
--	--	---	--	--

A-Yrs.

B-Mos.

QSORRESU='YEAR'

G16. Date of birth:

QSORRESU='MONTH'

		/			/				
(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: _____
- A place, theoretically, without access to drugs/alcohol.

QSEVLINT = -P30D

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.

Comments: THIS DATA NOT ENTERED

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STUDYID

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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 ☐ 1-Yes ☐ 0-No which continue to interfere with your life?
- 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 ☐ 1-Yes ☐ 0-No a regular basis for a physical problem?
- 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 ☐ 1-Yes ☐ 0-No disability?
- 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.).

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

- M7. How troubled or bothered have you been by these ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 medical problems in the past 30 days?
- Restrict response to problem days of question M6.
- M8. How important to you *now* is treatment for these ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 medical problems?
- 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

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STUDYID

SerialNumber:

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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.

Comments:

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 driver's license? ☐ 1-Yes ☐ 0-No
- Valid license; not suspended/revoked.

- E5. Do you have an automobile available for use? ☐ 1-Yes ☐ 0-No
- 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
- See Hollingshead categories on page 16

(Specify in detail)

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

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

E10. Usual employment pattern, past three years:

- ☐ 1-Full time (35+ hours) ☐ 5-Military Service
- ☐ 2-Part time (reg. hrs) ☐ 6-Retired/disability
- ☐ 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.

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

STUDYID

SerialNumber:

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Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)
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For questions E12-17: **How much money did you receive from the following sources in the past 30 days?**

- E12. Employment: \$

--	--	--	--	--	--
- Net or "take home" pay, include any "under the table" money.
- E13. Unemployment compensation: \$

--	--	--	--	--	--
- E14. Welfare: \$

--	--	--	--	--	--
- Include food stamps, transportation money provided by an agency to go to and from treatment.
- E15. Pensions, benefits, or social security: \$

--	--	--	--	--	--
- Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.
- E16. Mate, family or friends: \$

--	--	--	--	--	--
- Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g., gambling). Record **cash** payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.).
- E17. Illegal \$

--	--	--	--	--	--
- Cash** obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc.
 - Do not** attempt to convert drugs exchanged to a dollar value.
- E18. How many people depend on you for the majority of their food, shelter, etc.?

--	--
- Must be regularly depending on patient, do include alimony/child support, do not include the patient or self-supporting spouse, etc.
- E19. How many days have you experienced employment problems in the past 30?

--	--
- Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized.

Comments: THIS DATA NOT ENTERED

QSEVLINT = -P30D

QSORRESU='DOLLAR'

QSEVLINT = -P30D

QSORRESU = 'DAY'

QSEVLINT = -P30D

QSEVLINT = -P30D

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? (0 1 2 3 4)
- If the patient has been incarcerated or detained during the past 30 days, they cannot have employment problems.
- E21. How important to you *now* is counseling for these employment problems? (0 1 2 3 4)
- 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.

CONFIDENCE RATINGS

Is the above information significantly distorted by:

- E23. Patient's misrepresentation? ☐ 1-Yes ☐ 0-No
- E24. Patient's inability to understand? ☐ 1-Yes ☐ 0-No



22325

QSSCAT=

ALCOHOL/DRUGS

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SerialNumber:

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STUDYID

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QSEVLINT= -P30D

QSTEST

QSORRES

 Past 30 A-Days B-Years
 QSORRESU='YEAR'

 D1. Alcohol - (any use at all)

 D2. Alcohol - (to intoxication)

QSORRESU = 'DAY'

 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
☐ Smoke ☐ IV

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

 D12. Inhalants
☐ Nasal

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

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.

Comments:

THIS DATA NOT ENTERED

 SERIAL number on this page
 should match number on page 1

A	B	C	D	E	F	G	H	I	J	K	L	M
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Alcohol/Drugs (continued)

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STUDYID

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- 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 \$

--	--	--	--	--

- D24. Drugs \$

--	--	--	--	--

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

- D25. How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days?

--	--

- Include AA/NA

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?

--	--

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

- 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.

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

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

CONFIDENCE RATINGS

Is the above information **significantly** distorted by:

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

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

QSEVLINT = -P30D QSORRESU='DOLLAR'

QSEVLINT = -P30D QSORRESU='DOLLAR'

QSEVLINT = -P30D

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QSTEST

QSORRES

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

- L2. Are you on probation or parole? ☐ 1-Yes ☐ 0-No
- 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**

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LEGAL STATUS (continued)

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STUDYID

SerialNumber:

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

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A	B	C	D	E	F	G	H	I	J	K	L	M
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LEGAL STATUS (continued)

SerialNumber:

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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
- 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.

- L27. How many days in the past 30 have you engaged in illegal activities for profit?
- Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with question E17 under Employment/Family Support section.

For questions L28 & 29, 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 significantly distorted by:

- L31. Patient's misrepresentation? ☐ 1-Yes ☐ 0-No
- L32. Patient's inability to understand? ☐ 1-Yes ☐ 0-No

Comments: THIS DATA NOT ENTERED

QSEVLINT = -P30D

QSORRESU = 'DAY'

QSEVLINT = -P30D

QSORRESU = 'DAY'

Please
PRINT CLEARLY

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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	

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:

<input type="checkbox"/>	<input type="checkbox"/>
0	0
1	1

CQIComments:

- ☐ Entireform
☐ Question#(s):

QA Corrections:

- ☐ QA1 ☐ QA2 ☐ QA3 ☐ QA4

Study Day:

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Form Completed By:

--	--	--

VISITNUM / VISIT QSEVAL

QSTEST

QSORRES

- F1. Marital Status:
- | | |
|-----------------------------------|---------------------------------------|
| <input type="radio"/> 1-Married | <input type="radio"/> 4-Separated |
| <input type="radio"/> 2-Remarried | <input type="radio"/> 5-Divorced |
| <input type="radio"/> 3-Widowed | <input type="radio"/> 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.):
- | | |
|--|--|
| <input type="radio"/> 1-With sexual partner and children | <input type="radio"/> 6-With friends |
| <input type="radio"/> 2-With sexual partner alone | <input type="radio"/> 7-Alone |
| <input type="radio"/> 3-With children alone | <input type="radio"/> 8-Controlled environment |
| <input type="radio"/> 4-With parents | <input type="radio"/> 9-No stable arrangements |
| <input type="radio"/> 5-With family | |

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

Comments: THIS DATA NOT ENTERED

QSEVLINT = -P3Y

Please
PRINT CLEARLY

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FAMILY/SOCIAL RELATIONSHIPS (continued)

Approved 10/24/00

Page 12 of 16



41616

STUDYID

SerialNumber:

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Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)																											
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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	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	
F19.	Father	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	
F20.	Brothers/sisters	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	
F21.	Sexual partner/spouse	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	
F22.	Children	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	
F23.	Other significant family: (specify) <table border="1"><tr><td></td></tr></table>		<input type="radio"/> 1-Yes <input type="radio"/> 0-No	<input type="radio"/> 1-Yes <input type="radio"/> 0-No
F24.	Close friends	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	
F25.	Neighbors	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	
F26.	Co-workers	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	

"Serious problems" mean those that endangered the relationship.

A "problem" requires contact of some sort, either by telephone or in person.

Did anyone abuse you:

A. Past 30 days

B. In your life

F28.	Physically (cause you physical harm)?	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	<input type="radio"/> 1-Yes <input type="radio"/> 0-No
F29.	Sexually (force sexual advances/acts)?	<input type="radio"/> 1-Yes <input type="radio"/> 0-No	<input type="radio"/> 1-Yes <input type="radio"/> 0-No

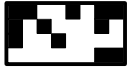
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41616

FAMILY/SOCIAL RELATIONSHIPS (continued)

SerialNumber:

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Approved 10/24/00

Page 13 of 16

STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
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F30.

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

--	--

QSORRESU = 'DAY'

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 significantly distorted by:

F37.

Patient's misrepresentation?

☐ 1-Yes ☐ 0-No

F38.

Patient's inability to understand?

☐ 1-Yes ☐ 0-No

Comments: THIS DATA NOT ENTERED

Please
PRINT CLEARLY

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41616

PSYCHIATRIC STATUS

SerialNumber:

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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

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.

☐ 1-Yes ☐ 0-No

☐ 1-Yes ☐ 0-No

Record "Yes" if a medication was prescribed *even if* the patient is not taking it.

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

Comments:

THIS DATA NOT ENTERED

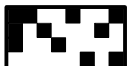
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PSYCHIATRIC STATUS (continued)

Approved 10/24/00
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SerialNumber:

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STUDYID

Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)																														
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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 bothered by these psychological or emotional problems in the past 30 days? 0 1 2 3 4

QSEVLINT = -P30D

- Patient should be rating the problem days from question P12

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

CONFIDENCE RATINGS

Is the above information significantly distorted by:

- P22. Patient's misrepresentation? 0 1-Yes 0 0-No
- P23. Patient's inability to understand? 0 1-Yes 0 0-No

Please
PRINT CLEARLY

1	2	3	4	5	6	7	8	9	0
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N	O	P	Q	R	S	T	U	V	W	X	Y	Z

CODES

Approved 10/24/00

Page 16 of 16



41616

SerialNumber:

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Site:	Name Code:	ID Number:	Date of Assessment: (mm/dd/yyyy)																												
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Patient Rating Scale**Comments (include question number)**

- 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.

Please
PRINT CLEARLY

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A	B	C	D	E	F	G	H	I	J	K	L	M
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CTN Ancillary Medication Dispensed

DOMAIN: CM
Approved 10/24/00
Page 1 of 2

Version# 1



2908

Protocol Number: STUDYID

Serial Number:

Form #

210

Node:	Site:	Name Code:	ID Number:	Date of BASELINE Interview: (mm/dd/yyyy)
06			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:

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

CQI Comments:

- ☐ Entire form
- ☐ 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.

CMINDIC

A. FOR ANXIETY AND RESTLESSNESS:

CMTRT

CMDOSETXT

- Oxazepam (Serax) 15-30 mg. po q6 hours prn; NTE 120 mg. per 24 hours **OR**
- Phenobarbital (Arco-lase plus Donnatal) 15-30 mg. po q6 hours prn; NTE 120 mg. per 24 hours **OR**
- Hydroxyzine hydrochloride (Atarax, Marax, Vistaril) 50 mg. po q6 hours prn; NTE 200 mg. per 24 hours **OR**
- Lorazepam (Ativan) 1-2 mg. q6 hours prn; NTE 8 mg. per 24 hours **OR**
- Oxazepam (Serax) 15-30 mg. po q6 hours prn; NTE 60 mg. per 24 hours **OR**
- Phenobarbital (Arco-lase plus Donnatal) 15-30 mg. po q6 hours prn; NTE 60 mg. per 24 hours

VISITNUM / VISIT

	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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
2.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
3.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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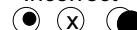
CMOCCUR

Please mark bubbles FULLY

Correct



Incorrect



Ancillary Medications (continued)

Approved 10/24/00

Page 2 of 2

SerialNumber:



2908

Site:	Name Code:	ID Number:	SerialNumber:			
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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
7.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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14.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

F. IF NO ANCILLARY MEDICATIONS GIVEN, PLEASE MARK HERE:

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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Signature of physician at final review:

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DateSigned:

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

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

CTN Prior and Concomitant Medications

Version# **1** Approved 10/24/00
Page 1 of 2



53909

Protocol Number: **STUDYID**

Serial Number:

Form #
220

CMCAT = PRIOR AND CONCOMITANT MEDICATIONS

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

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:

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

CQIComments:

☐ Entire form
☐ 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 4=intravenous 7=nasal
2=subcutaneous 5=topical 8=inhaled
3=intramuscular 6=rectal 9=other

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

CMTRT

CMINDC

CMROUTE

CMDOSTOT

CMDOSU

Drug type

A. Medication (generic)

B. Purpose/Indication

C. Route code

D. Total daily dosage in grams:

1. **Beta 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 ☐ 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 ☐ FU1

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 ☐ FU1

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 ☐ FU1

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

Approved 10/24/00

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SerialNumber:

Site:	Name Code:	ID Number:
<div></div> <div></div> <div></div> <div></div>	<div></div> <div></div> <div></div> <div></div>	<div></div> <div></div> <div></div> <div></div>

--	--	--	--	--

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: / / 										
F. Study days having taken this medication:										
<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10 <input type="radio"/> 11 <input type="radio"/> 12 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> FU 1										
<input type="radio"/> Possible interaction with study medication										

6. Methadone							.			
E. Last use within last 30 days: / / 										
F. Study days having taken this medication:										
<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10 <input type="radio"/> 11 <input type="radio"/> 12 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> FU 1										
<input type="radio"/> Possible interaction with study medication										

7. LAAM							.			
E. Last use within last 30 days: / / 										
F. Study days having taken this medication:										
<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10 <input type="radio"/> 11 <input type="radio"/> 12 <input type="radio"/> 13 <input type="radio"/> 14 <input type="radio"/> FU 1										
<input type="radio"/> Possible interaction with study medication										

☐ 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

$$\boxed{}\boxed{} / \boxed{}\boxed{} / \boxed{}\boxed{}\boxed{}\boxed{}$$

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

		/			/				
CNAM - NOINTEAR									

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



31296

ProtocolNumber:

STUDYID

SerialNumber:

Form #

2 2 1

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

CMDTC

CQI Codes:

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

CQI:

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

CQIComments:

☐ Entireform
☐ Question#(s):

QA Corrections:

☐ QA1 ☐ QA2 ☐ QA3 ☐ QA4

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

CMCAT = PRIOR AND CONCOMITANT MEDICATIONS

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

1. Other					
	E. Last use within last 30 days:				
	F. Study days having taken this medication:				
2. Other					
	E. Last use within last 30 days:				
	F. Study days having taken this medication:				
3. Other					
	E. Last use within last 30 days:				
	F. Study days having taken this medication:				
4. Other					
	E. Last use within last 30 days:				
	F. Study days having taken this medication:				
5. Other					
	E. Last use within last 30 days:				
	F. Study days having taken this medication:				

☐ Possible interaction with study medication

☐ Possible interaction with study medication

☐ Possible interaction with study medication

☐ Possible interaction with study medication

☐ Possible interaction with study medication

VISITNUM / VISIT

CMSPID

Please PRINT CLEARLY

1	2	3	4	5	6	7	8	9	0
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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 Serious Adverse Event

DOMAIN: AE

Version#

1

Approved 10/24/00
Page 1 of 4

60796

ProtocolNumber: STUDYID

SerialNumber:

Form #

230

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

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

CQIComments:

- ☐ Entireform
☐ Question#(s):

QA Corrections:

- ☐ QA1 ☐ QA2 ☐ QA3 ☐ QA4

Study Day:

--	--	--

VISITNUM /
VISITForm
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

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

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

specify:

5. Height:

--	--	--

☐ inches☐ centimeters

6. Weight:

--	--	--

☐ pounds☐ kilograms

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

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

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

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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



60796

**SAE
(continued)**

Approved 10/24/00

Page 2 of 4

SerialNumber:

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

11. Action taken regarding Investigational Agent: **AEACN**
- ☐ None
☐ Discontinued permanently
☐ Discontinued temporarily
- ☐ Reduced dose
☐ Increased dose
☐ Delayed dose

12. Other action(s) taken: **AEACNOTH**
- ☐ None
☐ Remedial therapy-pharmacologic
☐ Remedial therapy-nonpharmacologic
☐ Hospitalization (new or prolonged)

13. Outcome: **AEOUT**
- AESDEATH** ☐ Death
AESLIFE ☐ Life-threatening event
AESHOSP ☐ Hospitalization
- ☐ Disability
☐ Congenital anomaly
☐ Other
- AEDISAB**
AESCONG
AESMIE

14. Relevant tests/laboratory data, including dates:

QNAM=AEOUTOT
QLABEL=OUTCOME - OTHER, SPECIFY
IDVAR=AESEQ

specify:

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
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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)

Approved 10/24/00

Page 3 of 4

SerialNumber:

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STUDYID

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.
IDVAR=AESEQ AGENT INFORMATION
KNOWN?

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
IDVAR=AESEQ EXPIRATION DATE

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

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:

23. Quantity:

QNAM = IAQUANT
QLABEL = INV AGENT QUANTITY
IDVAR = AESEQ

QNAM = IAFRQOTH
QLABEL=INV AGENT
FREQUENCY - OTHER, SPECIFY
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:

25. Start date:

		/			/				
--	--	---	--	--	---	--	--	--	--

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

26. Stop date:

		/			/				
--	--	---	--	--	---	--	--	--	--

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

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

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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



STUDYID

Page 4 of 4

SerialNumber:

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

[illegible]

Please print in UPPERCASE letters only.

CIN SAE Addendum for
Secondary Investigational Agents

Version#

1

Approved 10/24/00

Page 1 of 1

Form #

2 3 1

38819

Protocol Number: STUDYID

Serial Number:

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

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:

- ☐ ☐
☐ ☐
☐ ☐

CQI Comments:

- ☐ Entire form

- ☐ Question#(s):

QA Corrections:

- ☐ QA1 ☐ QA2 ☐ QA3 ☐ QA4

Study Day:

Form

Completed By:

QNAM=SAKNWN01-15

QLABEL=IS

SECONDARY INV
AGENT KNOWN?

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

2. If yes, secondary Investigational Agent name:

QNAM=SANAME01-15 QLABEL=SECONDARY
INVESTIGATIONAL AGENT NAME

3. Lot number:

QNAM=SALOT01-15 QLABEL=SECONDARY
INV AGENT LOT NUMBER

4. Expiration date:

QNAM=SAEXTD01-15
QLABEL=SECONDARY INV AGENT EXP
DATE

5. Route of administration:

- ☐ auricular ☐ intravenous ☐ sublingual
☐ inhaled ☐ nasal ☐ transdermal
☐ intra-articular ☐ oral ☐ vaginal
☐ intramuscular ☐ rectal ☐ unknown
☐ intraocular ☐ subcutaneous ☐ other

QNAM=SAROUT01-15

QLABEL=SECONDARY INV AGENT ROUTE

QNAM=SAROTH01-15 QLABEL=SECONDARY
INV AGENT ROUTE OTHER SPEC

specify:

6. Frequency:

QNAM=SAFREQ01-15
QLABEL=SECONDARY INV
AGENT FREQUENCY

- ☐ single dose ☐ twice daily ☐ as needed
☐ every other day ☐ three times a day ☐ other
☐ once daily ☐ four times a day

specify:

QNAM=SAFRQO01-15
QLABEL=SECONDARY INV
AGENT FREQ - OTHER, SPECIFY

7. Quantity:

QNAM=SAQUNT01-15 QLABEL=SECONDARY
INV AGENT QUANTITY

8. Unit code:

QNAM=SAUNIT01-15
QLABEL=SECONDARY INV
AGENT UNIT

- ☐ capsule ☐ microliter ☐ puff ☐ teaspoon
☐ drop ☐ milligram ☐ spray/squirt ☐ unknown
☐ grain ☐ milliliter ☐ suppository ☐ other
☐ gram ☐ ounce ☐ tablespoon
☐ microgram ☐ patch ☐ tablet

QNAM=SAUNTO01-15

QLABEL=SECONDARY INV
AGENT UNIT - OTHER, SPECIFY

specify:

9. Start date:

QNAM=SASTDC01-15 QLABEL=SECONDARY
INV AGENT START DATE

10. Stop date:

QNAM=SAENDC01-15 QLABEL=SECONDARY
INV AGENT END DATE

11. Name of investigator:

QNAM=SAINVN01-15 QLABEL=SECONDARY INV INVESTIGATOR NAME

Investigator's signature:

THIS DATA NOT ENTERED

Date signed:

THIS DATA NOT ENTERED

12. Name of physician:

QNAM=SAIVSD01-15 QLABEL=SECONDARY INV AGENT INVEST. SIGNED

QNAM=SADRNM01-15 QLABEL=SECONDARY INV PHYSICIAN NAME

Physician's signature:

THIS DATA NOT ENTERED

Date signed:

THIS DATA NOT ENTERED

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

CTN Study Discharge Report

DOMAIN: DS

1

Approved 10/24/00

Page 1 of 1

Version#

ProtocolNumber: STUDYID

SerialNumber:

Form #

63799

2 1 5

Node:	Site:	Name Code:	ID Number:	Date of Assessment:	(mm/dd/yyyy)
0 6	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	USUBJID	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

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:

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

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

- ☐ 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

Please clarify all reasons for discharge:

THIS DATA NOT ENTERED

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:☐ ☒ ☐ ☐