

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010 STUDYID	Node ID __ __	Site ID __ _ _ _ _	Subject ID USUBJID
Visit Date __ __ / __ __ / __ IEDTC	Phase EPOCH	Visit Week VISIT	Sequence Number __ __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

NOTE: Boxed annotations indicate supplemental qualifier variables. Result found in QVAL field.

Inclusion/Exclusion

Study STUDYID

DOMAIN: IE, SC

USUBJID

Date ___/___/___/IEDTC/SCDTC

Inclusion/Exclusion NOTE: Only exceptions to IE are in the database. That includes “No” responses for Inclusion and “YES” responses for exclusion criteria.

IECAT Inclusion Criteria

1. The participant is between the ages of SC.SCTEST =INCLUSION/EXCLUSION AGE
 1=(14-17) _____
 2=(18-21) _____
2. The participant is SC.SCTEST=INCLUSION/EXCLUSION GENDER
 1=Male _____
 2=Female _____

IETEST	IEORRES		
	NO	YES	UNK
3. Has the participant signed the assent/consent for screening?	0	1	8
4. Is the participant seeking outpatient treatment for opiate dependence?	0	1	8
5. Does the participant meet DSM-IV criteria for opiate dependence with physiologic dependence as evidenced by tolerance or withdrawal?	0	1	8
6. Has the participant passed the informed assent/consent quiz?	0	1	8
7. Has the participant provided written informed assent/consent for the study?	0	1	8
	NO	YES	UNK

<i>For participant between the age of 14-17</i>			
8. Has a parent/legal guardian passed the informed consent quiz?	0	1	8
9. Has a parent/legal guardian provided written informed consent for the study?	0	1	8

If any inclusion questions above are answered NO or UNKNOWN, then the participant is not eligible to participant in the study.

Inclusion/Exclusion**IECAT Exclusion Criteria**

IETEST	IEORRES		
	NO	YES	UNK
1. Does the participant have any of the following conditions:			
a. unstable medical conditions in need of immediate treatment?	0	1	8
b. acute hepatitis?	0	1	8
c. endocarditis?	0	1	8
d. any single liver enzyme test greater than five times the top limit of normal?	0	1	8
e. renal failure?	0	1	8
f. advanced HIV disease (multiple opportunistic infections, wasting syndrome)?	0	1	8
g. abnormal ECG?	0	1	8
h. acute, severe psychiatric condition in need of immediate treatment, or imminent homicide or suicide risk?	0	1	8
j. known sensitivity to buprenorphine or naloxone?	0	1	8
2. Does the participant report using benzodiazepines for more than 15 days in the last month <i>or</i> have a urine test that is positive for benzodiazepines?	0	1	8
3. Does the participant have current abuse <i>or</i> dependence in any of the following:			
a. benzodiazepines?	0	1	8
b. alcohol?	0	1	8
c. other sedative?	0	1	8
4. Does the participant have a positive urine for methadone?	0	1	8
5. Is the participant receiving any unapproved psychiatric medications?	0	1	8
6. Does the participant report using either within the last two weeks:			
a. LAAM (licit or illicit)?	0	1	8
b. Naltrexone?	0	1	8
7. Is the participant expecting to leave the geographic area prior to study completion or has pending legal action that is likely to result in incarceration?	0	1	8
8. Does the participant have a treatment plan that involves greater than seven days for inpatient detoxification or seven days of residential or inpatient substance abuse treatment?	0	1	8

Study STUDYID

DOMAIN: IE, SC

ID USUBJID
Date ___/___/___ IEDTC

Inclusion/Exclusion

IECAT Exclusion Criteria

IETEST	IEORRES		
	NO	YES	UNK
9. Is the participant planning inpatient hospitalization during the first three months of the study?	0	1	8
10. Is the participant planning to receive an opioid agonist other than for short-term detoxification during the first three months of the study?	0	1	8
	NO	YES	UNK

<i>For female participant's</i>			
11. Is the participant pregnant or nursing?	0	1	8
12. Does the participant have a positive pregnancy test?	0	1	8
13. Is the participant <i>unwilling</i> to use at least one of the acceptable modes of contraception?	0	1	8

If any exclusion questions above are answered YES or UNKNOWN, then the participant is not eligible to participate in the study.

SC.SCTEST	SC.SCORRES	
	NO	YES
14. Is the participant eligible for the study?	0	1

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct and complete.

Clinician Name (please print): THIS DATA NOT DATABASSED

Clinician Signature: THIS DATA NOT DATABASSED

Date Signed ___/___/___ THIS DATA NOT DATABASSED

Study _____

DOMAIN: LB

ID _____
Date ____/____/____

BUP-NX For Adolescent/Young Adult Opiate Dependency

USUBJID

Protocol Number NIDA-CTN-0010 STUDYID	Node ID __	Site ID _____	Subject ID _____
Visit Date IEDTC ____/____/____	Phase EPOCH __	Visit Week VISIT __	Sequence Number _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Blood Chemistry Results

Study STUDYID

DOMAIN: LB

Date / / ID USUBJID
LBDTC

Blood Chemistry Results

1. LBCAT='CHEMISTRY'

LBTEST	Test Result:		Normal	LBNRIND Out of Normal Range
	LBBORRES	LBORRESU		
Glucose	__ __	mg/dL	1	2
BUN	__ __ . __	mg/dL	1	2
Creatinine	__ __ . __	mg/dL	1	2
Na	__ __	mEq/L	1	2
CL	__ __	mEq/L	1	2
K	__ __ . __	mEq/L	1	2

** If All Answers for Question 1 are Normal skip to Clinician Name **

2. Do any of these abnormalities preclude safe entry or continuation in the study? 0 = No
1 = Yes

QNAM=LBCHEMAB
QLABEL=CHEM ABNORMALITY PREVENTS CONTINUATION
IDVAR=LBSEQ

By affixing my signature, I certify that the above information to the best of my Knowledge is true, correct and complete.

Clinician Name (please print): THIS DATA NOT DATABASD

THIS DATA NOT DATABASD

Clinician Signature _____

Date Signed __/__/____-THIS DATA NOT DATABASD

Study STUDYID

DOMAIN: BR

ID _____
Date ____/____/____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010 STUDYID	Node ID __	Site ID _____	Subject ID _____ USUBJID
Visit Date ____/____/____ BRDTC	Phase EPOCH __	Visit Week VISIT __	Sequence Number _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Alcohol Breathalyzer

Alcohol Breathalyzer

1. **BRORRES** **BRTEST** Was an Alcohol Breathalyzer performed?
 0 = No
 1 = Yes

2. **BRORRES** **BRTEST** mg/ml Alcohol Breathalyzer result
 BRORRESU

3. COMMENTS:

DOMAIN: CO
COVAL
RDOMAIN=BR
IDVAR=BRSEQ

Study _____ **DOMAIN: LB** ID _____
 e ____/____/____

STUDYID

USUBJID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID _____
Visit Date LB ____/____/____	Phase DT EPOCH ____	Visit Week IT VISIT	Sequence Number _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Complete Blood Count/Differential Results

Study STUDYID

DOMAIN: LB

ID USUBJID
Date ___/___/___ LB DTC

CBC/Differential Results

1. **LBCAT='HEMATOLOGY'**

LBTEST	Test Result:		LBNRIND	
	LBORRES	LBORRESU	Normal	Out of Normal Range
White Cell Count	___ . ___	thousands/mm ³	1	2
Band	___	%	1	2
Segmented	___	%	1	2
Monos	___	%	1	2
Lymphs	___	%	1	2
EOS	___	%	1	2
BASOS	___ . ___	%	1	2
Red Cell Count	___ . ___	x 10 ⁶ /mm ³	1	2
Hemoglobin	___ . ___	gm/dL	1	2
Hematocrit	___ . ___	%	1	2
Platelet Count	___ ___	thousands/mm ³	1	2

**** If All Answers for Question 1 are Normal skip to Clinician Name ****

2. Do any of these abnormalities preclude safe entry or continuation in the study?

0 = No
1 = Yes
QNAM=LBCBCABN
QLABEL=CBC ABNORMALITY PREVENTS CONTINUATION
IDVAR=LBSEQ

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct and complete.

Clinician Name (please print): THIS DATA NOT DATABAS

Clinician Signature THIS DATA NOT DATABAS

Date Signed ___ / ___ / ___ THIS DATA NOT DATABAS

Study _____ **DOMAIN: DM** ID _____
 Date ____/____/_____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

USUBJID

<i>Protocol Number</i> NIDA-CTN-0010	<i>Node ID</i> __ __	<i>Site ID</i> _____	<i>Subject ID</i> _____
<i>Visit Date</i> ____/____/____ DMDTC	<i>Phase</i> EPOCH __	<i>Visit Week</i> VISIT __	<i>Sequence Number</i> __
		<i>For use with</i> <i>Phase Two Only</i>	<i>For use with AE or</i> <i>SAE Only</i>

Demographics Form

Demographics Form

1. Sex

1 = Male **DM.SEX**
2 = Female

2. Date of Birth ___/___/___ **DM.BRTHDTC**

3. Ethnicity/Race

For each of the following, choose "Yes" to all that apply to you and "No" to those that do not.

SCORRES	Yes	No	SCTEST	DM.RACE (if multiple, then 'MULTIPLE')	
	1	0	White		
	1	0	Black , African-American		
	1	0	American Indian or Alaskan Native		
	1	0	Spanish, Hispanic, or Latino (mark all that apply)		DM.ETHNIC
				1 = Mexican, Mexican-American, Chicano	
				1 = Puerto-Rican	
				1 = Cuban	
				1 = Other (specify) _____	
	1	0	Asian		QNAM=SOTHERS QLABEL=SPANISH, HISPANIC, OR LATINO: OTHER TEXT IDVAR=SCSEQ
			(mark all that apply)		
				1 = Asian-Indian	
				1 = Chinese	
				1 = Filipino	
				1 = Japanese	
				1 = Korean	
				1 = Vietnamese	
				1 = Other (specify) _____	QNAM=AOTHERS QLABEL=ASIAN: OTHER TEXT IDVAR=SCSEQ
	1	0	Native Hawaiian or Pacific Islander		QNAM=NOTHERS QLABEL=NATIVE HAWAIIAN OR PACIFIC ISLANDER: OTHER TEXT IDVAR=SCSEQ
			(mark all that apply)		
				1 = Native Hawaiian	
				1 = Guamanian or Chamorro	
				1 = Samoan	
				1 = Other (specify) _____	
	1	0	Other (specify) _____		QNAM=OOTHERS QLABEL=ETHNICITY/RACE: OTHER TEXT IDVAR=SCSEQ
			1 = Participant chooses not to answer		

Demographics Form (continued)

SCTEST

SCORRES

SCORRESU

4. Education completed: ___ ___
(GED = 12 years)

5. Usual employment pattern:

a. Past 3 years

- 1 = Full time (35+ hrs/wk)
- 2 = Part time (regular hours)
- 3 = Part time (irreg., day-work)
- 4 = Student

- 5 = Service
- 6 = Retired/Disability
- 7 = Homemaker
- 8 = Unemployed
- 9 = In controlled environment

b. Past 30 days:

- 1 = Full time (35+ hrs/wk)
- 2 = Part time (regular hours)
- 3 = Part time (irreg., daywork)
- 4 = Student

- 5 = Service
- 6 = Retired/Disability
- 7 = Homemaker
- 8 = Unemployed
- 9 = In controlled environment

6. Marital Status:

- 1 = Legally Married
- 2 = Living with partner/cohabitating
- 3 = Widowed
- 4 = Separated
- 5 = Divorced
- 6 = Never married

Demographics Form (continued)

SUCAT=DRUG/ALCOHOL USE

7. Drug/Alcohol Use:

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

SUEVLINT= -P30D SUEVLINT=blank SUROUTE

SUTRT SUBSTANCE:	SUDUR	Past 30 Days	Lifetime Use Years	Most frequent route of administration	Comments
Alcohol (any use at all)		___ ___	___ ___	___	
Alcohol (to intoxication)		___ ___	___ ___	___	
Heroin		___ ___	___ ___	___	
Methadone/ LAAM prescribed		___ ___	___ ___	___	
Methadone/ LAAM (illicit)		___ ___	___ ___	___	
Other opiates/ analgesics		___ ___	___ ___	___	
Barbituates		___ ___	___ ___	___	
Other Sedatives/Hypnotics /Tranquilizer/incl Benzodiazapines		___ ___	___ ___	___	
Cocaine		___ ___	___ ___	___	
Amphetamines/ Methamphetamine		___ ___	___ ___	___	
Cannabis		___ ___	___ ___	___	
Hallucinogens		___ ___	___ ___	___	
Inhalants		___ ___	___ ___	___	
>1 substance per day (including alcohol)		___ ___	___ ___		
Nicotine (tobacco products)		___ ___	___ ___	___	

Code for Route of of Administration: 1= oral; 2= nasal; 3= smoking; 4=IV/non-IV injection; 8=N/A

SUCAT=MAJOR DRUG PROBLEM

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

- SUTRT
- 0= No problem
 - 5= Methadone/LAAM (illicit)
 - 10= Amphetamine
 - 1= Alcohol (any)
 - 6= Opiates/Analgesics
 - 11= Cannabis
 - 16 = Alc and Drug (Dual addiction)
 - 2= Alcohol (intox)
 - 7= Barbituates
 - 12= Hallucinogens
 - 17 = Polydrug
 - 3= Heroin
 - 8= Sed/Hyp/Tranq/Benz
 - 13= Inhalants
 - 4= Methadone/LAAM (presc)
 - 9= Cocaine
 - 15= Nicotine

THIS DATA NOT ENTERED

Study _____

DOMAIN: EG

ID _____
Date ____/____/____

BUP-NX For Adolescent/Young Adult Opiate Dependency

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Visit Date ____/____/____ EGDTC	Phase ____ EPOCH	Visit Week ____ EGDTC	Sequence Number ____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Electrocardiogram

Electrocardiogram

EGCAT=MEASUREMENT

EGTEST

1. MEASUREMENTS

EGORRES

EGORRESU

- a. Ventricular Rate ___ ___ ___ bpm
- b. PR ___ ___ ___ ms
- c. QRS ___ ___ ___ ms
- d. QT ___ ___ ___ ms
- e. QTc ___ ___ ___ ms

EGCAT=INTERPRETATION

EGTEST

EGORRES
No Yes

- 2. Does the ECG have an abnormal rhythm? 0 1
- 3. Was the ECG interpreted as abnormal? 0 1

If question 3 is Yes, proceed to question 4
If question 3 is No, skip to question 5

- 4. If the ECG is abnormal, is it clinically significant? 0 1
- 5. Has the ECG changed since the previous ECG? (if screening
leave blank). 0 1

6. If any question 2 – 5 is YES please specify:

QNAM=EGSPECIFY
QLABEL=ECG INTERPRETATION SPECIFIED
IDVAR=EGSEQ

7. Does the ECG reveal any of the following: No Yes

EGTEST

- a. PR interval > 200 ms 0 1
- b. QRS interval > 100 ms 0 1
- c. QT interval corrected for heart rate > 450 ms 0 1
- d. Arrhythmia 0 1

Study _____ **STUDYID**

DOMAIN: EG

Date _____ / _____ / _____ ^{ID} **USUBJID**
~~EGDTC~~

EGCAT=INTERPRETATION

Electrocardiogram

EGORRES

EGTEST

No

Yes

8. Do any of these ECG findings preclude safe entry
or continuation in the study?

0

1

If question 8 is yes, and identified at screening, individual is to be excluded from the study. If question 8 is yes, and the participant is currently enrolled in the study complete AE/SAE form.

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct and complete.

Clinician Name (please print): **THIS DATA NOT DATABASSED** _____

THIS DATA NOT DATABASSED

THIS DATA NOT DATABASSED

Clinician Signature _____ Date Signed ____ / ____ / _____

Study _____

DOMAIN: LB

ID _____
Date ____/____/____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number STUDYID NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID USUBJID _____
Visit Date LB ____/____/____	Phase EPOCH	Visit Week VISIT	Sequence Number ____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Hepatitis B & C

Study STUDYID

ID USUBJID

DOMAIN: LB

Date / / **LB DTC**

Form Completion Status: <input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required

LBCAT=HEPATITIS

Hepatitis B & C

**LBTEST
Hepatitis B**

LBORRES

	Negative	Positive	Indeterminate
--	----------	----------	---------------

- | | | | |
|---------------------------------|---|---|---|
| 1. Hepatitis B surface antigen | 0 | 1 | 2 |
| 2. Hepatitis B surface antibody | 0 | 1 | 2 |
| 3. Antibody to hepatitis B core | 0 | 1 | 2 |

Hepatitis C

- | | | | |
|-------------------------------|---|---|---|
| 4. Hepatitis C virus antibody | 0 | 1 | 2 |
|-------------------------------|---|---|---|

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct, and complete.

Clinician Name (please print): THIS DATA NOT DATABASSED

THIS DATA NOT DATABASSED

Clinician Signature _____

Date Signed / / **THIS DATA NOT DATABASSED**

Study _____

DOMAIN: LB

ID _____
Date __/__/____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010 STUDYID	Node ID __	Site ID _____	Subject ID USUBJID _____
Visit Date / /	Phase EPOCH	Visit Week VISIT	Sequence Number
LBDC		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Liver Enzymes

Study STUDYID

DOMAIN: LB

ID USUBJID
Date ___/___/___ LBDTC

Liver Enzymes

1. Liver Enzymes **LBCAT='LIVER'**

LBTEST	Test Result:		LBNRIND	
	LBORRES	LBORRESU	Normal	Out of Normal Range
ALT (SGPT)	___	___ mU/mL	1	2
AST (SGOT)	___	___ mU/mL	1	2
GGTP / GGT	___	___ mU/mL	1	2
LDH	___	___ U/L	1	2
Total Bilirubin	___	___ mg/L	1	2
Alkaline phosphatase	___	___ mU/mL	1	2

2. Is *any* single enzyme value greater than five times the top limit of normal range?

0 = No
1 = Yes

QNAM=LBENZYME
QLABEL=ANY ENZYME VALUE > 5X ULN
IDVAR=VISITNUM

Note: **If yes, and identified at screening, individual is to be excluded from the study.
If yes, and currently enrolled in the study complete AE/SAE form.**

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct and complete.

Clinician Name (please print): THIS DATA NOT DATABASD

Clinician Signature THIS DATA NOT DATABASD

Date Signed ___/___/___ THIS DATA NOT DATABASD

Study _____

DOMAIN: MH

ID _____
Date __ __ / __ __ / __ __ __ __

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010 STUDYID	Node ID __ __	Site ID __ __ __ __	Subject ID USUBJID
Visit Date MHDTC __ __ / __ __ / __ __ __ __	Phase EPOCH __	Visit Week VISIT __ __	Sequence Number __ __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Medical History

MEDICAL HISTORY

Indicate “Yes” or “No” under the Normal column. If “Yes” is selected in the normal column DO NOT record any comments under the “Disease and/or Surgery” column. If the patient has an abnormal finding in any category select “No”, then complete the “Disease and/or “Surgery” column. Use only a medical diagnosis and/or previous surgery in this column. Please record only ONE medical diagnosis or surgery per line.

Complete the year diagnosed using four digits.

Indicate “Yes” or “No” in the Active column indicating if the disease is currently active.

If a disease has occurred more than once, make two separate entries (see example below).

Example:

Disease category	Normal		Disease (use only a medical diagnosis) and/or Surgery	Year Diagnosed (Y Y Y Y)	Active	
	Yes 1	No 0			Yes 1	No 0
<u>Cardiac</u>	1	0	<i>Myocardial Infarction</i>	<u>1</u> <u>9</u> <u>7</u> <u>4</u>	1	0
			<u>Myocardial Infarction</u>	<u>1</u> <u>9</u> <u>8</u> <u>0</u>	1	0
			<u>Coronary Artery Bypass</u>	<u>1</u> <u>9</u> <u>8</u> <u>0</u>	1	0

Disease category	Normal		Disease (use only a medical diagnosis) and/or Surgery	Year Diagnosed (Y Y Y Y)	Active	
	Yes	No			Yes	No
	1	0			1	0
MHCAT	MHOCCUR		MHTERM	MHSTDTC	1	0
<u>HEENT</u>	1	0	_____	_____	1	0
			_____	_____	1	0
			_____	_____	1	0
<u>Cardiac</u>	1	0	_____	_____	1	0
			_____	_____	1	0
			_____	_____	1	0
<u>Pulmonary</u>	1	0	_____	_____	1	0
			_____	_____	1	0
			_____	_____	1	0
<u>Gastro-Intestinal</u>	1	0	_____	_____	1	0
			_____	_____	1	0
			_____	_____	1	0
<u>Neurological</u>	1	0	_____	_____	1	0
			_____	_____	1	0
			_____	_____	1	0

If "Active",
MHENRF=
'DURING/
AFTER'

Disease category	Normal		Disease (use only a medical diagnosis) and/or Surgery	Year Diagnosed (Y Y Y Y)	Active	
	Yes	No			Yes	No
	1	0			1	0
MHCAT <u>Musculo-skeletal</u>	MHOCCUR		MHTERM _____ _____	MHSTDTC _____ _____ _____	1	0
<u>Endocrine</u>	1	0	_____ _____	_____ _____ _____	1	0
<u>Genito-urinary</u>	1	0	_____ _____	_____ _____ _____	1	0
<u>Skin</u>	1	0	_____ _____	_____ _____ _____	1	0

If "Active",
MHENRF=
'DURING/
AFTER'

STUDYID

Study _____

USUBJID

ID _____

DOMAIN: MH

Date ___/___/___ MHDTC

Disease category	Normal		Disease (use only a medical diagnosis) and/or Surgery	Year Diagnosed (Y Y Y Y)	Active	
	Yes	No			Yes	No
	1	0			1	0
MHCAT	MHOCCUR		MHTERM	MHSTDTC	1	0
<u>Psychiatric</u>	1	0	_____	____	1	0
			_____	____	1	0
			_____	____	1	0
<u>Medication Allergies</u>	1	0		____	1	0
			_____	____	1	0
			_____	____	1	0

If "Active",
MHENRF=
'DURING/
AFTER'

Comments:

DOMAIN: CO
COVAL
RDOMAIN=MH
IDVAR=VISITNUM

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct and complete.

Clinician Name (please print): THIS DATA NOT DATABASSED

Clinician Signature THIS DATA NOT DATABASSED

Date Signed ___/___/___ THIS DATA NOT DATABASSED

Study _____

DOMAIN: PE, VS

ID _____
Date ___/___/_____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID <u>USUBJID</u>
Visit Date PEDTC / ___ / ___ / ___ VSDTC	Phase EPOCH __	Visit Week VISIT __	Sequence Number __
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Physical Examination

DOMAIN: PE,VS

Study STUDYID

ID USUBJID PEDTC /
Date ___/___/___ VSDTC

PHYSICAL EXAMINATION

VSTEST
VSORRES
A. Height ___ ___ ___ 1= inches
2=centimeters

VSTEST
VSORRES
B. Weight ___ ___ ___ 1= pounds
2=kilograms

PETEST

PEORRES

*Bold items represent required minimum physical exam	Normal	Abnormal Not clinically significant	Abnormal Clinically significant	Not Done
1. Oral	1	2	3	9
2. Head and Neck	1	2	3	9
3. Ears, Eyes, Nose and Throat	1	2	3	9
4. Cardiovascular	1	2	3	9
5. Chest	1	2	3	9
6. Lungs	1	2	3	9
7. Abdomen	1	2	3	9
8. Extremities	1	2	3	9
9. Skin, hair, nails	1	2	3	9
10. Neuropsychiatric, mental status	1	2	3	9
11. Neuropsychiatric sensory	1	2	3	9
12. Musculoskeletal	1	2	3	9
13. General Appearance	1	2	3	9
14. Rectal	1	2	3	9
15. Prostate	1	2	3	9
16. Breast	1	2	3	9
17. Lymph	1	2	3	9
18. Genital	1	2	3	9
19. Pelvic	1	2	3	9
20. Other:				
_____	1	2	3	9

**IF NOT DONE THEN
PESTAT=NOT DONE
AND PEREASND=NOT
DONE**

Study _____ **STUDYID** _____

DOMAIN: PE

ID _____ **USUBJID**
Date ____/____/____

PEDTC

PHYSICAL EXAMINATION

<u>Comments:</u>	DOMAIN: CO COVAL RDOMAIN=PE IDVAR=PESEQ
-------------------------	---------------------------------------------------------

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct and complete.

Clinician Name (please print): _____

QNAM=PECSG QLABEL=PHYSICAL EXAM CLINICIAN SIG IDVAR=VISITNUM

Clinician Signature **THIS DATA NOT ENTERED** _____

Date ____/____/____

QNAM=PESGDTTC QLABEL=PHYSICAL EXAM CLINICIAN SIG DATE IDVAR=VISITNUM

Study _____

DOMAIN: RP

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

<i>Protocol Number</i> NIDA-CTN-0010	<i>Node ID</i> ____	<i>Site ID</i> _____	<i>Subject ID</i> USUBJID _____
<i>Visit Date</i> ____/____/____ RPDTC	<i>Phase</i> EPOCH	<i>Visit Week</i> VISIT	<i>Sequence Number</i> _____
		<i>For use with</i> <i>Phase Two Only</i>	<i>For use with AE or</i> <i>SAE Only</i>

Pregnancy Test

Form Completion Status: <input type="checkbox"/> 1 = Completed as required 2 = Form not required

Pregnancy Test

Circle the appropriate answer

RPTEST

RPORRES

1. Was a pregnancy test performed?

1 = Yes

0 = No (If No, skip to question 3.)

2. What was the result?

1 = Positive

2 = Negative

3. Is the subject lactating?

1 = Yes

0 = No

4. Does the subject report using an acceptable method of birth control?

1 = Yes

0 = No (If No, end of questionnaire.)

5. What method of birth control does the subject report using?

1 = oral contraceptives

2 = barrier w/ spermicide

3 = IUD

4 = levonorgestrel implant (Norplant)

5 = medroxyprogesterone (Depo provera)

6 = surgical sterilization

7 = contraceptive patch

8 = vaginal contraceptive ring

9 = complete abstinence

Study _____

DOMAIN: CM

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __ __	Site ID __ _ _ _	Subject ID USUBJID
Visit Date __ __ / __ __ / __ __ CMDTC	Phase EPOCH	Visit Week VISIT	Sequence Number __ __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Prior / Concomitant Medication

Study STUDYID

DOMAIN: CM

ID USUBJID

CMSPID

CMTRT

CMCAT

Date

CMDDTC

QNAM=CMAENUM

QLABEL=MEDICATION AE NUMBER

IDVAR=CMSEQ

1=No Prior / Concomitant Medication

a. Medication Number _____			b. Drug Type _____		c. Purpose / Indication _____	
Medication Name: _____						
d. A.E. Number _____	e. Route _____ CMROUTE	f. Frequency _____ CMDOSFRQ	g. Quantity _____ CMDOSTXT	n. strength _____ CMDOSTXT	h. Dosage _____ CMDOSU	i. Dose Form _____ CMDOSEFRM
j. Start Date _____/_____/_____ CMSTDTDC		k. Stop Date _____/_____/_____ CMENDTC		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes

a. Medication Number _____			b. Drug Type _____		c. Purpose / Indication _____	
Medication Name: _____						
d. A.E. Number _____	e. Route _____	f. Frequency _____	g. Quantity _____	n. strength _____		
j. Start Date _____/_____/_____ CMSTDTDC		k. Stop Date _____/_____/_____ CMENDTC		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes

a. Medication Number _____			b. Drug Type _____		c. Purpose / Indication _____	
Medication Name: _____						
d. A.E. Number _____	e. Route _____	f. Frequency _____	g. Quantity _____	n. strength _____	h. Dosage _____	i. Dose Form _____
j. Start Date _____/_____/_____ CMSTDTDC		k. Stop Date _____/_____/_____ CMENDTC		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes

a. Medication Number _____			b. Drug Type _____		c. Purpose / Indication _____	
Medication Name: _____						
d. A.E. Number _____	e. Route _____	f. Frequency _____	g. Quantity _____	n. strength _____	h. Dosage _____	i. Dose Form _____
j. Start Date _____/_____/_____ CMSTDTDC		k. Stop Date _____/_____/_____ CMENDTC		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes

Dosage Administration Coding Sheet

Routes of Admin (ICH-m2 Numeric Codes) 001=Auricular (otic) 002=Buccal 003=Cutaneous 014=Intra-articular 030=Intramuscular 031=Intraocular 042=Intravenous (not otherwise specified) 046=Ophthalmic 047=Oral 049=Other 053=Rectal 054=Respiratory (inhalation) 057=Subcutaneous 059=Sublingual 060=Topical 061=Transdermal 064=Unknown 066=Vaginal	Drug Type 1=Prior 2=Concomitant	Frequency 1=Single dose 2=Every other day 3=Once daily 4=Twice daily 5=Three times a day 6=Four times a day 7=As needed 8=Other 9=Unknown	Dosage 1=grain(s) 2=gram(s) 3=international units 4=microcurie(s) 5=microgram(s) 6=micrograms(s)/kilogram meter 7=microgram(s)/sq. meter 8=microlitre(s) 9=millicurie(s) 10=milliequivalent(s) 11=milligram(s) 12=milligram(s)/kilogram 13=milligram(s)/sq. meter 14=millilitre(s) 88=Other 99=Unknown	Dosage Form 1=Capsule 2=Drop 3=Gum 4=Lollipop 5=Lotion/Ointment 6=Lozenge 7=Ounce 8=Patch 9=Puff 10=Spray/Squirt 11=Suppository 12=Tablespoon 13=Tablet 14=Teaspoon 15=Wafer 88=Other 99=Unknown
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Annotated same as previous page.

a. Medication Number _____ Medication Name: _____			b. Drug Type _____	c. Purpose / Indication _____		
d. A.E. Number _____	e. Route _____	f. Frequency _____	g. Quantity _____	n. strength _____	h. Dosage _____	i. Dose Form _____
j. Start Date ____/____/____		k. Stop Date ____/____/____		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes
a. Medication Number _____ Medication Name: _____			b. Drug Type _____	c. Purpose / Indication _____		
d. A.E. Number _____	e. Route _____	f. Frequency _____	g. Quantity _____	n. strength _____	h. Dosage _____	i. Dose Form _____
j. Start Date ____/____/____		k. Stop Date ____/____/____		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes
a. Medication Number _____ Medication Name: _____			b. Drug Type _____	c. Purpose / Indication _____		
d. A.E. Number _____	e. Route _____	f. Frequency _____	g. Quantity _____	n. strength _____	h. Dosage _____	i. Dose Form _____
j. Start Date ____/____/____		k. Stop Date ____/____/____		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes
a. Medication Number _____ Medication Name: _____			b. Drug Type _____	c. Purpose / Indication _____		
d. A.E. Number _____	e. Route _____	f. Frequency _____	g. Quantity _____	n. strength _____	h. Dosage _____	i. Dose Form _____
j. Start Date ____/____/____		k. Stop Date ____/____/____		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes

Dosage Administration Coding Sheet

Routes of Admin (ICH-m2 Numeric Codes)	Drug Type	Frequency	Dosage	Dosage Form
001=Auricular (otic) 002=Buccal 003=Cutaneous 014=Intra-articular 030=Intramuscular 031=Intraocular 042=Intravenous (not otherwise specified) 046=Ophthalmic 047=Oral 049=Other 053=Rectal 054=Respiratory (inhalation) 057=Subcutaneous 059=Sublingual	060=Topical 061=Transdermal 064=Unknown 066=Vaginal 1=Prior 2=Concomitant	1=Single dose 2=Every other day 3=Once daily 4=Twice daily 5=Three times a day 6=Four times a day 7=As needed 8=Other 9=Unknown	1=grain(s) 2=gram(s) 3=international units 4=microcurie(s) 5=microgram(s) 6=micrograms(s)/kilogram 7=microgram(s)/sq. meter 8=microlitre(s) 9=millicurie(s) 10=milliequivalent(s) 11=milligram(s) 12=milligram(s)/kilogram 13=milligram(s)/sq. meter 14=millilitre(s) 88=Other 99=Unknown	1=Capsule 2=Drop 3=Gum 4=Lollipop 5=Lotion/Ointment 6=Lozenge 7=Ounce 8=Patch 9=Puff 10=Spray/Squirt 11=Suppository 12=Tablespoon 13=Tablet 14=Teaspoon 15=Wafer 88=Other 99=Unknown

DOMAIN: CM
Annotated same as previous page.

a. Medication Number _____ Medication Name: _____			b. Drug Type _____	c. Purpose / Indication _____		
d. A.E. Number _____	e. Route _____	f. Frequency _____	g. Quantity _____	n. strength _____	h. Dosage _____	i. Dose Form _____
j. Start Date ____/____/____		k. Stop Date ____/____/____		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes

a. Medication Number _____ Medication Name: _____			b. Drug Type _____	c. Purpose / Indication _____		
d. A.E. Number _____	e. Route _____	f. Frequency _____	g. Quantity _____	n. strength _____	h. Dosage _____	i. Dose Form _____
j. Start Date ____/____/____		k. Stop Date ____/____/____		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes

a. Medication Number _____ Medication Name: _____			b. Drug Type _____	c. Purpose / Indication _____		
d. A.E. Number _____	e. Route _____	f. Frequency _____	g. Quantity _____	n. strength _____	h. Dosage _____	i. Dose Form _____
j. Start Date ____/____/____		k. Stop Date ____/____/____		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes

a. Medication Number _____ Medication Name: _____			b. Drug Type _____	c. Purpose / Indication _____		
d. A.E. Number _____	e. Route _____	f. Frequency _____	g. Quantity _____	n. strength _____	h. Dosage _____	i. Dose Form _____
j. Start Date ____/____/____		k. Stop Date ____/____/____		l. Continuing 0 = No 1 = Yes		m. Given for AE 0 = No 1 = Yes

Dosage Administration Coding Sheet

Routes of Admin (ICH-m2 Numeric Codes) 001=Auricular (otic) 002=Buccal 003=Cutaneous 014=Intra-articular 030=Intramuscular 031=Intraocular 042=Intravenous (not otherwise specified) 046=Ophthalmic 047=Oral 049=Other 053=Rectal 054=Respiratory (inhalation) 057=Subcutaneous 059=Sublingual	Drug Type 1=Prior 2=Concomitant	Frequency 1=Single dose 2=Every other day 3=Once daily 4=Twice daily 5=Three times a day 6=Four times a day 7=As needed 8=Other 9=Unknown	Dosage 1=grain(s) 2=gram(s) 3=international units 4=microcurie(s) 5=microgram(s) 6=microgram(s)/kilogram 7=microgram(s)/sq. meter 8=microlitre(s) 9=millicurie(s) 10=milliequivalent(s) 11=milligram(s) 12=milligram(s)/kilogram 13=milligram(s)/sq. meter 14=millilitre(s) 88=Other 99=Unknown	Dosage Form 1=Capsule 2=Drop 3=Gum 4=Lollipop 5=Lotion/Ointment 6=Lozenge 7=Ounce 8=Patch 9=Puff 10=Spray/Squirt 11=Suppository 12=Tablespoon 13=Tablet 14=Teaspoon 15=Wafer 88=Other 99=Unknown
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Study _____ **DOMAIN: QS**

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __ __	Site ID __ _ _ _	Subject ID USUBIID __
Visit Date __ __ / __ __ / CMDTC	Phase EPOCH	Visit Week VISIT	Sequence Number __ __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

**Substance Dependence Severity Scale – Lite
(SDSS Lite – Opiate)**

Study STUDYID

DOMAIN: QS

ID USUBJID
Date ___/___/___ QSSTDTC

SUBSTANCE DEPENDENCE SEVERITY SCALE – LITE

(SDSS - LITE)

Time begun: QSSTDTC (hh:mm, 24 hour clock)

QSSCAT='ALCOHOL/DRUGS'
QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE'

Statement. Now I'm going to ask you about experiences and problems related to drug use. In all of these questions, I'll be asking you about the last 30 days, that is, since (DATE 30 DAYS AGO).

1. DSM-IV DEPENDENCE: SUBSTANCE OFTEN TAKEN IN LARGER AMOUNTS OR OVER LONGER PERIOD THAN WAS INTENDED

QSTEST

QSEVLINT='-P30D'

√BOX FOR EACH DRUG USED IN PAST 30 DAYS

OF DAYS (0-30)
SEVERITY RATING (0-5)

ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:

During the past 30 days, have you.....

.....had times when you ended up (using more DRUG) than you meant to?

.....found that you ended up (using DRUG) over a longer period of time than you had planned to, for example, later in the evening?

FOR SEVERITY OF "1" OR MORE:

Since (DAY/MONTH) how many days (altogether) did you (use DRUG) more or over a longer period than you meant to?

(How much did you think you would use? How much did you end up using? How (long/late) did you think you would (use DRUG)?

QSORRES

QSORRES

HEROIN

PAINKILLERS

METHADONE

SEVERITY RATING

0 = ABSENT – Did not use larger/longer than intended

1 = SUBTHRESHOLD – Larger/longer use was minimal and of doubtful clinical significance

2 = MILD – Used slightly more/longer than intended

3 = MODERATE – Used somewhat more/longer than intended

4 = SEVERE – Used a great deal more/longer than intended

5= EXTREME – Used constantly, even though did not intend to

SDSS – LITE

2a. DSM-IV DEPENDENCE: PERSISTENT DESIRE TO CUT DOWN OR CONTROL SUBSTANCE USE

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST

QSEVLINT='-P30D'

√ BOX FOR EACH DRUG
USED IN PAST 30 DAYS

QSORRES

OF DAYS
(0-30)

QSORRES

SEVERITY
RATING
(0-5)

Next I'll be asking you about a persistent desire to cut down or control your drug use.

ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:

In the last 30 days, have you felt that you should cut down or control your (DRUG use) or stop completely?

FOR SEVERITY OF "1" OR MORE:

Since (DAY/MONTH), how many *days* (altogether) did you feel that way?

How much did you want to stop? How often did you think about it? How long did the desire to (cut down/stop) last?

<input type="checkbox"/>	<u>HEROIN</u>	__ __	__
<input type="checkbox"/>	<u>PAINKILLERS</u>	__ __	__
<input type="checkbox"/>	<u>METHADONE</u>	__ __	__

SEVERITY RATING

- 0 = **ABSENT** – No desire to cut down or control substance use
- 1 = **SUBTHRESHOLD** – Desire to cut down was very mild or uncertain, e.g., fleeting thought to control use
- 2 = **MILD** – Mild desire to control use, thought comes and goes throughout the day
- 3 = **MODERATE** – Moderate desire to control use, thought about it often throughout the day
- 4 = **SEVERE** – Strong desire to control use, thought about it often throughout the day
- 5 = **EXTREME** – Strong desire to control use, thought about it (almost) constantly

Study STUDYID

DOMAIN: QS

ID USUBJID
Date ___/___/___ QSSTDTC

SDSS – LITE

2b. DSM-IV DEPENDENCE: ONE OR MORE UNSUCCESSFUL ATTEMPTS TO CUT DOWN OR CONTROL SUBSTANCE USE

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST

QSEVLINT='-P30D'

√ BOX FOR EACH DRUG
USED IN PAST 30 DAYS

QSORRES
OF DAYS
(0-30)

QSORRES
SEVERITY
RATING
(0-2)

ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:

During the past 30 days, have you.....

....tried to cut down on your (DRUG) use?

FOR SEVERITY OF "1" OR MORE:

How many days did you try to control your (DRUG use) but found you couldn't?

(What happened? Were you able to (cut back/stop) at all?)

HEROIN

PAINKILLERS

METHADONE

SEVERITY RATING

0 = ABSENT – No attempt to cut down or control substance use

1 = SUBTHRESHOLD – Tried to control use and was able to do so

2 = PRESENT – 1 or more unsuccessful efforts to cut down/control

SDSS – LITE

3. DSM-IV DEPENDENCE: A GREAT DEAL OF TIME SPENT IN ACTIVITIES NECESSARY TO GET SUBSTANCE, IN USING SUBSTANCE, OR IN RECOVERING FROM THE EFFECTS OF SUBSTANCE

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST	QSEVLINT='-P30D'	QSORRES	QSORRES	
ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:		√ BOX FOR EACH DRUG USED IN PAST 30 DAYS	# OF DAYS (0-30)	SEVERITY RATING (0-5)
During the past 30 days, have you.....				
.....spent much time doing things to make sure you had (DRUG) available?				
.....spent several hours in a day or night (using DRUG)?				
.....spent an hour or more in a day or night feeling sick, bad, hung over or spaced out from the effects of (DRUG)? IF DRUG USE: Or feeling withdrawal symptoms from DRUG?				
FOR SEVERITY OF “1” OR MORE:				
How many days did this happen (altogether)?				
(Can you describe a typical day? How much time did it take for you to get (DRUG)? How much (DRUG) did you actually use? How much time did you spend feeling sick or hung over from (DRUG)? If you add up the time you were getting, using, and recovering during a given day, how much time would that be?)				
	<input type="checkbox"/>	<u>HEROIN</u>	___	___
	<input type="checkbox"/>	<u>PAINKILLERS</u>	___	___
	<input type="checkbox"/>	<u>METHADONE</u>	___	___

SEVERITY RATING SCALE

- 0 = **ABSENT** - Did not spend a great deal of time in activities related to substance use
- 1 = **SUBTHRESHOLD** - A limited amount of time in substance-related activities
- 2 = **MILD** - Spent approximately 25% of waking hours in substance-related activities
- 3 = **MODERATE** - Spent approximately 50% of waking hours in substance-related activities
- 4 = **SEVERE** - Spent approximately 75% of waking hours in substance-related activities
- 5 = **EXTREME** - Spent virtually all waking hours in substance-related activities

SDSS – LITE

4. DSM-IV DEPENDENCE: IMPORTANT SOCIAL, OCCUPATIONAL/ACADEMIC, OR RECREATIONAL ACTIVITIES REDUCED OR GIVEN UP AS A RESULT OF SUBSTANCE USE

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST

QSEVLINT='-P30D'

QSORRES

QSORRES

Next I'll be asking you about reducing or giving up important activities because of your drug use, like work, school, social or recreational activities.

ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:

During the past 30 days, have you.....

.....spent time (using DRUG) instead of working doing school work?

.....spent time (using DRUG) instead of spending time with family or old friends?

.....spent time (using DRUG) instead of doing things you used to enjoy, like sports, or some kind of regular activity or hobby?

FOR SEVERITY OF "1" OR MORE:

How many days altogether did you reduce or discontinue any of these activities?

(Which activities did you reduce? Which activities did you discontinue? Had these (RELEVANT ACTIVITIES) been important to you before?

√ BOX FOR EACH DRUG
USED IN PAST 30 DAYS

OF DAYS
(0-30)

SEVERITY
RATING
(0-5)

HEROIN

PAINKILLERS

METHADONE

SEVERITY RATING SCALE

0 = **ABSENT**- No activities reduced or given up

1 = **SUBTHRESHOLD** – Reduced activities slightly and of doubtful clinical significance

2 = **MILD** – Reduced activities in 1 or 2 areas, but still functions in others

3 = **MODERATE** – Completely discontinued activities in 1 area OR reduced in all 3 areas

4 = **SEVERE** – Completely discontinued in 2 areas

5 = **EXTREME** – Discontinued virtually all non-substance-related social, occupational and recreational activities

Study STUDYID

DOMAIN: QS

ID USUBJID
Date ___/___/___ QSSTDTC

SDSS – LITE

5. DSM-IV DEPENDENCE: MARKED TOLERANCE: NEED FOR MARKEDLY INCREASED AMOUNTS OF SUBSTANCE TO ACHIEVE INTOXICATION OR DESIRED EFFECT, OR MARKEDLY DIMINISHED EFFECT OF SUBSTANCE WITH THE CONTINUED USE OF THE SAME AMOUNT

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST

QSEVLINT='-P30D'

√ BOX FOR EACH DRUG
USED IN PAST 30 DAYS

QSORRES SEVERITY
OF DAYS RATING
(0-30) (0-2)

QSORRES

Next I'll be asking you about having tolerance to drugs. What I mean by tolerance is needing to use more to get the same effect, or getting less effect from the amount you were using.

ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:

During the past 30 days, have you.....

.....found that the same amount of (DRUG) has less of an effect than it used to?

.....found that you need to (use MORE DRUG) to get the same effect?

IF YES:

Since (DATE 30 DAYS AGO), how many *days* did this happen altogether?

HEROIN

PAINKILLERS

METHADONE

SEVERITY RATING SCALE

0 = ABSENT – No tolerance

1 = SUBTHRESHOLD – Needs slightly more substance for desired effect OR same amount has slightly less effect

2 = PRESENT – Needs markedly increased amount to achieve desired effect OR same amount has markedly diminished effect.

SDSS – LITE

6A. DSM-IV DEPENDENCE: CHARACTERISTIC SUBSTANCE WITHDRAWAL SYMPTOMS AFTER CESSATION OR REDUCTION OF HEAVY AND PROLONGED SUBSTANCE USE OR BINGE USE

QSTEST	QSEVLINT='-P30D'	✓ BOX FOR EACH DRUG USED IN PAST 30 DAYS	QSORRES # OF DAYS (0-30)	QSORRES SEVERITY RATING (0-2)
<p>Next I'll be asking you about withdrawal, that is, how you were feeling when the effects of the drugs were wearing off.</p> <p>ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:</p> <p>People can have a number of unpleasant experiences when the effects of drugs are wearing off, for instance, several hours after using a substance or a day or so after using it.</p> <p>During the past 30 days, when the effects of (DRUG) were wearing off, have you ever.... (SEE SYMPTOMS FOR SPECIFIC SUBSTANCE BELOW)</p> <p>FOR SEVERIT OF "1" OR MORE: During the past 30 days, how often did you have these experiences? On how many days in the past 30 days? (How many times (per week)?)</p>				
		<input type="checkbox"/> HEROIN	_ _ _	_ _
		<input type="checkbox"/> PAINKILLERS	_ _ _	_ _
		<input type="checkbox"/> METHADONE	_ _ _	_ _

SEVERITY RATING SCALE
 0 = **ABSENT** – Never experienced withdrawal symptoms
 1 = **SUBTHRESHOLD** – Had fewer than required number of symptoms for substance
 2 = **PRESENT** – Experienced required number of symptoms for substance.

QSSCAT='ALCOHOL/DRUGS'
 QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

**For each drug, if 3 or more checked,
code "2" and number of days**

QSORRES	QSTEST
HER PAI MET	DSM-IV
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	had nausea or vomiting?
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	had goose bumps, sweating, or enlarged pupils?
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	had muscle aches?
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	had diarrhea?
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	had a lot of yawning?
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	had fever?
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	had watery eyes or runny nose?
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	had trouble sleeping?
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	been depressed, irritable or anxious?

Study _____ STUDYID _____

DOMAIN: QS

ID _____ USUBJID _____
Date ____/____/____ QSSTDTTC

SDSS – LITE

6B. DSM-IV DEPENDENCE: SUBJECTIVE EXPERIENCE OF SEVERITY OF WITHDRAWAL IN PAST 30 DAYS

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST	QSEVLINT='-P30D'	✓ BOX FOR EACH DRUG USED IN PAST 30 DAYS	QSORRES # OF DAYS (0-30)	QSORRES SEVERITY RATING (0-5)
During the past 30 days.....				
ASK ONLY FOR SUBSTANCES CODED "2" IN Q.6a:				
.....how bad were the after-effects of (using DRUG)? (REMIND SUBJECT OF DSM-IV WITHDRAWAL SYMPTOMS FOR EACH INDIVIDUAL SUBSTANCE, AS NEEDED). On the whole, would you say they were mild, moderate, severe, or extreme?		<input type="checkbox"/> HEROIN	__ __	__
		<input type="checkbox"/> PAINKILLERS	__ __	__
		<input type="checkbox"/> METHADONE	__ __	__

SEVERITY RATING SCALE
0 = **ABSENT**- No withdrawal for substance
1 = **SUBTHRESHOLD** – Subject experienced fewer than required number of withdrawal symptoms for substance
2 = **MILD** – Subject reports mild withdrawal symptoms
3 = **MODERATE** – Subject reports moderate withdrawal symptoms
4 = **SEVERE** – Subject reports severe withdrawal symptoms
5 = **EXTREME** – Subject reports extreme withdrawal symptoms

SDSS – LITE

6C. DSM-IV DEPENDENCE: THE SAME OR CLOSELY-RELATED SUBSTANCE WAS TAKEN TO RELIEVE OR AVOID WITHDRAWAL SYMPTOMS (CLOSELY RELATED SUBSTANCES ARE ALCOHOL AND SEDATIVES; COCAINE AND STIMULANTS; HEROIN, METHADONE AND OPIATES)

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST

QSEVLINT='-P30D'

√ BOX FOR EACH DRUG
USED IN PAST 30 DAYS

QSORRES

OF DAYS
(0-30)

QSORRES

SEVERITY
RATING
(0-2)

Next I'll be asking you about using alcohol or drugs to feel better when you were withdrawing, or to avoid withdrawal.

ASK FOR EACH OF THESE SUBSTANCE USED IN PAST 30 DAYS:

ASK ABOUT ALL SUBSTANCES USED:

During the past 30 days.....

....(use DRUG) to get over any of these after-effects of (using DRUG)? Or did you (use DRUG) to keep from having any of these after-effects? (REMIND SUBJECT OF DSM-IV WITHDRAWAL SYMPTOMS FROM Q.6a, IF NECESSARY) (What did you take?)

FOR SEVERITY OF "1" OR MORE:
How many *days* did this happen?

HEROIN

PAINKILLERS

METHADONE

SEVERITY RATING SCALE

0 = ABSENT – Never used DRUG to relieve / avoid withdrawal

1 = SUBTHRESHOLD – Used only unrelated substance to relieve / avoid withdrawal

2 = PRESENT – Used to relieve/avoid withdrawal

SDSS – LITE

7A. DSM-IV DEPENDENCE: CONTINUED SUBSTANCE USE DESPITE KNOWLEDGE OF A PERSISTENT OR RECURRENT PSYCHOLOGICAL PROBLEM THAT IS CAUSED OR EXACERBATED BY SUBSTANCE USE – DEPRESSION, SUSPICIOUSNESS, PSYCHOTIC SYMPTOMS OR ANXIETY

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST

QSEVLINT='-P30D'

QSORRES

QSORRES

√ BOX FOR EACH DRUG
USED IN PAST 30 DAYS

OF DAYS
(0-30)

SEVERITY
RATING
(0-5)

Next I'll be asking you about continuing to use drugs even though you knew it was making you feel depressed, nervous, paranoid, or anxious.

ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:

During the Past 30 days, have you....

....been depressed, down or uninterested in things when it was related to your (DRUG) use)? This might be when you were (WITHDRAWING) from (DRUG), or other times, too.

....been suspicious or distrustful of others when it was related to your (DRUG use) or its aftereffects.

....felt very upset or nervous related to your (DRUG use) or its aftereffects?

IF YES TO ANY OF ABOVE AND NOT KNOWN:

Do you think that this/these (PSYCHOLOGICAL PROBLEM/S) was/were related to your (DRUG use)?

IF YES AND NOT KNOWN:

Did that affect your (DRUG use)? (Can you describe that to me?)

FOR SEVERITY OF "1" OR MORE:

How many days did you continue to (use DRUG) and feel that way?

(Can you describe this/these (PSYCHOLOGICAL PROBLEM/S) to me? How much did (it/each one) bother you?).

HEROIN

PAINKILLERS

METHADONE

SEVERITY RATING SCALE

- 0 = **ABSENT**- Absent or stopped using when became aware of psychological problem
- 1 = **SUBTHRESHOLD** – Problem is very mild and of doubtful clinical significance OR problem exists but subject is unaware of its relationship to substance use or cuts down to minimal level or use
- 2 = **MILD** – Continued use despite knowledge of at least one mild psychological problem (e.g., low mood, unwarranted suspiciousness, sporadic anxiety)
- 3 = **MODERATE** – Continued use despite knowledge of at least one moderate psychological problem (e.g., significant depression, avoids others due to distrust, intense anxiety)
- 4 = **SEVERE** – Continued use despite knowledge of one severe problem (e.g., severe depression resulting in significant impairment, paranoid delusions, severe anxiety or panic attacks)
- 5 = **EXTREME** – Continued use despite knowledge of more than one severe problem

SDSS – LITE

7B. DSM-IV DEPENDENCE: CONTINUED SUBSTANCE USE DESPITE KNOWLEDGE OF A PERSISTENT OR RECURRENT PHYSICAL PROBLEM THAT IS CAUSED OR EXACERBATED BY SUBSTANCE USE

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST

QSEVLINT='-P30D' BOX FOR EACH DRUG USED IN PAST 30 DAYS

QSORRES

QSORRES

OF DAYS (0-30)

SEVERITY RATING (0-5)

Next I'll be asking you about continuing to use drugs even though you knew it was contributing to a physical problem.

ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:

During the Past 30 days, have you...

...had a health or medical problem that was caused or made worse by your (DRUG use) or its aftereffects? IF APPLICABLE: How about breathing problems related to smoking (crack/pot/SOE)?

IF YES AND NOT KNOWN:

Did you think that this (PHYSICAL PROBLEM/S) was/were related to your (DRUG use)?

IF YES AND NOT KNOWN:

Did knowing that you had (PHYSICAL PROBLEM/S) affect your (DRUG use)? (Can you describe that to me?)

FOR SEVERITY OF "1" OR MORE:

How many days did you continue to (use DRUG) when you had (PHYSICAL PROBLEM/S)?

(What was the health problem? Was there more than one physical problem? What did the doctor say?)

HEROIN

PAINKILLERS

METHADONE

SEVERITY RATING SCALE

- 0 = **ABSENT**- Absent or stopped using when became aware of physical problem
- 1 = **SUBTHRESHOLD** – Problem is very mild and of doubtful clinical significance OR problem exists but subject cut down to minimal level or use
- 2 = **MILD** – Continued use despite knowledge of at least one mild physical problem (e.g., abnormal liver test and alcohol use with no diagnosis of liver disease; minor breathing problems and smoking crack, heroin, marijuana)
- 3 = **MODERATE** – Continued use despite knowledge of at least one moderate physical problem (e.g., ulcers, medicated hypertension, or liver disease and alcohol use; cardiac problem, high blood pressure and cocaine use)
- 4 = **SEVERE** – Continued use despite knowledge of one severe physical problem (e.g., hepatitis, cellulites and I.V. drug use; cirrhosis, diabetes and alcohol use; HIV (weakened immune system due to persistent substance use)
- 5 = **EXTREME** – Continued use despite knowledge of severe problem in more than one area

Question 8 has been intentionally omitted.

SDSS – LITE

9. DSM-IV ABUSE: RECURRENT SUBSTANCE USE RESULTING IN A FAILURE TO FULFILL MAJOR ROLE OBLIGATIONS AT WORK, SCHOOL, OR HOME

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSORRES

QSORRES

QSTEST

QSEVLINT='-P30D'

√ BOX FOR EACH DRUG
USED IN PAST 30 DAYS

OF DAYS
(0-30)

SEVERITY
RATING
(0-5)

Next I'll be asking you about problems taking care of your responsibilities at work, school, or at home because of your drug use.

IF SAYS QUESTION WAS ALREADY ANSWERED: Before I asked you about giving up work, school, social or recreational activities. Now I am asking just about problems with work, school or taking care of things at home.

ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:

During the last 30 days, have you...

...found that you couldn't get to work or school, or do your work well because of your (DRUG use) or its aftereffects?

...been absent, suspended or expelled from school because of your (DRUG use) ? Did it affect your schoolwork or grades?

...had a time when your (DRUG use) or its aftereffects made it hard for you to take care of (your/someone else's) children or do housework that needed to be done?

FOR SEVERITY OF "1" OR MORE:

How many days altogether in the past 30 days did you have difficulty with (WORK/SCHOOL/HOME)?

(What happened at (WORK/SCHOOL/HOME)? What happened as a result? Did you have difficulty with more than one of these areas because of your (DRUG use)?

HEROIN

PAINKILLERS

METHADONE

SEVERITY RATING SCALE

- 0 = **ABSENT**- No failure in role obligation (code "0" if subject always performs poorly at school/work/home, even when not using or recovering from substance use)
- 1 = **SUBTHRESHOLD** – Problem is very mild and of doubtful clinical significance
- 2 = **MILD** –At least one mild problem (e.g., difficulty getting to or performing well at work; difficulty doing necessary housework due to substance use or its aftereffects)
- 3 = **MODERATE** –At least one moderate problem with no problem at a severe level (e.g., habitual substance use and/or recovering from it rather than studying; reprimanded or disciplined at work or school, e.g., "written up", received detention)
- 4 = **SEVERE** – One severe problem (e.g., suspended, expelled, fired or could not hold a job due to substance; children placed in foster care)
- 5 = **EXTREME** –More than one severe problem

Study STUDYID

DOMAIN: QS

ID USUBJID
Date ___/___/___ QSSTDTC

SDSS – LITE

10. DSM-IV ABUSE: RECURRENT SUBSTANCE USE WHEN PHYSICALLY HAZARDOUS:DRIVING (WITH OR WITHOUT LICENSE) OR SITUATIONS OTHER THAN DRIVING

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST

QSEVLINT='-P30D'

✓ BOX FOR EACH DRUG
USED IN PAST 30 DAYS

QSORRES
OF DAYS
(0-30)

QSORRES
SEVERITY
RATING
(0-5)

Next I'll be asking you about doing things after using drugs that might have been dangerous, like driving or swimming.

ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:

During the past 30 days, have you...

...driven a car after (using DRUG)? (PAUSE) or when you (were high on DRUG)? How about driving a motorcycle, van, boat, or any other vehicle when you (were high on DRUG)?

...been in any other situation while (you were using DRUG) or (high on DRUG) that increased your or someone else's chances of getting hurt? Some examples are swimming, using machinery or power equipment, doing construction work or hunting. (What did you do?)

FOR SEVERITY OF "1" OR MORE:

Since (DATE 30 DAYS AGO), how many *days* did you drive or do something else dangerous after (using DRUG)?

(How much did you feel the effects of DRUG at (that/those) times?)

HEROIN

PAINKILLERS

METHADONE

SEVERITY RATING SCALE

0 = **ABSENT**- No hazardous use

1 = **SUBTHRESHOLD** – Engaged in hazardous activity when but did not feel the effects of substance

2 = **MILD** –Engaged in hazardous activity when felt mild effects of substance but did not feel impaired

3 = **MODERATE** – Engaged in hazardous activity when felt clearly intoxicated

4 = **SEVERE** Engaged in hazardous activity when felt severely intoxicated

5 = **EXTREME** –Passed out/blacked out when engaged in hazardous activity

SDSS – LITE

11. DSM-IV ABUSE: CONTINUED SUBSTANCE USE DESPITE HAVING A PERSISTENT OR RECURRENT SOCIAL/INTERPERSONAL PROBLEM THAT IS CAUSED OR EXACERBATED BY SUBSTANCE USE- ARGUMENTS, FRICTION, SOCIAL REJECTION, OR OTHER

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST	QSEVLINT='-P30D'	√ BOX FOR EACH DRUG USED IN PAST 30 DAYS	QSORRES # OF DAYS (0-30)	QSORRES SEVERITY RATING (0-5)
<p>Next I'll be asking you about social or interpersonal problems related to your drug use, like arguments or fights.</p> <p>ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:</p> <p>During the past 30 days, have you.....</p> <p>....had a problem getting along with people because of your (use of DRUG)? Examples could be arguments or friction with family members, friends, people at work, or anyone else. Did that also happen when you weren't (using DRUG)? Was it worse when you were (using DRUG)?</p> <p>....found that people stayed away from you because of your (use of DRUG) or its aftereffects? Did that also happen when you weren't (using DRUG)? Was it worse when you were (using DRUG)?</p> <p>....had a time when you had physical fights with people when you were (using DRUG)? Did you have any other problems with people because of your (use of DRUG)? Did that also happen when you weren't (using DRUG)? Was it worse when you were (using DRUGS)?</p> <p>IF YES TO ANY AND NOT KNOWN: Was there any change in your (DRUG use) as the result of (this/these) experience(s)? (Can you describe that to me?)</p> <p>FOR SEVERITY OF "1" OR MORE: How many <i>days</i> did you (use DRUG) when you had these experiences?</p> <p>(Did you have more than one of these experiences? Can you describe them to me? How much did (INTERPERSONAL PROBLEM/S) affect your relationships?)</p>				
		<input type="checkbox"/> HEROIN	_ _ _	_ _
		<input type="checkbox"/> PAINKILLERS	_ _ _	_ _
		<input type="checkbox"/> METHADONE	_ _ _	_ _

SEVERITY RATING SCALE

- 0 = **ABSENT**- Absent or stopped using when became aware of social/interpersonal problem
- 1 = **SUBTHRESHOLD** – Problem is very mild and of doubtful clinical significance OR there is a problem but subject cut down to a minimal level of use
- 2 = **MILD** – Continued use despite at least one mild problem (e.g., arguments with friends or coworkers related to substance use; avoided by others because of substance use or its aftereffects)
- 3 = **MODERATE** – Continued use despite at least one moderate problem (e.g., friendship ended because of substance use; conflicts with employer/supervisor)
- 4 = **SEVERE** – Continued use despite at least one severe problem (e.g., left by spouse or significant other because of substance use; physical fights related to substance use; rejection by family members)
- 5 = **EXTREME** – Continued use despite More than one severe problem

Study STUDYID

DOMAIN: QS

ID USUBJID
Date ___/___/___ QSSTDT

SDSS – LITE

12. DSM-IV ABUSE: RECURRENT SUBSTANCE-RELATED LEGAL PROBLEMS

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

QSTEST

QSEVLINT='-P30D'

✓ BOX FOR EACH DRUG
USED IN PAST 30 DAYS

QSORRES

OF DAYS
(0-30)

QSORRES

SEVERITY
RATING
(0-5)

Last, I'll be asking you about legal problems related to your drug use.

ASK FOR EACH OF THESE SUBSTANCES USED IN PAST 30 DAYS:

During the past 30 days, have you.....

.....had any legal problems related to your (use of DRUG)? Examples could include being arrested or picked up by police for how you were acting when (you were high on DRUG), or having a car accident (when you were high on DRUG). Did you have any contact with the police about anything to do with (DRUG), for example, stealing, selling drugs or having sex to get money for (DRUG)?

FOR SEVERITY OF "1" OR MORE:
How many *days* did that happen altogether?

(What happened? What was the charge? Did you have any other legal problems related to (DRUG use)?)

HEROIN

PAINKILLERS

METHADONE

SEVERITY RATING SCALE

0 = **ABSENT**- No substance- related legal problem

1 = **SUBTHRESHOLD** – Engaged in illegal substance-related activity but no legal problems

2 = **MILD** – Was arrested or received summons for substance-related disorderly conduct (e.g., possession of small amounts of marijuana, high in public, OR has charges pending for substance-related crime committed prior to past 30 days

3 = **MODERATE** – Was arrested for substance-related misdemeanor (e.g., driving under the influence (DUI); possession of cocaine or heroin OR is on probation/parole for substance-related crime committed prior to past 30 days

4 = **SEVERE** – Was arrested for substance-related felony not involving serious injury OR had more than 1 mild to moderate legal problem (e.g., DUI that involved accident and/or minor injury; arrest for sale of intent to sell illicit drugs) OR was in jail for substance-related crime committed prior to past 30 days

5 = **EXTREME** – Was arrested for substance-related felony that involved injury or fatality OR more than 1 moderate to severe legal problem (e.g., DUI that involved serious injury or fatality; conviction and prison sentence for any substance-related felony)

Study STUDYID

DOMAIN: QS

Date ID USUBJID
QSSDTC

QSSCAT='ALCOHOL/DRUGS'

QSCAT='SUBSTANCE DEPENDENCY SEVERITY SCALE - LITE

SDSS – LITE

QSENDTC

Time ended: _____ (hh:mm, 24 hour clock)

Total time to complete

___ hours ___ minutes

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct and complete.

Clinician Name (please print): _____

QNAM=QSCSG
QLABEL=QUESTIONNAIRE CLINICIAN SIG
IDVAR=VISITNUM

Clinician Signature THIS DATA NOT ENTERED

Date Signed ___ / ___ / _____

QNAM=QSSGDTC
QLABEL= QUESTIONNAIRE CLINICIAN SIG DATE
IDVAR=VISITNUM

Study _____

DOMAIN: LB

ID _____

Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ LBDTC	Phase EPOCH ____	Visit Week VISIT _____	Sequence Number _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

URINE ANALYSIS RESULTS

Study STUDYID

DOMAIN: LB

ID USUBJID
Date ___/___/___ LBDTC

LBCAT=URINALYSIS

Urine Analysis Results

LBTEST

LBORRES

1. Overall UA results

1 = Normal
2 = Abnormal

a. If any abnormalities, are they clinically significant?

0 = No
1 = Yes

QNAM=LBCLSIG
QLABEL=CLINICALLY SIGNIFICANT
ABNORMALITY
IDVAR=LBSEQ

b. If yes, specify _____

QNAM=CSABN
QLABEL=SPECIFY CLINICALLY
SIGNIFICANT ABNORMALITY
IDVAR=LBSEQ

2. Does the abnormality preclude safe entry or continuation in the study?

0 = No
1 = Yes

QNAM=URINEABN
QLABEL=URINE ABNORMALITY PREVENTS CONTINUATION
IDVAR=LBSEQ

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct and complete.

Clinician Name (please print): THIS DATA NOT DATABASSED

Clinician Signature THIS DATA NOT DATABASSED

Date Signed ___/___/___ THIS DATA NOT DATABASSED

Study _____

DOMAIN: LB ID _____
date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ LBDTC	Phase EPOCH ____	Visit Week VISIT _____	Sequence Number _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Urine Drug Screening Results

Study STUDYID

DOMAIN: LB

ID USUBJID
Date ___/___/___

URINE DRUG SCREENING RESULTS
LBCAT=URINE DRUG SCREEN

QNAM=LBTEMP
QLABEL=URINE TEMP WITHIN
EXPECTED RANGE
IDVAR=LBSEQ

1. Date urine collected: LB DTC ___/___/___

2. Urine temperature within expected range? 0 = No
(95° F - 99.5° F) 1 = Yes
9 = Unknown

LBTEST		<u>NEG</u>	<u>POS</u>	<u>Not Assessed</u> LBORRES
3. Amphetamines	AMP	0	1	2
4. Barbiturates	BAR	0	1	2
5. Benzodiazepines	BZO	0	1	2
6. Methadone	MTD	0	1	2
7. Tricyclic Antidepressants	TCA	0	1	2
8. Cocaine	COC	0	1	2
9. Methamphetamines	M-AMP	0	1	2
10. Cannabinoids	THC	0	1	2
11. Oxycodone	OXY	0	1	2
12. Morphine/Opiates	MOR/OP	0	1	2
13. Phencyclidine	PCP	0	1	2

14. Was urine collection supervised? 0 = No
1 = Yes

QNAM=LBSUPER
QLABEL=URINE COLLECTION SUPERVISED
IDVAR=LBSEQ

Study _____

DOMAIN: VS

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ VSDTC	Phase EPOCH __	Visit Week VISIT __	Sequence Number __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Vital Signs

Study _____ **STUDYID**

DOMAIN: VS

ID _____ **USUBJID**

Date ____/____/____ **VSDTC**

Form Completion Status: <input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required

Vital Signs

VSDTC

____ : ____ 1. Time (*24 hour clock, hh:mm*)

VSTEST

VSORRES

____ . ____ 2. Temperature (*Degrees Fahrenheit - Oral*)

VSORRESU

____ / ____ 3. Sitting Blood pressure (*mm Hg*)
3a. Systolic/ 3b. Diastolic

____ 4. Heart rate (*bpm*)

____ 5. Respirations (*1 minute*)

____ 6. Weight (*round to nearest pound*)

7. Comments:

DOMAIN: CO
COVAL
RDOMAIN=VS
IDVAR= VSSEQ

Study _____

DOMAIN: QS

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ QSDTC	Phase EPOCH __	Visit Week VISIT __	Sequence Number __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Addiction Recovery Scale

ADDICTION RECOVERY SCALE

QSCAT='ADDICTION RECOVERY SCALE'

INSTRUCTIONS: *Using the 5 point scale below, please indicate how much you agree or disagree with the following statements.*

QSORRES

1	2	3	4	5
Strongly Disagree		Neutral		Strongly Agree

QSTEST/QSTESTCD

- _____ 1. I don't know what triggers me to go out and use drugs.
- _____ 2. I just can't get myself to go to an NA (AA or CA) meeting.
- _____ 3. I recognize the signs of craving for cocaine.
- _____ 4. I don't agree with the idea of a "higher power".
- _____ 5. When I tell myself "I can use just one time", I recognize this as my addictive thinking.
- _____ 6. It doesn't bother me to be around friends when they are getting high.
- _____ 7. When I experience drug craving, I am able to wait it out.
- _____ 8. I think starting a new romantic relationship can help one to stay clean.
- _____ 9. When I experience craving, I go to a 12-step meeting.
- _____ 10. I structure my daily routine to avoid having idle time.
- _____ 11. I am not willing to tell anyone about my drug problem because I am ashamed.
- _____ 12. I believe that participating in 12-step groups is helping me to recover.
- _____ 13. Drinking alcohol helps me to resist my desire for cocaine.
- _____ 14. I don't think I have to change many of my old behaviors to recover.
- _____ 15. I think it is important to spend time with drug-free friends.
- _____ 16. I think I can get sober on my own without anyone's help.
- _____ 17. I can enjoy myself without using drugs or alcohol.
- _____ 18. I believe that I can limit my drug use.
- _____ 19. I haven't gotten around to getting a sponsor.
- _____ 20. I believe that I am powerless over drugs.
- _____ 21. I rely on my higher power to help me stay clean.
- _____ 22. If I get a craving, I will most likely go out and use.
- _____ 23. Going to an NA (AA or CA) meeting every day helps me.
- _____ 24. My drug use has not hurt anybody but myself.
- _____ 25. I understand the idea of taking a personal inventory.

ADDICTION RECOVERY SCALE

QSCAT='ADDICTION RECOVERY SCALE'

1	2	3	4	5
Strongly Disagree		Neutral		Strongly Agree

QSORRES

QSTEST/QSTESTCD

- _____ 26. I am making amends to people whom I have injured through my addiction.
- _____ 27. When I start to think that I no longer need to work on my recovery, I know that that is the beginning of a relapse process.
- _____ 28. I am too busy to spend much time in recovery activities like treatment, and 12-step meetings.
- _____ 29. I view relapse as a process that may begin with the loss of a humble attitude toward addiction.
- _____ 30. I know that recovery from addiction is a lifelong process.
- _____ 31. My problem with drugs isn't really that bad.
- _____ 32. I stay away from people, places and things that trigger drug cravings.
- _____ 33. I don't think using marijuana occasionally contributes to one's addiction.
- _____ 34. I try to manage my stress because I know that too much stress will damage my recovery.
- _____ 35. I think that people at NA meetings tell a lot of "war stories" that could trigger an urge for drugs so I don't often go to meetings.
- _____ 36. I think that someday I'll be able to use cocaine on occasion and not get out of control again.
- _____ 37. Sometimes I "test" myself by going by a place where I have copped drugs.
- _____ 38. Breaking down my denial is an important part of my recovery.
- _____ 39. I spend a lot of time thinking about the good times I had using drugs.
- _____ 40. I know what my triggers to drug use are.

Study _____

DOMAIN: QS

ID _____

Date ___/___/_____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

<i>Protocol Number</i> NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID _____
Visit Date ___/___/_____ QSDTC	Phase EPOCH	Visit Week VISIT_	Sequence Number USUBIID
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Quality of Life

QSCAT= Quality of Life

Instructions: Please enter the number that best describes your current health today.

1. Mobility **QSTEST/QSTESTCD**

- 0. I have no problems walking about
 - 1. I have some problems walking about
 - 2. I am confined to bed
- QSORRES**

2. Self-Care

- 0. I have no problems with self-care
- 1. I have some problems washing and dressing myself
- 2. I am unable to wash or dress myself

3. Usual Activities

- 0. I have no problems with performing my usual activities (e.g., work, study, housework, family or leisure activities)
- 1. I have some problems with performing my usual activities
- 2. I am unable to perform my usual activities

4. Pain/Discomfort

- 0. I have no pain or discomfort
- 1. I have some pain or discomfort
- 2. I have extreme pain or discomfort

5. Anxiety/Depression

- 0. I am not anxious or depressed
- 1. I am moderately anxious or depressed
- 2. I am extremely anxious or depressed

Study STUDYID

ID USUBJID

DOMAIN: QS

Date ___/___/___ **QSDTC**

Quality of Life

To help people say how good or bad a health state is, we have a scale on which the best state you can imagine is marked by 100, and the worst state you can imagine is marked by 0.

QSTEST/QSTESTCD

We would like you to indicate based on this scale how good or bad your health is today. Please do this by entering the number in the box below that indicates how good or bad your health is currently.

Your own health state today: **QSORRES**

Study _____

DOMAIN: QS

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ QSDTC	Phase EPOCH __	Visit Week VISIT __	Sequence Number _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Non-Study Medical Services

Study _____ **STUDYID**

DOMAIN: QS

ID _____ **USUBJID**
Date ____/____/____ **QSDTC**

QSCAT= Non-Study Medical Services

**QNAM=QSFRMDTC
QLABEL=DATE PARTICIPANT LAST
COMPLETED FORM
IDVAR=QSSEQ**

____/____/____

When did the participant last complete this form?

(Interview note: For Baseline Visit use the last 30 days and leave date blank)

QSEVLINT=-P30D at VISITNUM=-1

We'd like you to answer these questions for the medical services you've received that are **not** part of this outpatient program. **Since your last assessment on** <date recorded above>. **QSTEST/QSTESTCD**

QSORRES

- 1. Have you seen a therapist, that is a psychiatrist, psychologist, counselor, or social worker for drug, psychological, or emotional problems? **1=Yes 0 = No** _____
 - 1a. (If yes), how many times did you see a psychiatrist or psychologist? _____
 - 1b. (If yes), how many times did you see a counselor or social worker? _____
- 2. Have you visited a medical office, not including your therapist? **1=Yes 0 = No** _____
(Include all visits to a physician, nurse, nurse practitioner, or physician's assistant)
 - 2a. (If yes), how many visits to a medical office have you had? _____
 - 2b. (If yes), how many of these visits did you see a doctor? _____
- 3. Have you been admitted into a residential program, halfway house, or other controlled environment (not including "jail") where detoxification was part of their services, or for some other service that they may have provided? **1=Yes 0 = No** _____
 - 3a. (If yes), how many admissions? _____
 - 3b. (If admitted), how many nights for all stays? _____
- 4. Have you been admitted into a hospital to detoxify? **1=Yes 0 = No** _____
 - 4a. (If yes), how many admissions? _____
 - 4b. (If admitted), how many nights for all stays? _____
- 5. Have you been admitted to the hospital for any other reason? **1=Yes 0 = No** _____
 - 5a. (If yes), how many times were you admitted? _____
 - 5b. (If at least once), how many nights for all stays? _____
- 6. Have you visited an emergency room and not been admitted to the hospital? **1=Yes 0 = No** _____
 - 6a. (If yes), how many times did you visit the emergency room? _____

Study _____

STUDYID

DOMAIN: SC, DM, DS

ID _____

Date ___/___/_____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	<i>Node ID</i> __ __	<i>Site ID</i> __ __ __ __	<i>Subject ID</i> USUBJID __ __ __ __
<i>Visit Date</i> _ / _ / _	<i>Phase</i> EPOCH	<i>Visit Week</i> VISIT	<i>Sequence Number</i> _____
SCDTC/DMDTC/DSDTC		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Enrollment / Randomization

Study STUDYID

DOMAIN: SC, DM, DS

ID USUBJID
Date __/__/__-SCDTC/DMDTC/DSDTC

Enrollment / Randomization

SC.SCTEST

SC.SCORRES

- 1. Does the participant continue to meet the eligibility criteria?
0 = No
1 = Yes
- 2. Did the subject or minor subject and parent / guardian sign the informed consent/assent to participate?
0 = No
1 = Yes
- 3. Was the participant randomized?
(If no, skip to question 4)
0 = No
1 = Yes

3a. If yes, Randomization Group:

Usual)

DM.ARM

1 = Group 1 (Treatment As

2 = Group 2

(Buprenorphine/Naloxone)

3b. Date of randomization: __/__/____ (mm/dd/yyyy)

DM.RFSTDTC

DS.DSCAT=DISPOSITION EVENT

DS.DSOCCUR

- 4. If not randomized, reasons not randomized:
DS.DSTERM
- 4a. Failed to return to clinic
0 1
- 4b. Declined study participation (specify in comments)
0 1
- 4c. Failed informed consent/assent quiz
0 1
- 4d. Failed to meet inclusion criteria or met exclusion criteria
(specify in comments)
0 1
- 4e. Moved from area (current or pending)
0 1
- 4f. Incarceration (current or pending)
0 1
- 4g. Death
0 1
- 4h. Other (specify in comments)
0 1

5. Comments: **DOMAIN: CO**
COVAL
RDOMAIN=DM
IDVAR=DSSEQ

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct, and complete.

Clinician Name (please print): THIS DATA NOT DATABAS

Clinician Signature THIS DATA NOT DATABAS
Date Signed __/__/____ THIS DATA NOT DATABAS

Study _____

DOMAIN: QS

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ QSDTC	Phase EPOCH __	Visit Week VISIT __	Sequence Number __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Risk Behaviors Survey (RBS)

QSCAT=RISK BEHAVIORS SURVEY

Risk Behaviors Survey (RBS)

QSSCAT=DRUG USE

INTERVIEWER: The RBS contains sensitive information on drug use and sexual behavior. Please ensure that you have developed rapport with the participant before asking these questions.

QSTEST QSORRES QSEVLINT=-P30D

A. DRUG USE

I'm going to ask you some questions about your drug use. I'll ask what types of drugs you've used and how often you use them.		a.				b.	c.	d.	e.	f.
		Have you ever used? <i>(If no use, skip to next drug)</i>				How many days did you use ____ in the last 30 days? <i>(If 00, do not ask parts c-f, and skip to next drug)</i>	How many days did you inject ____ in the last 30 days? <i>(If 00, skip to part e)</i>	How many times a day did you inject ____? <i>(Average # of injections/day)</i>	How many days did you use ____ without injecting (smoking, snorting, swallowing) in the last 30 days? <i>(If 00, then skip to next drug class)</i>	How many times a day did you use ____ without injecting?
		NO	YES	UNK	REF					
1.	Cocaine by itself (injected or snorted)	0	1	9	7	____	____	____	____	____
2.	Heroin by itself	0	1	9	7	____	____	____	____	____
3.	Heroin & Cocaine mixed together (Speedball)	0	1	9	7	____	____	____	____	____
4.	Other Opiates (Demerol, Codeine, Dilaudid)	0	1	9	7	____	____	____	____	____
5.	Amphetamines (Speed, Methamphetamine, Crank)	0	1	9	7	____	____	____	____	____

DOMAIN: QS

QSCAT=RISK BEHAVIORS SURVEY

QSSCAT=DRUG INJECTION

Risk Behaviors Survey (RBS)

QSTEST

QSEVLINT=-P30D

B. DRUG INJECTION (if no injection use in past 30 days, skip to Section C)

QSORRES

- 1. In the last 30 days, how many times (# of injections) did you inject using works (needle/syringes) that you know had been used by somebody else?
2. Of the times you injected after someone, how many times did you clean the works with full-strength bleach?
3. How many times in the last 30 days did you use a cooker/cotton/rinse water that had been used by another injector?
4. How many times in the last 30 days did you fix drugs with another person, then split the drug solution...

C. SEXUAL ACTIVITY QSSCAT='SEXUAL ACTIVITY'

Now I'm going to ask you some questions about sex. I'm referring here to anybody you've had sex with in the last 30 days.

- 1. During the last 30 days, with how many people did you have vaginal, oral or anal sex?
2. How many of your partners were female?
3. How many of your partners were male?

Please use the following coding for frequency of sexual events and condom/barrier use.

Table with 2 columns: Frequency scale: use scale and Condom/Barrier. Lists various frequency levels (e.g., Once or irregularly, Less than once a week) and condom usage levels (e.g., Never, Less than half the time).

- 4. Interviewer: Code gender of respondent (1=Male, 2=Female, 9=Don't Know)
(If Male, complete sections D, E, F, G & I)
(If Female, complete sections D, G, H, & I)
(If Don't Know, ask ALL sex/gender specific questions and allow client to answer as they like.)

QSSCAT=MALE/FEMALE CLIENT WITH FEMALE PARTNERS

D. Ask Male/Female Clients who had Female Partners

- 1.a How many women performed oral sex ("went down") on you?
1.b How often did your partner(s) perform oral sex ("go down") on you?
1.c How often did you use condoms/dental dams when your partner(s) perform oral sex ("went down") on you?
2.a How many women did you perform oral sex ("go down") on?
2.b How often did you perform oral sex ("go down") on your partner(s)?
2.c How often did you use condoms/dental dams when you performed oral sex ("went down") on your partner(s)?

DOMAIN: QS

Risk Behaviors Survey (RBS)

Frequency scale:		Condom/Barrier use scale:	
Once or irregularly	01	Never	0
Less than once a week	02	Less than half the time	1
About once a week	03	About half the time	2
2-6 times a week	04	More than half the time	3
About once a day	05	Always	4
2-3 times a day	06	Don't know/unsure	9
4 or more times a day	07	Refused	7
Don't know/unsure	99		
Refused	77		

QSSCAT=MALE CLIENT WITH FEMALE PARTNERS

E. Ask Male Clients who had Female Partners:

- ___ 1.a How many women did you have vaginal sex with?
(If 0, then skip to question 2a. Number cannot exceed total number of female partners (qC2))
- QSORRES** ___ 1.b How often did you have vaginal sex? **QSTEST**
- ___ 1.c How often did you use a condom?
- ___ 2.a How many women did you have (insertive) anal sex with?
(If 0, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of female partners (qC2))
- ___ 2.b How often did you have (insertive) anal sex?
- ___ 2.c How often did you use a condom?

F. Ask Male Clients who had Male Partners: QSSCAT=MALE CLIENT WITH MALE PARTNERS

- ___ 1.a How many men did you have (insertive) anal sex with?
(If 0, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of male partners (qC3))
- ___ 1.b How often did you have (insertive) anal sex?
- ___ 1.c How often did you use a condom? **QSSCAT=MALE/FEMALE CLIENT WITH MALE PARTNERS**

G. Ask Male/Female Clients who had Male Partners

- ___ 1.a How many men performed oral sex ("went down") on you?
(If 0, then skip to question 2a. Number cannot exceed total number of male partners (qC3))
- ___ 1.b How often did your partner(s) perform oral sex ("go down") on you?
- ___ 1.c How often did you use condoms/dental dams when your partner(s) perform oral sex ("went down") on you?
- ___ 2.a How many men did you perform oral sex ("go down") on?
(If 0, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of male partners (qC3))
- ___ 2.b How often did you perform oral sex ("go down") on your partner(s)?
- ___ 2.c How often did you use condoms/dental dams when you performed oral sex ("went down") on your partner(s)?

H. Ask Female Clients who had Male Partners: QSSCAT=FEMALE CLIENT WITH MALE PARTNERS

- ___ 1.a How many men did you have vaginal sex with?
(If 0, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of male partners (qC3))
- ___ 1.b How often did you have vaginal sex?
- ___ 1.c How often did you use a condom? **QSSCAT=MALE CLIENT WITH MALE PARTNERS**

I. Ask Male/Female Clients who had Male Partners

- ___ 1.a How many men did you have (receptive) anal sex with?
(If 0, end questionnaire. Number cannot exceed total number of male partners (qC3))
- ___ 1.b How often did you have (receptive) anal sex?
- ___ 1.c How often did you use a condom?

DOMAIN: QS

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number <i>NIDA-CTN-0010</i>	Node ID __ __	Site ID __ __ __ __	Subject ID USUBJID __ __ __ __
Visit Date __ __ / __ __ / __ __ QSDTC	Phase EPOCH	Visit Week VISIT	Sequence Number __ __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Sedation Scale

Form Completion Status: <input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required

QSCAT= Sedation Scale

Indicate on the following line how you feel RIGHT NOW by drawing a slash mark on the line.

How sedated (drowsy/sleepy) do you feel right now? **QSTEST**

Not at all **Extremely**

QSORRES

___/___/___
(mm)

QSORRESU

Study _____

DOMAIN: AE

ID _____
Date __/__/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID USUBID __
Visit Date __/__/AEDTC__	Phase EPOCH	Visit Week VISIT _	Sequence Number __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Serious Adverse Events (SAE)

QNAM=RPTTYP IDVAR=AESEQ
QLABEL=TYPE OF REPORT

Serious Adverse Events

QNAM=AEPHASE
QLABEL=AE STUDY PHASE
IDVAR=AESEQ

1. **Type of Report**
1 = Initial
2 = Follow-Up

QNAM=AEGROUP
QLABEL=SAE GROUP
ASSIGNMENT
IDVAR=AESEQ

2. **Study Phase**
1 = Pre-Randomization
2 = Active
3 = Follow-Up

QNAM=AE1ST
QLABEL=SAE DATE OF FIRST TREATMENT
IDVAR=AESEQ

3. **Group Assignment**

QNAM=AECONT
QLABEL=CONTACT PERSON
IDVAR=AESEQ

4. **Date of First Study Treatment**

5.a **Date of Start of Event**

QNAM=AECPH
QLABEL=CONTACT PERSON PHONE
IDVAR=AESEQ

5.b **Date of End of Event**

EVENT CONTACT PERSON

6.a **Name of person to whom SAE questions should be addressed.**

6.b **Phone Number of Person to whom SAE questions should be addressed.**

PARTICIPANT DATA

7. **Sex**
1 = Male
2 = Female

QNAM=AESEX QLABEL=SEX (SAE PAGE)

8. **Age**

QNAM=AEAGE
QLABEL=AGE (SAE PAGE)
IDVAR=AESEQ

9. **Race/Ethnicity**

- 1 = White
- 2 = African American or Black
- 3 = Native American or Native Alaskan
- 4 = Hispanic or Latino
- 5 = Asian
- 6 = Native Hawaiian or Pacific Islander
- 8 = Other (Specify _____)

QNAM=AERACE
QLABEL=RACE (SAE PAGE)
IDVAR=AESEQ

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

10.a **Weight** (10.a & 10.b, are not required for behavioral studies)

10.b **Units**

- 1 = pounds
- 2 = kilograms

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

11. CATEGORIZATION OF SERIOUS ADVERSE EVENT (SAE) per FDA criteria:

NO	YES	11. CATEGORIZATION OF SERIOUS ADVERSE EVENT (SAE) per FDA criteria:
0	1	a. Death
0	1	b. Life Threatening
0	1	c. Hospitalization (initial or prolonged)
0	1	d. Disability
0	1	e. Congenital Anomaly
0	1	f. Required intervention to prevent permanent impairment/damage
0	1	g. Other (h. Specify: _____)

QNAM=AESCATOT
QLABEL=CATEGORIZATION-OTHER (H.SPECIFY SAE)
IDVAR=AESEQ

AESMIE

AESPID 12.a Adverse Event Number
AETERM / AEBODSYS/ AEDECOD 12.b Adverse Event Term
Serious Adverse Events

12.c Description of adverse event: symptoms, course, duration, action taken, outcome, treatment and sequelae
(max. 1600 characters)

QNAM=AEDESC1-AEDESC8 IDVAR=AESEQ
QLABEL=SAE DESCRIPTION 1 (2,3)

13. Relevant tests/laboratory/toxicology data, including dates: (max. 600 characters)

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

14. Other relevant history, including pre-existing medical & psychiatric conditions: AIDS, high blood pressure, hepatic/renal dysfunction, pregnancy, drug, alcohol, smoking use, allergies, etc. (max. 600 characters)

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

NO	YES	SUBSTANCE USE
0	1	15. Is there increased drug use?
0	1	16. Is there increased alcohol use?
		17. Describe drug/alcohol use: (max. 200 characters)
		18. Amount/Days of drug/alcohol use: (max. 200 characters)

QNAM=AEIDRUG IDVAR=AESEQ
QLABEL=INCREASED DRUG USE

QNAM=AEDRUGD
IDVAR=AESEQ
QLABEL=DESCRIBE
DRUG/ALCOHOL USE

QNAM=AEIALC IDVAR=AESEQ
QLABEL=INCREASED ALCOHOL USE

QNAM=AEDRUGDY
IDVAR=AESEQ
QLABEL=DAYS OF
DRUG/ALCOHOL USE

NO	YES	PSYCHIATRIC HISTORY
0	1	19.a Is there a history of psychotic episodes?
0	1	19.b Is the participant taking neuroleptic medications? (If yes, fill in concomitant medication section)
0	1	19.c Is the participant taking any other type of medications? (If yes, fill in concomitant medication section)
0	1	20.a Is there a history of suicidal ideation?
0	1	20.b Is there a history of suicidal behavior?
0	1	21. Is there a history of homicidal ideation?
0	1	22. Is there a history of homicidal/violent behavior?

QNAM=AEHISP IDVAR=AESEQ
QLABEL=HISTORY OF PSYCHOTIC EPISODES

QNAM=AESUICI IDVAR=AESEQ
QLABEL=HISTORY OF SUICIDAL IDEATION

QNAM=AESUICB IDVAR=AESEQ
QLABEL=HISTORY OF SUICIDAL BEHAVIOR

QNAM=AESTDRUG IDVAR=AESEQ
QLABEL=STUDY DRUG INFO KNOWN

QNAM=AE4DRUGS IDVAR=AESEQ
QLABEL=MORE THAN 4
MEDICATIONS KNOWN

QNAM=AEHOMI IDVAR=AESEQ
QLABEL=HISTORY OF HOMICIDAL IDEATION

QNAM=AEHOMB IDVAR=AESEQ
QLABEL=HISTORY OF HOMICIDAL BEHAVIOR

QNAM=AENEURO
IDVAR=AESEQ
QLABEL=TAKING
NEUROLEPTIC
MEDICATIONS

QNAM=AEOMEDS
IDVAR=AESEQ
QLABEL=TAKING
OTHER
MEDICATIONS

Study
 QNAM=AESDRG1-4
 QLABEL= DRUG
 NAME 1-4
 IDVAR=AESEQ

QNAM=AESROUT1-4
 QLABEL=ROUTE 1-4
 IDVAR=AESEQ

QNAM=AESFRQ1-4
 QLABEL=FREQUENCY
 1-4
 IDVAR=AESEQ

DOMAIN: AE
 QNAM=AESQNT1-4
 LABEL=QUANTITY 1-4
 IDVAR=AESEQ

QNAM=AESLOT1-4
 QLABEL=LOT NUMBER
 1-4
 IDVAR=AESEQ

Serious Adverse Events

Complete For Study Drug

25a. Study Drug Name			b. Lot Number		
c. Expiration Date	d. Route	e. Frequency	f. Quantity	g. Dosage	h. Dose Form
___/___/___ other	_____	___	_____	___	_____
i. Start Date	j. Stop Date		k. Continuing		
___/___/___	___/___/___		0 = No 1 = Yes		
26a. Study Drug Name			b. Lot Number		
c. Expiration Date	d. Route	e. Frequency	f. Quantity	g. Dosage	h. Dose Form
___/___/___ other	_____	___	_____	___	_____
i. Start Date	j. Stop Date		k. Continuing		
___/___/___	___/___/___		0 = No 1 = Yes		
27a. Study Drug Name			b. Lot Number		
c. Expiration Date	d. Route	e. Frequency	f. Quantity	g. Dosage	h. Dose Form
___/___/___ other	_____	___	_____	___	_____
i. Start Date	j. Stop Date		k. Continuing		
___/___/___	___/___/___		0 = No 1 = Yes		
28a. Study Drug Name			b. Lot Number		
c. Expiration Date	d. Route	e. Frequency	f. Quantity	g. Dosage	h. Dose Form
___/___/___ other	_____	___	_____	___	_____
i. Start Date	j. Stop Date		k. Continuing		
___/___/___	___/___/___		0 = No 1 = Yes		

Dosage Administration Coding Sheet

Routes of Admin (IC-H-m2 Numeric Codes)

001=Auricular (otic)
 002=Buccal
 003=Cutaneous
 014=Intra-articular
 030=Intramuscular
 031=Intraocular
 042=Intravenous
 (not otherwise specified)
 046=Ophthalmic
 047=Oral
 049=Other
 053=Rectal
 054=Respiratory (inhalation)
 057=Subcutaneous
 059=Sublingual

Frequency

1=Single dose
 2=Every other day
 3=Once daily
 4=twice daily
 5=Three times a day
 6=Four times a day
 7=As needed
 8=Other
 9=Unknown

Dosage

1=grain(s)
 2=gram(s)
 3=international units
 4=microcurie(s)
 5=microgram(s)
 6=micrograms(s)/kilogram
 7=microgram(s)/sq. meter
 8=microlitre(s)
 9=millicurie(s)
 10=milliequivalent(s)
 11=milligram(s)
 12=milligram(s)/kilogram
 13=milligram(s)/sq. meter
 14=millilitre(s)
 88=Other
 99=Unknown

Dosage Form

1=Capsule
 2=Drop
 3=Gum
 4=Lollipop
 5=Lotion/Ointment
 6=Lozenge
 7=Ounce
 8=Patch
 9=Puff
 10=Spray/Squirt
 11=Suppository
 12=Tablespoon
 13=Tablet
 14=Teaspoon
 15=Wafer
 88=Other
 99=Unknown

QNAM=AESTDT1-4
 QLABEL=START DATE 1-4
 IDVAR=AESEQ

QNAM=AEENDT1-4
 QLABEL=STOP DATE 1-4
 IDVAR=AESEQ

This page is annotated the same as the previous page, but the variables are numbers 5-8 instead of 1-4.

Serious Adverse Events

Complete For Concomitant Drug					
29a. Study Drug Name			b. Lot Number		
c. Expiration Date ____/_____ other	d. Route _____	e. Frequency _____	f. Quantity _____	g. Dosage _____	h. Dose Form _____
i. Start Date ____/____/____	j. Stop Date ____/____/____		k. Continuing 0 = No 1 = Yes		
30a. Study Drug Name			b. Lot Number		
c. Expiration Date ____/_____ other	d. Route _____	e. Frequency _____	f. Quantity _____	g. Dosage _____	h. Dose Form _____
i. Start Date ____/____/____	j. Stop Date ____/____/____		k. Continuing 0 = No 1 = Yes		
31a. Study Drug Name			b. Lot Number		
c. Expiration Date ____/_____ other	d. Route _____	e. Frequency _____	f. Quantity _____	g. Dosage _____	h. Dose Form _____
i. Start Date ____/____/____	j. Stop Date ____/____/____		k. Continuing 0 = No 1 = Yes		
32a. Study Drug Name			b. Lot Number		
c. Expiration Date ____/_____ other	d. Route _____	e. Frequency _____	f. Quantity _____	g. Dosage _____	h. Dose Form _____
i. Start Date ____/____/____	j. Stop Date ____/____/____		k. Continuing 0 = No 1 = Yes		

Dosage Administration Coding Sheet

Routes of Admin (ICH-m2 Numeric Codes)

- 001=Auricular (otic)
- 002=Buccal
- 003=Cutaneous
- 014=Intra-articular
- 030=Intramuscular
- 031=Intraocular
- 042=Intravenous
(not otherwise specified)
- 046=Ophthalmic
- 047=Oral
- 049=Other
- 053=Rectal
- 054=Respiratory (inhalation)
- 057=Subcutaneous
- 059=Sublingual
- 060=Topical
- 061=Transdermal
- 064=Unknown
- 066=Vaginal

Frequency

- 1=Single dose
- 2=Every other day
- 3=Once daily
- 4=Twice daily
- 5=Three times a day
- 6=Four times a day
- 7=As needed
- 8=Other
- 9=Unknown

Dosage

- 1=grain(s)
- 2=gram(s)
- 3=international units
- 4=microcurie(s)
- 5=microgram(s)
- 6=micrograms(s)/kilogram
- 7=As needed
- 8=microlitre(s)
- 9=millicurie(s)
- 10=milliequivalent(s)
- 11=milligram(s)
- 12=milligram(s)/kilogram
- 13=milligram(s)/sq. meter
- 14=millilitre(s)
- 88=Other
- 99=Unknown

Dosage Form

- 1=Capsule
- 2=Drop
- 3=Gum
- 4=Lollipop
- 5=Lotion/Ointment
- 6=Lozenge
- 7=Ounce
- 8=Patch
- 9=Puff
- 10=Spray/Squirt
- 11=Suppository
- 12=Tablespoon
- 13=Tablet
- 14=Teaspoon
- 15=Wafer
- 88=Other
- 99=Unknown

Serious Adverse Events

ASSESSMENT OF SAE

PRINCIPAL INVESTIGATOR SECTION

AESEV ___ 33. Severity
1 = Lethal
2 = Life Threatening
3 = Severe
4 = Moderate
5 = Mild

___ 34. Expectedness
1 = Expected
2 = Unexpected

QNAM=AEEXPECT
QLABEL=EXPECTEDNESS (SAE PAGE)
IDVAR=AESEQ

AEOUT ___ 35.a Outcome
1 = Recovered or resolved
2 = Recovering or resolving
3 = Not recovered or not resolved
4 = Recovered or resolved with sequelae
5 = Fatal (if fatal, continue 35.b thru 35.d)
9 = Unknown

QNAM=AEDTHDTC
QLABEL=DATE OF DEATH (SAE PAGE)
IDVAR=AESEQ

35.b Date of Death

35.c Autopsy performed (0=No, 1=Yes)

QNAM=AEAUTO
QLABEL=AUTOPSY PERFORMED (SAE PAGE)
IDVAR=AESEQ

35.d Probable Cause of death: (max 600 characters)

QNAM=AEPROBC1-AEPROBC3
QLABEL=PROBABLE CAUSE OF DEATH 1 (2,3) (SAE PAGE)
IDVAR=AESEQ

AEREL ___ 36. Study Drug Related
1 = Definitely
2 = Probably
3 = Possibly
4 = Definitely not
9 = Unknown

ACTIONS RESULTING FROM SAE

AEACN ___ 37. Action Taken Re: Study Drug
1 = None
2 = Discontinued Permanently
3 = Discontinued Temporarily
4 = Reduced Dose
5 = Increased Dose
6 = Delayed Dose
8 = Not Applicable
9 = Unknown

38. NAME OF PRINCIPAL INVESTIGATOR (please print):

THIS DATA NOT DATABASED THIS DATA NOT DATABASED

SIGNATURE: _____ 39. Date signed: ___/___/___

Study STUDYID

DOMAIN: AE

ID USUBJID
Date ___/___/____. **AEDTC**

PHYSICIAN SIGNATURE REQUIRED FOR MEDICATION TRIALS

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct and complete.

40. NAME OF PHYSICIAN (please print):

THIS DATA NOT DATABASED

SIGNATURE: **THIS DATA NOT DATABASED**

THIS DATA NOT DATABASED
41. Date signed: ___/___/____

42. ADDITIONAL COMMENTS (Specify question number): (max.1600 characters)

DOMAIN: CO
COVAL
COVAL1-COVAL7
RDOMAIN=AE
IDVAR=AESEQ

Study _____

DOMAIN: AE

ID _____
Date ___/___/_____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ AEDTC	Phase EPOCH __	Visit Week VISIT ____	Sequence Number _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Serious Adverse Events - Addendum (SAA)

NOTE: There was no way to link the SAA data back against the SAE events reliably since the SAE question #24 wasn't a reliable link key to the SAA data and there was no key in the database to join the two SAA and SAE databases. So, if a subject had any SAA data then that was joined in its entirety against all SAE record for a subject.

QNAM=SASLOT1-31
QLABEL=LOT NUMBER
1-31
IDVAR=AESEQ

Study

QNAM=SASDRG1-31
QLABEL=DRUG
NAME 1-31
IDVAR=AESEQ

QNAM=SAROUT1-31
QLABEL=ROUTE 1-31
IDVAR=AESEQ

QNAM=SASFRQ1-31
QLABEL=FREQUENCY 1-31
IDVAR=AESEQ

QNAM=SASQNT1-31
QLABEL=QUANTITY 1-31
IDVAR=AESEQ

Page ___ of ___

If you answered yes to question 24 on the Serious Adverse Events, then these drugs must be listed below.

A1. Drug Name		b. Drug Type		c. Lot #	
d. Expiration Date		e. Route		f. Frequency	
g. Quantity		h. Dosage		i. Dose Form	
j. Start Date		k. Stop Date		l. Continuing 0 = No 1 = Yes	

A2. Drug Name		b. Drug Type		c. Lot #	
d. Expiration Date		e. Route		f. Frequency	
g. Quantity		h. Dosage		i. Dose Form	
j. Start Date		k. Stop Date		l. Continuing 0 = No 1 = Yes	

A3. Drug Name		b. Drug Type		c. Lot #	
d. Expiration Date		e. Route		f. Frequency	
g. Quantity		h. Dosage		i. Dose Form	
j. Start Date		k. Stop Date		l. Continuing 0 = No 1 = Yes	

A4. Drug Name		b. Drug Type		c. Lot #	
d. Expiration Date		e. Route		f. Frequency	
g. Quantity		h. Dosage		i. Dose Form	
j. Start Date		k. Stop Date		l. Continuing 0 = No 1 = Yes	

Dosage Administration Coding Sheet					
Routes of Admin (ICH-m2)	Numeric Codes	Drug Type	Frequency	Dosage	Dosage Form
001=Auricular (otic) 002=Buccal 003=Cutaneous 014=Intra-articular 030=Intramuscular 031=Intraocular 042=Intravenous (not otherwise specified) 046=Ophthalmic 047=Oral 049=Other 053=Rectal 054=Respiratory (inhalation) 057=Subcutaneous 059=Sublingual	060=Topical 061=Transdermal 064=Unknown 066=Vaginal	1=Study 2=Concomitant	1=Single dose 2=Every other day 3=Once daily 4=Twice daily 5=Three times a day 6=Four times a day 7=As needed 8=Other 9=Unknown	1=grain(s) 2=gram(s) 3=international units 4=microcurie(s) 5=microgram(s) 6=micrograms(s)/kilogram 7=microgram(s)/sq. meter 8=microlitre(s) 9=millicurie(s) 10=milliequivalent(s) 11=milligram(s) 12=milligram(s)/kilogram 13=milligram(s)/sq. meter 14=millilitre(s) 88=Other 99=Unknown	1=Capsule 2=Drop 3=Gum 4=Lollipop 5=Lotion/Ointment 6=Lozenge 7=Ounce 8=Patch 9=Puff 10=Spray/Squirt 11=Suppository 12=Tablet 13=Tablet 14=Teaspoon 15=Wafer 88=Other 99=Unknown

QNAM=SASTDT1-31
QLABEL=START DATE 1-31
IDVAR=AESEQ

QNAM=SAENDT1-31
QLABEL=STOP DATE 1-31
IDVAR=AESEQ

Study _____

DOMAIN: QS

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ QSDTC	Phase EPOCH	Visit Week VISIT __	Sequence Number ____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

TIME AND CRIME

QSCAT = TIME AND CRIME

TIME AND CRIME

Section A: Travel Time for Treatment: QSSCAT = Travel Time for Treatment
QSTEST/QSTESTCD

A1. Travel Time to the outpatient treatment program:

A1a. About how many miles do you travel to get to the treatment program (ONE WAY)?

QSORRES ___ ___ miles (If unsure, give best estimate) QSORRESU=MILES

A1b. About how long does the trip typically take? (ONE WAY)

___ ___ hour(s) ___ ___ minutes QSORRESU=MINUTES

QSORRESU=HOURS

A1c. How do you typically travel to this program? (RANK /a a ALL THAT APPLY (1 for most common. If more than one mode of typical transportation then 2 for second most common, 3 for third most common, ...)

- ___ Car
- ___ Public bus
- ___ Subway, BART, MUNI, Metro, SEPTA, etc.
- ___ Train (Amtrak, Commuter train, etc.)
- ___ Taxi
- ___ Bicycle
- ___ Walk
- ___ Other (specify:_____)

A1d. Are you typically driven to the program by a parent or guardian?

- 1 = Yes
- 0 = No (skip to A1g1)

A1e. If yes, does the parent/guardian typically need to take time off from work to bring you to the treatment program?

- 1 = Yes
- 0 = No

A1f. If yes, does the parent/guardian typically need to arrange child care to bring you to the program?

- 1 = Yes
- 0 = No

A1g. Question deleted

A1g1. If you have taken public transportation, what is the typical ONE WAY fare?

\$ ___ . ___ ONE WAY fare QSORRESU=DOLLARS
-3 = Not Applicable

QSTEST/QSTESTCD

A1h. Have transportation problems prevented you from attending treatment on a regular basis?

1 = Yes

0 = No

-3 = Not Applicable

QSORRES

A2. Travel time to your usual health care provider:

A2a. About how many miles do you travel to get to your usual health care provider (e.g. medical doctor)? (ONE WAY)

___ ___ miles (if unsure, give best estimate)

-3 = Not Applicable (skip to A3)

QSORRESU=MILES

A2b. About how long does the trip typically take? (ONE WAY)

___ ___ hour(s) ___ ___ minutes

QSORRESU=HOURS

QSORRESU=MINUTES

A3. Travel time to the Emergency Room:

A3a. About how many miles do you travel to get to the nearest emergency room? (ONE WAY)

___ ___ miles (if unsure, give best estimate)

-3 = Not Applicable (skip to A4)

QSORRESU=MILES

A3b. About how long does the trip typically take? (ONE WAY)

___ ___ hour(s) ___ ___ minutes

QSORRESU=HOURS

QSORRESU=MINUTES

A4. Travel time to 12 step meetings:

A4a. About how many miles do you travel to get to a typical 12 step meeting? (ONE WAY)

___ ___ miles (if unsure, give best estimate)

-3 = Not Applicable (skip to section B)

QSORRESU=MILES

A4b. About how long does the trip typically take? (ONE WAY)

___ ___ hour(s) ___ ___ minutes

QSORRESU=HOURS

QSORRESU=MINUTES

Section B: Employment and Education: QSSCAT = EMPLOYMENT AND EDUCATION**QSTEST/QSTESTCD**

B1. What is your highest level of education?

- 1 = High school not complete, provide last completed grade ___ **QSORRES**
2 = High school graduate or GED
3 = Some college or associates degree program
4 = Associates degree
5 = College degree
6 = Other (specify:_____)

B2. Are you currently enrolled in school?

- 1 = Yes (skip to B5)
0 = No

B3. Question deleted

B4. When did you leave school? (provide date)

___/___/_____

B5. When were you last employed?

- 1 = Never employed (skip to B9)
2 = Currently employed (skip to B7)
3 = Not employed now, but have been employed during the past 12 months
4 = Not employed now and last employment was longer than 12 months ago

B6. Why did your employment end? (Check all that apply)

- Related to drug problem
 Related to entering treatment
 Returned to school
 Laid-off
 Fired
 Quit

B7. How many hours per week did (or do) you usually work in your most recent job or your current job?

___ hours per week **QSORRESU=HOURS**

B8. What was (or is) your weekly salary before taxes, including tips and other compensation in your most recent job or your current job?

\$ ___ per week **QSORRESU=DOLLARS**

B9. Does your drug treatment interfere with your time for school or work?

- 1 = Yes
0 = No
-3 = Not Applicable

Section C: Crime and Legal Activities:

QSSCAT = CRIME AND LEGAL ACTIVITIES

For this section, at Baseline, please respond based on your activities over the last 90 days.

For post-baseline assessment, please respond based on your activities since your last assessment:

QSTEST/QSTESTCD

QSORRES

QSEVLINT=-P90D

C1. How many days have you participated in criminal activities?

___ Days QSORRESU=DAYS

C2. How many days were you detained or incarcerated?

___ Days QSORRESU=DAYS

C3. Have you committed, been charged with or been convicted of ...?

QSTEST	Committed (0=no/1=yes)	Charged (0=no/1=yes)	Convicted (0=no/1=yes)
Running away		QSORRES	
Truancy			
Driving Violations			
Loitering, Vagrancy			
Drug charges (not drug dealing)			
Drug dealing			
Shoplifting / Retail theft			
Robbery			
Auto Theft			
Assault			
Weapons Violation			
Theft/non-retail (from parents, etc)			
Other (specify:_____)			

Study _____

DOMAIN: QS

ID _____
Date ____/____/_____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/_____ QSDTC	Phase EPOCH	Visit Week VISIT	Sequence Number ____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Young Adult Self-Report For Ages 18-30

Form Completion Status: <input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required

QSCAT = YOUNG ADULT SELF-FREPORT FOR AGES 18-30

YOUNG ADULT SELF-REPORT FOR AGES 18-30

QSTEST

QSORRES

YOUR AGE ___

YOUR USUAL TYPE OF WORK, even if not working now. Please be specific – for example, auto mechanic; high school teacher; homemaker; laborer; lathe operator; shoe salesman; army sergeant; student (indicate what kind of student, such as high school or college):

Please fill out this form to reflect *your* views, even if other people might not agree. Feel free to print additional comments beside each item.

I. FRIENDS:

QSSCAT = FRIENDS

A. About how many close friends do you have? (Do not include family members.)

QSTEST/QSTESTCD

QSORRES

1 = None 2 = 1 3 = 2 or 3 4 = 4 or more

B. About how many times a month do you have contact with any of your close friends?
(including in-person contacts, phone, letters, email)

0 = Less than 1 1 = 1 or 2 2 = 3 or more

C. How well do you get along with your close friends?

0 = Not well 1 = Average 2 = Very well

D. About how many times a month do you invite people to your home?

0 = Less than 1 1 = 1 or 2 2 = 3 or more

II. EDUCATION

QSSCAT = EDUCATION

At any time in the past 6 months, *did you attend school, college, or any other educational or training program?*

QSTEST

QSORRES

0 = No – please skip to Section III. JOB.

QSEVLINT=-P6M

1 = Yes – what kind of school or program? _____

Study STUDYID
QSTEST

DOMAIN: QS

ID USUBJID
 Date ___/___/___ **QSDTC**

YOUNG ADULT SELF-REPORT FOR AGES 18-30 **QSORRES**

What degree or diploma are you seeking? _____ Major? _____

When do you expect to receive your degree or diploma? _____ / _____ **QSORRESU=YEAR**
 (mm) (yyyy) **QSORRESU=MONTH**

Circle **0, 1 or 2** beside items A-E to describe your educational experience *during the past 6 months*:

QSEVLINT=-P6M

0 = Not True			1 = Somewhat or Sometimes True			2 = Very True or Often True		
0	1	2	A. I get along well with other students	0	1	2	D. I am satisfied with my educational situation	
0	1	2	B. I achieve what I am capable of	0	1	2	E. I do things that may cause me to fail.	
0	1	2	C. I have trouble finishing assignments					

III. JOB

QSSCAT = JOB **QSEVLINT=-P6M**

At any time in the past 6 months, did you have any paid jobs (including military service)?

QSTEST

0 = No – please skip to Section IV. FAMILY. **QSORRES**

1 = Yes – please describe your job(s) _____

Circle **0, 1 or 2** beside items A-G to describe your work experience *during the past 6 months*:

0 = Not True			1 = Somewhat or Sometimes True			2 = Very True or Often True		
0	1	2	A. I work well with others	0	1	2	E. I am satisfied with my work situation	
0	1	2	B. I have trouble getting along with bosses	0	1	2	F. I do things that may cause me to lose my job	
0	1	2	C. I do my work well					
0	1	2	D. I have trouble finishing my work	0	1	2	G. I stay away from my job even when I'm not sick or not on vacation	
QSORRES			QSTEST	QSORRES			QSTEST	

YOUNG ADULT SELF-REPORT FOR AGES 18-30

IV. FAMILY

QSSCAT = FAMILY

Compared with others, how well do you:

QSTEST/QSTESTCD

Worse Average Better No Contact

QSORRES

- A. Get along with your brothers and sisters? 1 2 3 4 N = I have no brothers or sisters
- B. Get along with your mother? 1 2 3 4 N = Mother is deceased
- C. Get along with your father? 1 2 3 4 N = Father is deceased

V. SPOUSE OR PARTNER:

QSTEST

QSSCAT = SPOURSE OR PARTNER

What is your current marital status?

QSORRES

1 = Never been married

4 = Married but separated from spouse

2 = Married, living with spouse

5 = Divorced

3 = Widowed

6 = Other – please describe _____

At any time in the past 6 months, did you live with your spouse or with a partner?

0 = No – please skip to Section VI.

QSEVLINT=-P6M

1 = Yes – describe your living situation _____

Circle 0, 1 or 2 beside items A-G to describe your relationship *during the past 6 months*:

0 = Not True			1 = Somewhat or Sometimes True			2= Very True or Often True		
0	1	2	A. I get along well with my spouse or partner	0	1	2	E. My spouse or partner and I disagree about living arrangements, such as where we live	
0	1	2	B. My spouse or partner and I have trouble sharing responsibilities	0	1	2	F. I have trouble with my spouse or partner's family	
0	1	2	C. I feel satisfied with my spouse or partner	0	1	2	G. I like my spouse's or partner's friends	
0	1	2	D. My spouse or partner and I enjoy similar activities					

QSORRES

QSTEST

QSORRES

QSTEST

Study STUDYID

DOMAIN: QS

ID USUBJID
Date ___/___/____ QSDTC

YOUNG ADULT SELF-REPORT FOR AGES 18-30

QSSCAT = YOUNG ADULT SELF-REPORT FOR AGES 18-30

VI. Do you have any illness, disability or handicap? 0 = No 1 = Yes – please describe:

QSTEST

QSORRES

VII. Please describe any concerns or worries you have about work, school or other things: 0 = No Concerns QSORRES

QSTEST

VIII. Please describe the best things about yourself:

QSTEST

QSORRES

YOUNG ADULT SELF-REPORT FOR AGES 18-30

QSSCAT = YOUNG ADULT SELF-REPORT FOR AGES 18-30
Below is a list of items that describe people. For each item, please circle 0, 1 or 2 to describe yourself over the past 6 months. Please answer all items as well as you can, even if some do not seem to apply to you. **QSTEST/QSTESTCD** **QSORRES** **OSEVLINT=-P6M**

0 = Not True			1 = Somewhat or Sometimes True	2 = Very True or Often True		
0	1	2	1. I act too young for my age			
0	1	2	2. I make good use of my opportunities			
0	1	2	3. I argue a lot			
0	1	2	4. I work up to my ability			
0	1	2	5. I act like the opposite sex			
0	1	2	6. I use drugs (other than alcohol) for nonmedical purposes			
(describe):						
0	1	2	7. I brag			
0	1	2	8. I have trouble concentrating or paying attention			
0	1	2	9. I can't get my mind off certain thoughts			
(describe):						
0	1	2	10. I have trouble sitting still			
0	1	2	11. I'm too dependent on others			
0	1	2	12. I feel lonely			
0	1	2	13. I feel confused or in a fog			
0	1	2	14. I cry a lot			
0	1	2	15. I am pretty honest			
0	1	2	16. I am mean to others			
0	1	2	17. I daydream a lot			
0	1	2	18. I deliberately try to hurt or kill myself			
0	1	2	19. I try to get a lot of attention			
0	1	2	20. I destroy my things			
0	1	2	21. I destroy things belonging to others			
0	1	2	22. I worry about my future			
0	1	2	23. I break rules at school, work, or elsewhere			
0	1	2	24. I don't eat as well as I should			
0	1	2	25. I don't get along with other people			
0	1	2	26. I don't feel guilty after doing something I shouldn't			
0	1	2	27. I am jealous of others			
0	1	2	28. I get along badly with my family			
0	1	2	29. I am afraid of certain animals, situations, or places			
(describe):						
0	1	2	30. My relations with the opposite sex are poor			
0	1	2	31. I am afraid I might think or do something bad			
0	1	2	32. I feel that I have to be perfect			
0	1	2	33. I feel that no one loves me			
0	1	2	34. I feel that others are out to get me			
0	1	2	35. I feel worthless or inferior			
0	1	2	36. I accidentally get hurt a lot			
0	1	2	37. I get in many fights			
0	1	2	38. I get teased a lot			
0	1	2	39. I hang around with others who get in trouble			

YOUNG ADULT SELF-REPORT FOR AGES 18-30

0 = Not True 1 = Somewhat or Sometimes True 2 = Very True or Often True

0	1	2	40. I hear sounds or voices that other people think aren't there (describe):
0	1	2	41. I am impulsive or act without thinking
0	1	2	42. I would rather be alone than with others
0	1	2	43. I lie or cheat
0	1	2	44. I bite my fingernails
0	1	2	45. I am nervous or tense
0	1	2	46. Parts of my body twitch or make nervous movements (describe):
0	1	2	47. I lack self-confidence
0	1	2	48. I am not liked by others
0	1	2	49. I can do certain things better than other people
0	1	2	50. I am too fearful or anxious
0	1	2	51. I feel dizzy or lightheaded
0	1	2	52. I feel too guilty
0	1	2	53. I eat too much
0	1	2	54. I feel overtired
0	1	2	55. I am overweight
			56. Physical problems without known medical cause:
0	1	2	a. Aches or pains (not stomach or headaches)
0	1	2	b. Headaches
0	1	2	c. Nausea, feel sick
0	1	2	d. Problems with eyes (not if corrected by glasses) (describe):
0	1	2	e. Rashes or other skin problems
0	1	2	f. Stomachaches
0	1	2	g. Vomiting, throwing up
0	1	2	h. Heart pounding or racing
0	1	2	i. Numbness or tingling in body parts
0	1	2	j. Other (describe):
0	1	2	57. I physically attack people
0	1	2	58. I pick my skin or other parts of my body (describe):
0	1	2	59. I fail to finish things I should do
0	1	2	60. There is very little that I enjoy
0	1	2	61. My school work or job performance is poor
0	1	2	62. I am poorly coordinated or clumsy
0	1	2	63. I would rather be with older people than with people my own age
0	1	2	64. I would rather be with younger people than with people my own age
0	1	2	65. I refuse to talk
0	1	2	66. I repeat certain acts over and over (describe):
0	1	2	67. I have trouble making or keeping friends
0	1	2	68. I scream or yell a lot
0	1	2	69. I am secretive or keep things to myself
0	1	2	70. I see things that other people think aren't there (describe):
0	1	2	71. I am self-conscious or easily embarrassed

QSSCAT = YOUNG ADULT SELF-REPORT FOR AGES 18-30

0 = Not True

1 = Somewhat or Sometimes True

2 = Very True or Often True

0	1	2	72. I set fires
0	1	2	73. I meet my responsibilities to my family
0	1	2	74. I show off or clown
0	1	2	75. I am shy or timid
0	1	2	76. My behavior is irresponsible
0	1	2	77. I sleep more than most other people during day and/or night (describe):
0	1	2	78. I have trouble making decisions
0	1	2	79. I have a speech problem (describe):
0	1	2	80. I stand up for my rights
0	1	2	81. I worry about my job or school work (describe):
0	1	2	82. I steal
0	1	2	83. I store up too many things I don't need (describe):
0	1	2	84. I do things other people think are strange (describe):
0	1	2	85. I have thoughts that other people would think are strange (describe):
0	1	2	86. I am stubborn, sullen, or irritable
0	1	2	87. My moods or feelings change suddenly
0	1	2	88. I enjoy being with other people
0	1	2	89. I am suspicious
0	1	2	90. I drink too much alcohol or get drunk
0	1	2	91. I think about killing myself
0	1	2	92. I do things that may cause me trouble with the law (describe):
0	1	2	93. I talk too much
0	1	2	94. I tease others a lot
0	1	2	95. I have a hot temper
0	1	2	96. I think about sex too much
0	1	2	97. I threaten to hurt people
0	1	2	98. I like to help others
0	1	2	99. I enjoy a good joke
0	1	2	100. I have trouble sleeping (describe):
0	1	2	101. I have a good imagination
0	1	2	102. I don't have much energy
0	1	2	103. I am unhappy, sad, or depressed
0	1	2	104. I am louder than others
0	1	2	105. I like to make others laugh
0	1	2	106. I try to be fair to others
0	1	2	107. I feel that I can't succeed
0	1	2	108. I like to take life easy
0	1	2	109. I like to try new things
0	1	2	110. I wish I were of the opposite sex
0	1	2	111. I keep from getting involved with others
0	1	2	112. I worry a lot
0	1	2	113. I am too concerned about how I look
0	1	2	114. I fail to pay my debts or meet other financial responsibilities

QSSCAT = YOUNG ADULT SELF-REPORT FOR AGES 18-30

DOMAIN: QS

Study **STUDYID** _____

ID **USUBJID** _____

Date ___/___/___ **QSDTC**

YOUNG ADULT SELF-REPORT FOR AGES 18-30

0 = Not True 1 = Somewhat or Sometimes True 2 = Very True or Often True

0	1	2	115. I have nightmares
0	1	2	116. I worry about my relations with the opposite sex

QSTEST

QSORRES

117. *In the past 6 months*, about how many times per day did you use tobacco (including smokeless tobacco)? ___ ___ ___ times per day. **QSEVLINT=-P6M** **QSORRESU=PER DAY**

118. *In the past 6 months*, on how many days were you drunk? ___ ___ ___ days. **QSORRESU=DAYS**

119. *In the past 6 months*, on how many days did you use drugs for nonmedical purposes (including marijuana, glue, cocaine, and any other drugs)? ___ ___ ___ days **QSORRESU=DAYS**

Please write down anything else that describes your feelings, behavior, or interests:

DOMAIN: CO
COVAL COVAL1
RDOMAIN=QS
IDVAR=QSSEQ

PLEASE BE SURE YOU HAVE ANSWERED ALL ITEMS

Study _____

DOMAIN: QS

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID USUBJID
Visit Date ____/____/____ QSDTC	Phase EPOCH	Visit Week VISIT	Sequence Number __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Youth Self-Report For Ages 11-18

Study STUDYID

ID USUBJID

DOMAIN: QS

Date ___/___/___
QSDTC

Form Completion Status: <input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required

QSCAT = YOUTH SELF-REPORT FOR AGES 11-18

YOUTH SELF-REPORT FOR AGES 11-18

QSTEST

YOUR AGE ___ QSORRES GRADE IN SCHOOL _____ N = NOT ATTENDING SCHOOL IF YOU ARE WORKING, PLEASE STATE YOUR TYPE OF WORK: _____	PARENTS' USUAL TYPE OF WORK, even if not working now. <i>(Please be specific – for example, auto mechanic, high school teacher, homemaker, laborer, lathe operator, shoe salesman, army sergeant.)</i> FATHER'S TYPE OF WORK: _____ MOTHER'S TYPE OF WORK: _____
-----------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Please fill out this form to reflect *your* views, even if other people might not agree. Feel free to print additional comments beside each item and in the spaces provided on pages 5 and 9. **Be sure to answer all items.**

QSSCAT = PLEASE LIST THE SPORTS YOU MOST LIKE TO TAKE PART IN.

I. Please list the sports you most like to take part in. For example: swimming, baseball, skating, skate boarding, bike riding, fishing, etc. 0 = None QSTEST QSORRES a. _____ b. _____ c. _____	QSTEST Less Than Average More Than Average	QSTEST Compared to others of your age, about how much time do you spend in each? 1 2 3	QSTEST Compared to others of your age, how well do you do each one? Below Average Above Average 1 2 3
	QSORRES	QSORRES	

YOUTH SELF-REPORT FOR AGES 11-18

QSSCAT = PLEASE LIST YOUR FAVORITE HOBBIES, ACTIVITIES, AND GAMES, OTHER THAN SPORTS.

<p>II. Please list your favorite hobbies, activities, and games, other than sports. For example: cards, books, piano, crafts, cars, computers, etc. (Do <i>not</i> include listening to radio or TV.)</p> <p>0 = None</p>	<p>Compared to others of your age, about how much time do you spend in each?</p>	QSTEST			QSTEST		
		Less Than Average	Average	More Than Average	Below Average	Average	Above Average
a. <u>QSTEST</u> QSORRES	1	2	3	1	2	3	
b. _____	1	2	3	1	2	3	
c. _____	1	2	3	1	2	3	
	QSORRES			QSORRES			

<p>III. Please list any organizations, clubs, teams, or groups you belong to.</p> <p>0 = None</p>	<p>Compared to others of your age, how active are you in each?</p>	QSTEST		
		Less Active	Average	More Active
a. <u>QSTEST</u> QSORRES	1	2	3	
b. _____	1	2	3	
c. _____	1	2	3	
	QSORRES			

QSSCAT = PLEASE LIST ANY ORGANIZATIONS, CLUBS, TEAMS, OR GROUPS YOU BELONG TO.

YOUTH SELF-REPORT FOR AGES 11-18

QSSCAT = PLEASE LIST ANY JOBS OR CHORES YOU HAVE

IV. Please list any jobs or chores you have. For example: paper route, babysitting, making bed, working in store, etc. (Include *both* paid and unpaid jobs and chores.)

Compared to others of your age, how well do you carry them out?

		QSTEST			
		Below Average	Average	Above Average	
0 = None					
a.	QSTEST _____ QSORRES _____	1	2	3	
b.	_____	1	2	3	QSORRES
c.	_____	1	2	3	

QSSCAT = ABOUT HOW MANY CLOSE FRIENDS DO YOU HAVE

V. 1. About how many close friends do you have? 0 = (None) 1 = (1) 2 = (2 or 3) 4 = (4 or more)
 (Do not include brothers & sisters) QSTEST _____ QSORRES _____

2. About how many times a week do you do things with any friends outside of regular school hours?
 (Do not include brothers & sisters) QSTEST _____ 0 = (Less than 1) 2 = (1 or 2) 3 = (3 or more)
 QSORRES _____

VI. Compared to others of your age, how well do you:

QSSCAT = COMPARED TO OTHERS YOUR AGE, HOW WELL DO YOU

		QSTEST			
		Worse	Average	Better	
a.	Get along with your brothers & sisters?	1	2	3	N= I have no brothers or sisters
b.	Get along with other kids?	1	2 QSORRES	3	
c.	Behave with your parents?	1	2	3	
d.	Do things by yourself?	1	2	3	

YOUTH SELF-REPORT FOR AGES 11-18

QSSCAT = PERFORMANCE IN ACADEMIC SUBJECTS

VII. Performance in academic subjects. N = I do not attend school because _____

	QSTEST	Failing	Below Average	Average	Above Average
a. Reading, English, or Language Arts		1	2	3	4
b. History or Social Studies		1	2	3	4
c. Arithmetic or Math		1	2	3	4
d. Science		1	2	3	4
e. <u>QSTEST</u> <u>QSORRES</u>		1	2	3	4
f. _____		1	2	3	4
g. _____		1	2	3	4

Other academic subjects – for example: computer courses, foreign language, business. Do *not* include gym, shop, driver’s ed., or other nonacademic subjects.

Do you have any illness, disability, or handicap? 0 = No 1 = Yes - Please describe:

QSTEST QSORRES

Study STUDYID

DOMAIN: QS

Date ___/___/___ ID USUBJID
QSDTC

QSTEST

QSORRES

YOUTH SELF-REPORT FOR AGES 11-18

Please describe any concerns or problems you have about school:

Please describe any other concerns you have:

Please describe the best things about yourself:

YOUTH SELF-REPORT FOR AGES 11-18

QSORRES QSTEST

Below is a list of items that describe kids. For each item that describes you, **now or within the past 6 months**, please circle the **2** if the item is **very true or often true** of you. Circle the **1** if the item is **somewhat or sometimes true** of you. If the item is **not true** of you, circle the **0**.

QSEVLINT=-P6M

0 = Not True

1 = Somewhat or Sometimes True

2 = Very True or Often True

0	1	2	1. I act too young for my age
0	1	2	2. I drink alcohol without my parents' approval
			(describe):
0	1	2	3. I argue a lot
0	1	2	4. I fail to finish things I start
0	1	2	5. There is very little that I enjoy
0	1	2	6. I like animals
0	1	2	7. I brag
0	1	2	8. I have trouble concentrating or paying attention
0	1	2	9. I can't get my mind off certain thoughts
			(describe):
0	1	2	10. I have trouble sitting still
0	1	2	11. I'm too dependent on adults
0	1	2	12. I feel lonely
0	1	2	13. I feel confused or in a fog
0	1	2	14. I cry a lot
0	1	2	15. I am pretty honest
0	1	2	16. I am mean to others
0	1	2	17. I daydream a lot
0	1	2	18. I deliberately try to hurt or kill myself
0	1	2	19. I try to get a lot of attention
0	1	2	20. I destroy my own things
0	1	2	21. I destroy things belonging to others
0	1	2	22. I disobey my parents
0	1	2	23. I disobey at school
0	1	2	24. I don't eat as well as I should
0	1	2	25. I don't get along with other kids
0	1	2	26. I don't feel guilty after doing something I shouldn't
0	1	2	27. I am jealous of others
0	1	2	28. I break rules at home, school, or elsewhere
0	1	2	29. I am afraid of certain animals, situations, or places, other than school
			(describe):
0	1	2	30. I am afraid of going to school
0	1	2	31. I am afraid I might think or do something bad
0	1	2	32. I feel that I have to be perfect
0	1	2	33. I feel that no one loves me
0	1	2	34. I feel that others are out to get me
0	1	2	35. I feel worthless or inferior
0	1	2	36. I accidentally get hurt a lot
0	1	2	37. I get in many fights
0	1	2	38. I get teased a lot

Youth Self-Report For Ages 11-18

0 = Not True

1 = Somewhat or Sometimes True

2 = Very True or Often True

0	1	2	39. I hang around with kids who get in trouble
0	1	2	40. I hear sounds or voices that other people think aren't there
			(describe):
0	1	2	41. I act without stopping to think
0	1	2	42. I would rather be alone than with others
0	1	2	43. I lie or cheat
0	1	2	44. I bite my fingernails
0	1	2	45. I am nervous or tense
0	1	2	46. Parts of my body twitch or make nervous movements
			(describe):
0	1	2	47. I have nightmares
0	1	2	48. I am not liked by other kids
0	1	2	49. I can do certain things better than most kids
0	1	2	50. I am too fearful or anxious
0	1	2	51. I feel dizzy or lightheaded
0	1	2	52. I feel too guilty
0	1	2	53. I eat too much
0	1	2	54. I feel overtired without good reason
0	1	2	55. I am overweight
			56. Physical problems without known medical cause:
0	1	2	a. Aches or pains (not stomach or headaches)
0	1	2	b. Headaches
0	1	2	c. Nausea, feel sick
0	1	2	d. Problems with eyes (not if corrected by glasses)
			(describe):
0	1	2	e. Rashes or other skin problems
0	1	2	f. Stomachaches
0	1	2	g. Vomiting, throwing up
0	1	2	h. Other
			(describe):
0	1	2	57. I physically attack people
0	1	2	58. I pick my skin or other parts of my body
			(describe):
0	1	2	59. I can be pretty friendly
0	1	2	60. I like to try new things
0	1	2	61. My school work is poor
0	1	2	62. I am poorly coordinated or clumsy
0	1	2	63. I would rather be with older kids than kids my own age
0	1	2	64. I would rather be with younger kids than kids my own age
0	1	2	65. I refuse to talk
0	1	2	66. I repeat certain acts over and over
			(describe):
0	1	2	67. I run away from home
0	1	2	68. I scream a lot
0	1	2	69. I am secretive or keep things to myself
0	1	2	70. I see things that other people think aren't there
			(describe):
0	1	2	71. I am self-conscious or easily embarrassed
0	1	2	72. I set fires

Youth Self-Report For Ages 11-18

0 = Not True

1 = Somewhat or Sometimes True

2 = Very True or Often True

0	1	2	73. I can work well with my hands
0	1	2	74. I show off or clown
0	1	2	75. I am shy or timid
0	1	2	76. I sleep less than most kids
0	1	2	77. I sleep more than most kids during day and/or night.
			(describe):
0	1	2	78. I am inattentive or easily distracted
0	1	2	79. I have a speech problem
			(describe):
0	1	2	80. I stand up for my rights
0	1	2	81. I steal at home
0	1	2	82. I steal from places other than home
0	1	2	83. I store up too many things I don't need
			(describe):
0	1	2	84. I do things other people think are strange
			(describe):
0	1	2	85. I have thoughts that other people would think are strange
			(describe):
0	1	2	86. I am stubborn
0	1	2	87. My moods or feelings change suddenly
0	1	2	88. I enjoy being with people
0	1	2	89. I am suspicious
0	1	2	90. I swear or use dirty language
0	1	2	91. I think about killing myself
0	1	2	92. I like to make others laugh
0	1	2	93. I talk too much
0	1	2	94. I tease others a lot
0	1	2	95. I have a hot temper
0	1	2	96. I think about sex too much
0	1	2	97. I threaten to hurt people
0	1	2	98. I like to help others
0	1	2	99. I smoke, chew, or sniff tobacco
0	1	2	100. I have trouble sleeping
			(describe):
0	1	2	101. I cut classes or skip school
0	1	2	102. I don't have much energy
0	1	2	103. I am unhappy, sad, or depressed
0	1	2	104. I am louder than other kids
0	1	2	105. I use drugs for nonmedical purposes(<i>don't</i> include alcohol or tobacco)
			(describe):
0	1	2	106. I like to be fair to others
0	1	2	107. I enjoy a good joke
0	1	2	108. I like to take life easy
0	1	2	109. I try to help other people when I can
0	1	2	110. I wish I were of the opposite sex
0	1	2	111. I keep from getting involved with others
0	1	2	112. I worry a lot

Study STUDYID

DOMAIN: QS

Date / / ID **USUBJID**
QSDTC

Youth Self-Report For Ages 11-18

Please write down anything else that describes your feelings, behavior, or interests:

DOMAIN: CO
COVAL COVAL1
RDOMAIN=QS
IDVAR=QSSEQ

PLEASE BE SURE YOU HAVE ANSWERED ALL ITEMS

Study _____

DOMAIN: AE

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID <u>USUBJID</u>
Visit Date ____/____/____ AEDTC	Phase EPOCH	Visit Week VISIT	Sequence Number ____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Adverse Events (AE)

Adverse Events

Yes **No** **The AE dataset only has records for where there is an AE Description noted in 2b**

1 0 1. Did the participant have any new adverse events since the last visit?
If Yes, skip to question 2a.

1 0 1a. If No, was there an unresolved AE from the prior visit?
If No to both question 1 and 1a, skip to question 16 and sign and date.

AESPID

___ ___ 2.a Adverse Event Number

2.b Adverse Event Description:
(For New Adverse Event Only. Max 200 characters. One adverse event per form. List syndrome components on separate forms.)

_____ AETERM/AEBODSYS/AEDECOD

___ 3. Type of Report: QNAM=RPTTYP IDVAR=AESEQ
QLABEL=TYPE OF REPORT
1 = New Adverse Event
2 = Increase in severity, duration or frequency of an existing Adverse Event
3 = Same or decrease in severity, duration or frequency of an existing Adverse Event

AESTDTC

___/___/___ 4.a If new or increase severity of prior event, Date of onset (mm / dd / yyyy)

___ : ___ 4.b If new or increase severity of prior event, Time of onset
(hh:mm Use 24 hour clock)

___ 5. Study Drug Related AEREL
1=Definitely
2=Probably
3=Possibly
4=Definitely Not
9=Unknown

___ 6. Severity AESEV
1 = Lethal*
2 = Life Threatening
3 = Severe
4 = Moderate
5 = Mild

*** A Serious Adverse Event form must be completed.**

**** Complete a Concomitant Medication Form and enter the Medication Number.**

Adverse Events

- ___ 7. Action Taken Regarding Study Drug
- 1 = None
 - 2 = Discontinued Permanently AEACN
 - 3 = Discontinued Temporarily
 - 4 = Reduced Dose
 - 5 = Increased Dose
 - 6 = Delayed Dose
 - 8 = Not Applicable
 - 9 = Unknown

Yes	No	OTHER ACTION TAKEN (questions 8a-8d must be answered)
1	0	8.a NONE <i>If YES, then 8b thru 8d must be answered NO, and 8e must be blank.</i>
1	0	8.b Remedial Therapy – Pharmacologic** (OTC or Rx) <i>(If yes, medications must be listed in 8e)</i>
1	0	8.c Remedial Therapy – Non- Pharmacologic
1	0	8.d Hospitalization*
_____	_____	8.e.1 Medication Number 1
_____	_____	8.e.2 Medication Number 2
_____	_____	8.e.3 Medication Number 3

QNAM=AESMED1-AESMED3
IDVAR=AESEQ
QLABEL=MEDICATION NUMBER 1 (2 3) (AEPAGE)

AEACNOTH

9. Description of actions or comments:
(Max 200 characters)

DOMAIN: CO
COVAL
RDOMAIN=AE
IDVAR=AESEQ

- ___ 10. Outcome
- 1 = Recovered or resolved
 - 2 = Recovering or resolving
 - 3 = Not recovered or not resolved
 - 4 = Recovered or resolved with sequelae
 - 5 = Fatal *
 - 9 = Unknown

- 1 0 **11.** Was the Adverse Event Serious? * AESER

- 1 0 **12.** Did the Adverse Event resolve?
If YES, continue to 13.
If NO, continue to 15 and sign and Date.
- QNAM=AESRESLV
IDVAR=AESEQ
QLABEL=DID ADVERSE EVENT RESOLVE

* A Serious Adverse Event form must be completed.
** Complete a Concomitant Medication Form and enter the Medication Number.

Study STUDYID

DOMAIN: AE

ID USUBJID
Date ___/___/___

AEDTC

Adverse Events

If an Adverse Event has resolved then either question 13 (duration) OR questions 14.a and 14.b (date & time of resolution) must be answered. If the Adverse Event was less than 24 hours in length, then it MUST be answered in terms of duration of the event (i.e., 2 hrs, 45 minutes)

AEDUR

___ - ___ - ___

13. If the Adverse Event has resolved, then estimate the duration to the best of your ability. (**days – hours-- minutes**)

AEENDTC

___/___/___

14.a Date of resolution (**mm / dd / yyyy**)

___:___

14.b Time of resolution (**hh:mm, 24 hour clock**)

By affixing my signature, I certify that the above information to the best of my knowledge is true, correct and complete.

THIS DATA NOT DATABASSED

15. STUDY CLINICIAN'S NAME (please print): _____

THIS DATA NOT DATABASSED

STUDY CLINICIAN'S SIGNATURE: _____

DATE SIGNED: ___/___/___

THIS DATA NOT DATABASSED

* A Serious Adverse Event form must be completed.

** Complete a Concomitant Medication Form and enter the Medication Number.

Study _____

DOMAIN: TU

ID _____
Date ____/____/____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	<i>Node ID</i> __ __	<i>Site ID</i> __ _ _ _	<i>Subject ID</i> USUBJID __ _ _
<i>Visit Date</i> / / TUDTC	<i>Phase</i> EPOCH	<i>Visit Week</i> VISIT	<i>Sequence Number</i>
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Compliance Therapy

Compliance Therapy **TUTEST**

1. In the past week, did the participant attend any group sessions of 30 minutes or longer? 0 = No **TUORRES**
1 = Yes

1a. If yes, how many group sessions? **TUORRES**

TUTEST

2. In the past week, did the participant attend any individual sessions of 30 minutes or longer? 0 = No **TUORRES**
1 = Yes

2a. If yes, how many individual sessions? **TUORRES**

TUTEST

3. In the past week, did the participant attend any family therapy sessions? 0 = No **TUORRES**
1 = Yes

3a. If yes, how many family therapy sessions? **TUORRES**

TUTEST

4. In the past week, did the participant attend any other therapy sessions not listed above? 0 = No **TUORRES**
1 = Yes

If yes, specify **TUTEST**
a) _____ Number of sessions
b) _____ Number of sessions
c) _____ Number of sessions

TUTEST

5. Did the participant fail to meet the required therapy session for ongoing study participation? 0 = No **TUORRES**
1 = Yes

(If yes, participant should be discharged from active study participation.)

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID USUBJID
Visit Date __/__/____	Phase 2	Visit Week 0 1	Sequence Number _____
EXDTC/DADTC	EPOCH	VISIT	
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Dosing Logs
(Days 1 – 7)

Form Completion Status: 1 = Completed as required
 2 = Form not required

EXDOSTXT//DACAT

QNAM=EXPRES
IDVAR=EXSEQ
QLABEL=BUPRENORPHINE PRESCRIBED
Dosing Logs

QNAM=EXDRNUM
IDVAR=EXSEQ
QLABEL=PRESCRIBING
DOCTOR NUMBER

EXSPID/DASPID

EXTRT=BUPRENORPHINE

DA.DATEST
DA.DAORRES

DAY 1	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # <u>EXLOT</u> # Tabs Taken <u>EXDOSE</u> # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # <u>EXLOT</u> # Tabs Taken <u>EXDOSE</u> # Sent Home ____ # Returned ____
<i>Buprenorphine Tablets 0.4 mg</i>	
Lot # <u>EXLOT</u> # Tabs Taken <u>EXDOSE</u> # Sent Home ____ # Returned ____	
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____ EXDOSTOT EXDOSU=MG EXDOSFRM=TABLET	
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____	
Medication Compliant? 0 = No 1 = Yes	
DAY 2	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
<i>Buprenorphine Tablets 0.4 mg</i>	
Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____	
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____	
Medication Compliant? 0 = No 1 = Yes	

EXADJ

QNAM=EXDOSADM
IDVAR=EXSEQ
QLABEL=MEDICATION
ADMINISTERED BY

QNAM=EXMEDCOM
IDVAR=EXSEQ
QLABEL=MEDICATION
COMPLIANT

QNAM=EXNOMED
IDVAR=EXSEQ
QLABEL=NO MEDICATION GIVEN: OTHER SPECIFY

Dosing Logs

DAY 3	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

DAY 4	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

DAY 5	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

DOMAIN: EX

Annotation same as Dosing Log
Day 1 page

DOMAIN: EX

Annotation same as Dosing Log
Day 1 page

Dosing Logs

DAY 6	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 7	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

Enter day 1 – 7 in the data entry system under header information:

Phase: 2

Visit Week: 01

Study _____

DOMAIN: EX

ID _____
Date ___/___/_____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __ _	Site ID _ _ _ _ _	Subject ID _ _ _ _ _
Visit Date _ _ / _ _ / _ _ _ _	Phase <u>2</u>	Visit Week <u>0 2</u>	<i>Sequence Number</i> _ _ _ _
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Dosing Logs
(Days 8 – 14)

Form Completion Status:	<input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required
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Dosing Logs

Annotation same as Dosing Log
Day 1 page

DAY 8	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____		Medication Compliant? 0 = No 1 = Yes	
DAY 9	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____		Medication Compliant? 0 = No 1 = Yes	

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 10	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 11	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 12	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	

Annotation same as Dosing Log
Day 1 page

Dosing Logs

DAY 13	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 14	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

Enter day 8 – 14 in the data entry system under header information:

Phase: 2

Visit Week: 02

Study _____

DOMAIN: EX

ID _____
Date ___/___/_____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID _____
Visit Date ___/___/_____	Phase <u>2</u>	Visit Week <u>0 3</u>	<i>Sequence Number</i> _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Dosing Logs
(Days 15 – 21)

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 17	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 18	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 19	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	

Annotation same as Dosing Log
Day 1 page

Dosing Logs

DAY 20	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 21	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

**Enter day 15 – 21 in the data entry system under header information:
Phase: 2
Visit Week: 03**

Study _____

DOMAIN: EX

ID _____
Date ___/___/_____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID _____
Visit Date ___/___/_____	Phase <u>2</u>	Visit Week <u>0 4</u>	<i>Sequence Number</i> _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Dosing Logs
(Days 22 – 28)

Form Completion Status: <input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required

Annotation same as Dosing Log
Day 1 page

Dosing Logs

DAY 22	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____		Medication Compliant? 0 = No 1 = Yes	
DAY 23	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____		Medication Compliant? 0 = No 1 = Yes	

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 24	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 25	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 26	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 27	Prescribed ___ . ___ mg Buprenorphine by Dr. Number _____			
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>			
	Lot # _____	# Tabs Taken _____	# Sent Home _____	# Returned _____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>			
	Lot # _____	# Tabs Taken _____	# Sent Home _____	# Returned _____
	<i>Buprenorphine Tablets 0.4 mg</i>			
	Lot # _____	# Tabs Taken _____	# Sent Home _____	# Returned _____
Total Amount Taken ___ . ___ mg Buprenorphine Administer by _____				
No Medication Given		Medication Compliant?		
1 = Participant did not show		0 = No		
2 = Held due to AE/SAE		1 = Yes		
3 = Other _____				

DAY 28	Prescribed ___ . ___ mg Buprenorphine by Dr. Number _____			
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>			
	Lot # _____	# Tabs Taken _____	# Sent Home _____	# Returned _____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>			
	Lot # _____	# Tabs Taken _____	# Sent Home _____	# Returned _____
	<i>Buprenorphine Tablets 0.4 mg</i>			
	Lot # _____	# Tabs Taken _____	# Sent Home _____	# Returned _____
Total Amount Taken ___ . ___ mg Buprenorphine Administer by _____				
No Medication Given		Medication Compliant?		
1 = Participant did not show		0 = No		
2 = Held due to AE/SAE		1 = Yes		
3 = Other _____				

Enter day 22 – 28 in the data entry system under header information:

Phase: 2

Visit Week: 04

Study _____

DOMAIN: EX

Date ____/____/____ ID _____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID _____
Visit Date ____/____/____	Phase <u>2</u>	Visit Week <u>0 5</u>	<i>Sequence Number</i> _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Dosing Logs
(Days 29 – 35)

Form Completion Status:	<input type="checkbox"/>	1 = Completed as required
	<input type="checkbox"/>	2 = Form not required

Annotation same as Dosing Log
Day 1 page

Dosing Logs

DAY 29	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 30	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 31	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 32	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 33	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

Annotation same as Dosing Log Day 1
page

Dosing Logs

DAY 34	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 35	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

Enter day 29 – 35 in the data entry system under header information:

Phase: 2

Visit Week: 05

Study _____

DOMAIN: EX

ID _____
Date __/__/____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID _____
Visit Date __/__/____	Phase <u>2</u>	Visit Week <u>0 6</u>	<i>Sequence Number</i> _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Dosing Logs
(Days 36 – 42)

Form Completion Status: <input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required

Annotation same as Dosing Log Day 1
page

Dosing Logs

DAY 36	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____		Medication Compliant? 0 = No 1 = Yes	
DAY 37	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____		Medication Compliant? 0 = No 1 = Yes	

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 38	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____	
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>	
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____	
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>	
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____	
	<i>Buprenorphine Tablets 0.4 mg</i>	
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____	
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____		
No Medication Given	Medication Compliant?	0 = No
1 = Participant did not show		1 = Yes
2 = Held due to AE/SAE		
3 = Other _____		
DAY 39	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____	
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>	
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____	
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>	
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____	
	<i>Buprenorphine Tablets 0.4 mg</i>	
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____	
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____		
No Medication Given	Medication Compliant?	0 = No
1 = Participant did not show		1 = Yes
2 = Held due to AE/SAE		
3 = Other _____		
DAY 40	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____	
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>	
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____	
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>	
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____	
	<i>Buprenorphine Tablets 0.4 mg</i>	
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____	
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____		
No Medication Given	Medication Compliant?	0 = No
1 = Participant did not show		1 = Yes
2 = Held due to AE/SAE		
3 = Other _____		

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 41	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 42	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

Enter day 36 – 42 in the data entry system under header information:

Phase: 2

Visit Week: 06

Study _____

DOMAIN: EX

ID _____
Date ___/___/_____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ___	Site ID _____	Subject ID _____
Visit Date ___/___/_____	Phase <u>2</u>	Visit Week <u>0 7</u>	<i>Sequence Number</i> _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Dosing Logs
(Days 43 – 49)

Form Completion Status:	<input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required
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Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 43	Prescribed ___ . ___ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken _____	# Sent Home _____ # Returned _____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken _____	# Sent Home _____ # Returned _____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken _____	# Sent Home _____ # Returned _____
	Total Amount Taken ___ . ___ mg Buprenorphine Administer by _____		
No Medication Given		Medication Compliant?	0 = No 1 = Yes
1 = Participant did not show			
2 = Held due to AE/SAE			
3 = Other _____			
DAY 44	Prescribed ___ . ___ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken _____	# Sent Home _____ # Returned _____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken _____	# Sent Home _____ # Returned _____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken _____	# Sent Home _____ # Returned _____
	Total Amount Taken ___ . ___ mg Buprenorphine Administer by _____		
No Medication Given		Medication Compliant?	0 = No 1 = Yes
1 = Participant did not show			
2 = Held due to AE/SAE			
3 = Other _____			

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 45	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 46	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 47	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	

Annotation same as Dosing Log Day
1 page

Dosing Logs

DAY 48	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____			
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>			
	Lot # _____	# Tabs Taken ____	# Sent Home ____	# Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>			
	Lot # _____	# Tabs Taken ____	# Sent Home ____	# Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>			
	Lot # _____	# Tabs Taken ____	# Sent Home ____	# Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____				
No Medication Given		Medication Compliant?		
1 = Participant did not show		0 = No		
2 = Held due to AE/SAE		1 = Yes		
3 = Other _____				

DAY 49	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____			
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>			
	Lot # _____	# Tabs Taken ____	# Sent Home ____	# Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>			
	Lot # _____	# Tabs Taken ____	# Sent Home ____	# Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>			
	Lot # _____	# Tabs Taken ____	# Sent Home ____	# Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____				
No Medication Given		Medication Compliant?		
1 = Participant did not show		0 = No		
2 = Held due to AE/SAE		1 = Yes		
3 = Other _____				

**Enter day 43 – 49 in the data entry system under header information:
Phase: 2
Visit Week: 07**

Study _____

DOMAIN: EX

Date ____/____/____ ID _____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID _____
Visit Date ____/____/____	Phase <u>2</u>	Visit Week <u>08</u>	<i>Sequence Number</i> _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

**Dosing Logs
(Days 50 – 56)**

Form Completion Status: <input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 50	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____	Medication Compliant? 0 = No 1 = Yes
DAY 51	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____	Medication Compliant? 0 = No 1 = Yes

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 52	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 53	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 54	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 55	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 56	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

Enter day 50 – 56 in the data entry system under header information:

Phase: 2

Visit Week: 08

Study _____

DOMAIN: EX

ID _____
Date ___/___/_____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID _____
Visit Date ___/___/_____	Phase <u>2</u>	Visit Week <u>0 9</u>	<i>Sequence Number</i> _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Dosing Logs
(Days 57 – 63)

Form Completion Status:	<input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required
--------------------------------	------------------------------------------------------------------------------------------------------

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 57	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____												
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
	<i>Buprenorphine Tablets 0.4 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____													
<table style="width: 100%;"> <tr> <td style="width: 60%;">No Medication Given</td> <td style="width: 20%;">Medication Compliant?</td> <td style="width: 20%;">0 = No</td> </tr> <tr> <td>1 = Participant did not show</td> <td></td> <td>1 = Yes</td> </tr> <tr> <td>2 = Held due to AE/SAE</td> <td></td> <td></td> </tr> <tr> <td>3 = Other _____</td> <td></td> <td></td> </tr> </table>		No Medication Given	Medication Compliant?	0 = No	1 = Participant did not show		1 = Yes	2 = Held due to AE/SAE			3 = Other _____		
No Medication Given	Medication Compliant?	0 = No											
1 = Participant did not show		1 = Yes											
2 = Held due to AE/SAE													
3 = Other _____													
DAY 58	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____												
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
	<i>Buprenorphine Tablets 0.4 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____													
<table style="width: 100%;"> <tr> <td style="width: 60%;">No Medication Given</td> <td style="width: 20%;">Medication Compliant?</td> <td style="width: 20%;">0 = No</td> </tr> <tr> <td>1 = Participant did not show</td> <td></td> <td>1 = Yes</td> </tr> <tr> <td>2 = Held due to AE/SAE</td> <td></td> <td></td> </tr> <tr> <td>3 = Other _____</td> <td></td> <td></td> </tr> </table>		No Medication Given	Medication Compliant?	0 = No	1 = Participant did not show		1 = Yes	2 = Held due to AE/SAE			3 = Other _____		
No Medication Given	Medication Compliant?	0 = No											
1 = Participant did not show		1 = Yes											
2 = Held due to AE/SAE													
3 = Other _____													

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 59	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 60	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 61	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 62	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 63	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

Enter day 57 – 63 in the data entry system under header information:

Phase: 2

Visit Week: 09

Study _____

DOMAIN: EX

ID _____
Date ___/___/_____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __ _	Site ID _ _ _ _ _	Subject ID _ _ _ _ _
Visit Date __ _ / __ _ / _ _ _ _ _	Phase <u>2</u>	Visit Week <u>1 0</u>	<i>Sequence Number</i> _ _ _ _ _
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Dosing Logs
(Days 64 – 70)

Form Completion Status: <input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 64	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____		Medication Compliant? 0 = No 1 = Yes	
DAY 65	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given 1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____		Medication Compliant? 0 = No 1 = Yes	

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 66	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 67	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 68	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 69	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

DAY 70	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

Enter day 64 – 70 in the data entry system under header information:

Phase: 2

Visit Week: 10

Study _____

DOMAIN: EX

ID _____
Date ___/___/_____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ___	Site ID _____	Subject ID _____
Visit Date ___/___/_____	Phase <u>2</u>	Visit Week <u>1 1</u>	<i>Sequence Number</i> _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Dosing Logs
(Days 71 – 77)

Form Completion Status:	<input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required
--------------------------------	------------------------------------------------------------------------------------------------------

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 71	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____												
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
	<i>Buprenorphine Tablets 0.4 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____													
<table style="width: 100%;"> <tr> <td style="width: 60%;">No Medication Given</td> <td style="width: 20%;">Medication Compliant?</td> <td style="width: 20%;">0 = No</td> </tr> <tr> <td>1 = Participant did not show</td> <td></td> <td>1 = Yes</td> </tr> <tr> <td>2 = Held due to AE/SAE</td> <td></td> <td></td> </tr> <tr> <td>3 = Other _____</td> <td></td> <td></td> </tr> </table>		No Medication Given	Medication Compliant?	0 = No	1 = Participant did not show		1 = Yes	2 = Held due to AE/SAE			3 = Other _____		
No Medication Given	Medication Compliant?	0 = No											
1 = Participant did not show		1 = Yes											
2 = Held due to AE/SAE													
3 = Other _____													
DAY 72	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____												
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
	<i>Buprenorphine Tablets 0.4 mg</i>												
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____												
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____													
<table style="width: 100%;"> <tr> <td style="width: 60%;">No Medication Given</td> <td style="width: 20%;">Medication Compliant?</td> <td style="width: 20%;">0 = No</td> </tr> <tr> <td>1 = Participant did not show</td> <td></td> <td>1 = Yes</td> </tr> <tr> <td>2 = Held due to AE/SAE</td> <td></td> <td></td> </tr> <tr> <td>3 = Other _____</td> <td></td> <td></td> </tr> </table>		No Medication Given	Medication Compliant?	0 = No	1 = Participant did not show		1 = Yes	2 = Held due to AE/SAE			3 = Other _____		
No Medication Given	Medication Compliant?	0 = No											
1 = Participant did not show		1 = Yes											
2 = Held due to AE/SAE													
3 = Other _____													

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 73	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 74	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	
DAY 75	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given Medication Compliant? 0 = No 1 = Participant did not show 1 = Yes 2 = Held due to AE/SAE 3 = Other _____	

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 76	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 77	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

Enter day 71 – 77 in the data entry system under header information:

Phase: 2

Visit Week: 11

Study _____

DOMAIN: EX ID _____
 Date ____/____/____

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID _____
Visit Date ____/____/____	Phase <u>2</u>	Visit Week <u>1</u> <u>2</u>	<i>Sequence Number</i> _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

**Dosing Logs
 (Days 78 – 84)**

Form Completion Status:	<input type="checkbox"/> 1 = Completed as required <input type="checkbox"/> 2 = Form not required
--------------------------------	------------------------------------------------------------------------------------------------------

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 78	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given	
1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____	
Medication Compliant? 0 = No 1 = Yes	
DAY 79	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>
	Lot # _____ # Tabs Taken ____ # Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____	
No Medication Given	
1 = Participant did not show 2 = Held due to AE/SAE 3 = Other _____	
Medication Compliant? 0 = No 1 = Yes	

DAY 80	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 81	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 82	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

Annotation same as Dosing Log Day 1 page

Dosing Logs

DAY 83	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			
DAY 84	Prescribed ____ . ____ mg Buprenorphine by Dr. Number _____		
	<i>Buprenorphine/Naloxone Tablets 2.0 mg/ 0.5 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine/Naloxone Tablets 8.0 mg/ 2.0 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
	<i>Buprenorphine Tablets 0.4 mg</i>		
	Lot # _____	# Tabs Taken ____	# Sent Home ____ # Returned ____
Total Amount Taken ____ . ____ mg Buprenorphine Administer by _____			
No Medication Given		Medication Compliant?	0 = No
1 = Participant did not show			1 = Yes
2 = Held due to AE/SAE			
3 = Other _____			

**Enter day 78 – 84 in the data entry system under header information:
Phase: 2
Visit Week: 12**

Study _____

ID _____
Date ____/____/____

DOMAIN: QS

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ QSDTC	Phase EPOCH __	Visit Week VISIT __	Sequence Number __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Medication Experience - Participant Version

Form Completion Status:	<input type="checkbox"/>	1 = Completed as required
	<input type="checkbox"/>	2 = Form not required

Medication Experience - Participant Version

INSTRUCTIONS: Using the scale below, please rate your experience/satisfaction with the Bup/Nal medication.

QSCAT=MEDICATION EXPERIENCE-PARTICIPANT VERSION

1	2	3	4	5	6
Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree

QSTEST

QSORRES

1. I believe that taking the Bup/Nal was helpful to my recovery.

2. When I was taking the Bup/Nal I felt little or no side effects from the medication.

3. Based on this experience with the Bup/Nal medication, if I had the need to take medication in the future as a part of my treatment for opioid dependence, I would definitely take the Bup/Nal again.

Study _____

DOMAIN: QS

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID USUBJID
Visit Date ____/____/____ QSDTC	Phase EPOCH __	Visit Week VISIT __	Sequence Number __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Medication Experience - Staff Version

Study _____ **STUDYID**

DOMAIN: QS

ID _____ **USUBJID**
Date ___/___/_____

QSDTC

Form Completion Status:	<input type="checkbox"/>	1 = Completed as required
	<input type="checkbox"/>	2 = Form not required

Medication Experience - Staff Version

QSCAT=MEDICATION EXPERIENCE-STAFF VERSION

INSTRUCTIONS: Using the scale below, please rate your thoughts on this participant's experience with the Bup/Nal medication.

1	2	3	4	5	6
Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree

QSTEST

QSORRES

- _____ 1. I believe that taking the Bup/Nal was helpful to this participant's recovery.

- _____ 2. When taking the Bup/Nal this participant had little or no side effects from the medication.

- _____ 3. Based on this participant's experience with the Bup/Nal medication, if this participant needed to take medication in the future as a part of a treatment for opioid dependence, I would definitely recommend the Bup/Nal again.

Study _____

DOMAIN: QS

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number <i>NIDA-CTN-0010</i>	Node ID ____	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ QSDTC	Phase EPOCH	Visit Week VISIT	Sequence Number ____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

The Short Opiate Withdrawal Scale (SOWS)

Form Completion Status:	<input type="checkbox"/>	1 = Completed as required
	<input type="checkbox"/>	2 = Form not required

The Short Opiate Withdrawal Scale (SOWS)

QSCAT=SHORT OPIATE WITHDRAWAL SCALE (SOWS)

Please circle the appropriate answer if you have suffered from any of the following conditions in the last 24 hours

QSTEST ↓	None	Mild	Moderate	Severe
Feeling Sick	0	1	2	3
Stomach Cramps	0	1	2	3
Muscle Spasms/ Twitching	0	1	2	3
Feelings of Coldness	0	1	2	3
Heart Pounding	0	1	2	3
Muscular Tension	0	1	2	3
Aches and Pains	0	1	2	3
Yawning	0	1	2	3
Runny Eyes	0	1	2	3
Insomnia/ Problems Sleeping	0	1	2	3

Study _____

DOMAIN: SU

ID _____
Date __/__/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID __ USUBID
Visit Date __/__/____ SUDTC	Phase EPOCH	Visit Week VISIT	Sequence Number __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Weekly Timeline Followback (Self-Reported Drug and Alcohol Use)

SUCAT = WEEKLY TIMELINE FOLLOWBACK

Weekly Timeline Followback (Self-Reported Drug and Alcohol Use)

SUTRT ↓ In the past week how many days did you use:	SUDUR ↓	SUEVLINT=-P1W
1. Alcohol	—	
2. Heroin	—	
3. Methadone	—	
4. Other Opiates	—	
5. Barbituates	—	
6. Benzodiazepines	—	
7. Cocaine	—	
8. Amphetamines	—	
9. Cannabis	—	
10. Hallucinogens	—	
11. Inhalants	—	

Study _____

DOMAIN: QS

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ QSDTC	Phase EPOCH __	Visit Week VISIT __	Sequence Number __
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

The Helping Alliance Questionnaire Patient Version

Study _____

DOMAIN: SU

ID _____

Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID ____	Site ID _____	Subject ID USUBJID ____
Visit Date ____/____/____ SUDTC	Phase EPOCH ____	Visit Week VISIT ____	Sequence Number ____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

Monthly Timeline Followback (Self-Reported Drug and Alcohol Use)

Study STUDYID

DOMAIN: SU

ID USUBJID
Date ___/___/___

SUDTC

Monthly Timeline Followback (Self-Reported Drug and Alcohol Use)

SUTRT	SUOCCUR
In the past 30 days how many days did you use:	
1. Alcohol	—
2. Heroin	—
3. Methadone	—
4. Other Opiates	—
5. Barbituates	—
6. Benzodiazepines	—
7. Cocaine	—
8. Amphetamines	—
9. Cannabis	—
10. Hallucinogens	—
11. Inhalants	—

Study _____

DOMAIN: DS

ID _____
Date ____/____/____

STUDYID

BUP-NX For Adolescent/Young Adult Opiate Dependency

Protocol Number NIDA-CTN-0010	Node ID __	Site ID _____	Subject ID USUBJID _____
Visit Date ____/____/____ DSDTC	Phase EPOCH __	Visit Week VISIT _____	Sequence Number _____
		<i>For use with Phase Two Only</i>	<i>For use with AE or SAE Only</i>

End of Study / Termination

Form Completion Status: 1 = Completed as required
 2 = Form not required

DSCAT=DISPOSITION EVENT

End of Study/Termination

DSTERM	DSOCCUR	
	Yes	No
1. Did the participant complete the . . .		
a. Week 4 Follow-Up	1	0
b. Week 8 Follow-Up	1	0
c. Week 12 Follow-Up	1	0
d. Month 6 Follow-Up	1	0
e. Month 9 Follow-Up	1	0
f. Month 12 Follow-Up	1	0
g. Is the subject an early terminator?	1	0
If yes, when did the subject terminate?		
1=Week 4 Follow-Up		
2=Week 8 Follow-Up		
3=Week 12 Follow-Up		
4=Month 6 Follow-Up		
5=Month 9 Follow-Up		
6=Month 12 Follow-Up		

If Question 1g was answered as No, or Question 1g was answered as Yes, but subject was terminated at previous visit, skip to Question 3.
If Question 1g was answered as Yes, and subject terminated at the current visit, continue with Question 2.

DSCAT=DISPOSITION EVENT End of Study/Termination

		DSOCCUR	
		True	False
2. Reason(s) participant did not complete study. . .			
DSTERM			
a. Participant withdrew from study		1	0
b. Participant did not keep scheduled appointment(s)		1	0
c. Participant unable to be located		1	0
d. Participant is in a controlled environment		1	0
e. Participant has moved from the area		1	0
f. Participant was administratively withdrawn (<i>Specify in comments</i>)		1	0
g. Participant can no longer attend clinic		1	0
h. Participant no longer attends clinic		1	0
i. Participant transferred to another treatment program (<i>Indicate type program</i>)		1	0
Methadone		1	0
LAAM		1	0
Drug Free		1	0
Therapeutic Community		1	0
Inpatient Detox or Treatment		1	0
Residential		1	0
Other (<i>Specify in comments</i>)		1	0
j. Participant is pregnant		1	0
k. Participant was hospitalized or developed acute medical condition which would make further treatment hazardous		1	0
l. Participant has developed sensitivity or allergy to buprenorphine/naloxone		1	0
m. Death		1	0

DSTERM 3. Date treatment terminated/completed from the treatment condition **DSSTDTC**
 ___/___/_____
 (84 days = completed treatment condition including psychotherapy)

DSTERM 4. Date of last contact ___/___/_____
DSSTDTC
 (Date of last contact may or may not change at month 12 for early terminators)

5. Comments: **DOMAIN: CO**
COVAL
RDOMAIN=DS
IDVAR=DSSEQ