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

DOMAIN: QS

CURRY REASON FOR QUITTING QUESTIONNAIRE=QSCAT

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ___
NODE: ☐☐	STUDYID	EPOCH Screening Baseline VISITNUM
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one)	-1 1 2 3 4 5 6 7 8 9 10 11 12 13
PARTICIPANT ID : ☐☐☐☐	USUBJID	14 15 16 17 18 19 20 21 22 23 24 25 26
Assessment Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy) QSDTC		QSEVAL STAFF ID: ☐☐☐☐☐
☐ FORM COMPLETION STATUS	1=Form completed as required 2=Participant refused 3=Responsible person did not complete	4=Not enough time at the visit 5=Participant did not attend visit 6=Other (specify: _____)

This is a brief questionnaire about your interest or motivation to stop smoking. Please answer all questions. If you have NO interest in stopping smoking, please indicate that by circling the corresponding "not at all true" statement for each item.

Please begin by deciding how much the following statement applies to you:

		Not at all	A little true	Moderately true	Quite true	Extremely true
A.	I want to quit smoking	0	1	2	3	4

YOUR REASONS FOR QUITTING SMOKING

What are your reasons for wanting to quit smoking **at this time**? Below is a list of reasons that smokers may have for quitting. Read each reason and decide how much it applies to **you** right now. Then circle **one** reason. Remember, there are no "right" or "wrong" reasons for wanting to quit smoking – any reason is a good one.

I WANT TO QUIT SMOKING AT THIS TIME:

QSTESTCD/QSTEST — QSORRES

		Not at all	A little true	Moderately true	Quite true	Extremely true
1.	To show myself that I can quit smoking if I really want to.	0	1	2	3	4
2.	Because I will like myself better if I quit smoking.	0	1	2	3	4
3.	So that I can feel in control of my life.	0	1	2	3	4
4.	Because my spouse, children or other person I am close to will stop nagging me if I quit smoking.	0	1	2	3	4
5.	Because quitting smoking will prove that I can accomplish other things that are important to me.	0	1	2	3	4
6.	Because someone has given me an ultimatum (made a threat) to quit.	0	1	2	3	4
7.	Because I will receive a special gift if I quit.	0	1	2	3	4
8.	So that my hair and clothes won't smell.	0	1	2	3	4
9.	So that I will save money on smoking-related costs such as dry-cleaning.	0	1	2	3	4

Site ID: ☐☐☐☐	Participant ID ☐☐☐☐	Visit Date: __ __ / __ __ / __ __ __ __ (m m d d y y y y) QSDTC

QSTESTCD/QSTEST	Not at all	A little true	Moderately true	Quite true	Extremely true
	QSORRES				
10. Because I am concerned that I will suffer from a serious illness if I don't quit smoking.	0	1	2	3	4
11. Because I will receive a financial reward for quitting (money from a friend or family member, bonus from work, etc.)	0	1	2	3	4
12. Because people I am close to will be upset with me if I don't quit.	0	1	2	3	4
13. Because I won't burn holes in clothing or furniture.	0	1	2	3	4
14. Because I have noticed physical symptoms that indicate that smoking is hurting my health.	0	1	2	3	4
15. Because I want to save the money that I spend on cigarettes.	0	1	2	3	4
16. To prove to myself that I'm not addicted to cigarettes.	0	1	2	3	4
17. Because I can graphically picture the effects that smoking has on my body.	0	1	2	3	4
18. Because I have known other people who have died from serious illnesses that were caused by smoking.	0	1	2	3	4
19. So that I won't have to clean my house or car so often.	0	1	2	3	4
20. Because I am concerned that smoking will shorten my life.	0	1	2	3	4

DOMAIN: DM and SC

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1

NODE: ☐☐

CTP-SITE ID: ☐☐-☐☐

PARTICIPANT ID : ☐☐☐☐ USUBJID

STUDY WEEK: *(circle one)*

EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

Assessment Date: ___ ___ / ___ ___ / ___ ___ ___ ___ *(mm / dd / yyyy)*

STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify:)

DEMOGRAPHICS

_____ 1. **Sex** DM.SEX
(1 = Male, 2=female)

2. **Date of Birth** ___ ___ / ___ ___ / ___ ___ ___ ___ DM.BRTHDTC
m m d d y y y y

3. **ETHNICITY/RACE:** For each of the following, please circle '0' for 'NO" or '1' for YES'. You have the option of not answering by circling '1' for 'Participant chooses not to answer'. For those categories with further specification, please select at least one sub-category.

NO	YES	DM.RACE (If multiple, then = 'MULTIPLE')
0	1	White
0	1	Black, African American or Negro SCTEST
0	1	American Indian or Alaska Native
0	1	Spanish, Hispanic or Latino (enter "1" below for all that apply) ___ Mexican, Mexican-American, or Chicano ___ Puerto Rican ___ Cuban ___ Other (specify)_____
0	1	Asian (enter "1" below for all that apply) ___ Asian-Indian ___ Korean ___ Chinese ___ Vietnamese ___ Filipino ___ Other (specify)_____ ___ Japanese
0	1	Native Hawaiian or Pacific Islander (enter "1" below for all that apply) ___ Native Hawaiian ___ Guamanian or Chamarro ___ Samoan ___ Other (specify) _____
0	1	Other (specify)_____
	1	Participant chooses not to answer

SCTEST

SCORRES

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

SCORRES

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

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

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

SCORRES
___ ___ Yrs.

4. **Education completed** (GED = 12 years)
SCTEST

5. **Usual employment pattern:**

_____ a. Past 3 years?

_____ b. Past 30 days?

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

_____ 6. **Marital Status**

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

CTP -Site ID	Participant ID	Assessment Date:
☐☐-☐☐	☐☐☐☐	__ __ / __ __ / SUDTC __ __ (m m / d d / y y y y)

SUBSTANCE USE

7. Drug/Alcohol Use

SUCAT=DRUG/ALCOHOL USE

For the following, please record usage 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 generally considered regular use. The usual route of administration should be coded. If more than 1 route is frequently used, then choose the most severe. 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 0 years (6-12 months of use is coded as 1 year) and make a note on the form.

SUEVLINT=-P30D SUOCCUR=Y

SUTRT

Substance	A: Past 30 Days	B: Lifetime Use Years	C: Most Frequent Route of Administration				
			Oral	Nasal	Smoking	IV or Non-IV Injection	N/A
01 Alcohol (any use at all)	__ __	SUDUR__ __	1	2	3	4	8
02 Alcohol (to intoxication)	__ __	__ __	1	2	3	4	8
03 Heroin	__ __	__ __	1	2	3	4	8
04 Methadone/LAAM (prescribed)	__ __	__ __	1	2	3	4	8
05 Methadone/LAAM (illicit)	__ __	__ __	1	2	3	4	8
06 Other Opiates/Analgesics	__ __	__ __	1	2	3	4	8
07 Barbiturates	__ __	__ __	1	2	3	4	8
08 Other Sedatives/Hypnotics/Tranquilizers, including Benzodiazapines	__ __	__ __	1	2	3	4	8
09 Cocaine	__ __	__ __	1	2	3	4	8
10 Amphetamines/Methamphetamines	__ __	__ __	1	2	3	4	8
11 Cannabis	__ __	__ __	1	2	3	4	8
12 Hallucinogens	__ __	__ __	1	2	3	4	8
13 Inhalants	__ __	__ __	1	2	3	4	8
14 More than 1 substance per day (including alcohol)	__ __	__ __					
15 Nicotine (tobacco products)	__ __	__ __	1	2	3		8

SUCAT=MAJOR DRUG PROBLEM

SUTRT

8. According to the interviewer, which substance is the major problem?

Interviewer should determine the major drug of abuse. Code using the number next to the drug listed in question 7 - numbers **01-13, 15.** "**00**" = no problem, "**16**" = alcohol & drug (Dual addiction), "**17**" = Polydrug. Ask participant when not clear.

DOMAIN: QS

DSM-IV CHECKLIST: ADMINISTRATION WORKSHEET (DSM-IV) QSCAT

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: __ __
NODE: ☐☐	STUDYID	EPOCH Screening Baseline VISITNUM
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one)	-1 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26
PARTICIPANT ID : ☐☐☐☐	USUBJID	
Assessment Date: __ __ / __ __ / __ __ __ __ QSDTC (mm / dd / yyyy)		QSEVAL STAFF ID: ☐☐☐☐☐
☐ FORM COMPLETION STATUS	1=Form completed as required 2=Participant refused 3=Responsible person did not complete	4=Not enough time at the visit 5=Participant did not attend visit 6=Other (specify: _____)

SECTION 1 - GENERAL INFORMATION

QSTESTCD/QSTEST QSORRES

Q1. Have you used _____ in the past 12 months? (Start with Alcohol)

IF the answer to Q1 is "NO," circle "0" for NO USE (column "a"), and move on to the next drug class (ask Q1).
IF the answer to Q1 is "YES," then ask:

"Have you used _____ 10 or more days in any month over the past 12 months?"
IF the answer is "YES" circle "3" in column "b." for Dependence and move on to the next drug class (ask Q1).
IF the answer is "NO" then ask:

"Have you used _____ 2-9 days in any month over the past 12 months?"
IF the answer is "YES", then circle "2" in column "c" for Abuse and move on to the next drug class (ask Q1).
IF the answer is "NO", then circle "1" in column "d" and move on to the next drug class (ask Q1).

		a. NO USE If NO USE, move on to next drug class.	b. YES, Dependence (More than 10 days per month in the past 12 months) Start with Dependence Section	c. YES, Abuse (2-9 days per month in the past 12 months) Start with Dependence Section	d. YES, N (Less than 2 days per month in the past 12 months)
1.A	Alcohol	0	3	2	1
1.B	Amphetamines	0	3	2	1
1.C	Cannabis	0	3	2	1
1.D	Cocaine	0	3	2	1
1.E	Hallucinogens	0	3	2	1
1.F	Inhalants	0	3	2	1
1.G	Nicotine				
1.H	Opiates	0	3	2	1
1.I	PCP	0	3	2	1
1.J	Sedatives - Benzodiazepines	0	3	2	1
		For drugs in this column, DO NOT ASK ANY CRITERIA: Code all criteria as Not Asked (4)	For drugs in this column, START WITH THE DEPENDENCE symptoms section. IF DEPENDENCE IS NOT MET: assess for Abuse. If DEPENDENCE IS MET: DO NOT ask Abuse criteria section, code Abuse criteria as Not Asked (4)	For drugs in this column, START WITH DEPENDENCE symptoms section. IF DEPENDENCE IS NOT MET, assess for Abuse. IF DEPENDENCE IS MET: DONOT ask Abuse criteria section, code Abuse criteria as Not Asked (4)	For drugs in this column, DO NOT ASK ANY CRITERIA: Code all criteria as Not Asked (4)

CTP-Site ID	Participant ID	Assessment Date:
☐☐-☐☐	☐☐☐☐	__ __ / __ __ / QSDTC (m m / d d / y y y y)

SECTION A - DEPENDENCE

Now I'd like to ask you a few more questions about your use of (DRUGS). QSEVLINT=-P12M

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

QSTESTCD/QSTEST

A. *Place code for all drugs being evaluated. (D, A, or N) Use N for no use.*	A	B	C	D	E	F	G	H	I	J
	—	—	—	—	—	—	U	—	—	—
A.1 In the past 12 months, have you had times when you increased the amount of (DRUG) you used to get the same effect you got when you first started using it regularly (i.e., at least once a week for several weeks or more)? If YES: Have you used at least twice the amount of (DRUG) to try and get the same effect? If NO: What about finding that using the same amount of (DRUG) had much less effect than when you first started using it regularly? * *NOTE TO INTERVIEWER: If still uncertain how to code, provide example of symptom using operationally defined guidelines.*	Alcohol	Amphetamines	Cannabis	Cocaine	Hallucinogens	Inhalants	Nicotine *(Not Assessed)*	Opiates	PCP	Sedatives/Benzodiazepines
Tolerance, as defined by either a need for markedly increased amounts of the substance in order to achieve intoxication or desired effect, or markedly diminished effect with continued use of the same amount of substance.										
Present	1	1	1	1	1	1		1	1	1
Absent	2	2	2	2	2	2		2	2	2
Uncertain	3	3	3	3	3	3		3	3	3
Not Asked	4	4	4	4	4	4	4	4	4	4
A.2 In the past 12 months, have you had any withdrawal symptoms, that is felt sick or bad, hours or days after you cut down or stopped using (DRUG)? If YES: What symptoms did you have? (Give participant copy of "withdrawal list" and review symptoms.) If NO: Have you used (DRUG), or another drug like it to reduce feeling sick or bad because you hadn't taken it for a while (i.e., hours or days)? * *NOTE TO INTERVIEWER: If still uncertain how to code, provide example of symptom using operationally defined guidelines.*					QSORRES					
Withdrawal, as manifested by either the characteristic withdrawal syndrome for the substance (refer to drug withdrawal manual) or same (or closely related) substance is taken to relieve or avoid withdrawal symptoms.										
Present	1	1	1	1	1	1		1	1	1
Absent	2	2	2	2	2	2		2	2	2
Uncertain	3	3	3	3	3	3		3	3	3
Not Asked	4	4	4	4	4	4	4	4	4	4
A.3 In the past 12 months, have you had times when you used larger amounts of (DRUG) than you intended to? For example, you thought you would use a little and ended up spending the entire evening using (i.e., using larger amounts to get even more of the desired effects)? If YES: Did this happen repeatedly for several weeks or longer? If NO TO EITHER: Have you had times when you used (DRUG) much more often than when you first started using regularly (repeatedly using it throughout day and evening, beginning to take it daily or many days throughout the week, taking it over many weeks, months, or years)? If YES: Did this happen repeatedly for several weeks or longer? * *NOTE TO INTERVIEWER: If still uncertain how to code, provide example of symptom using operationally defined guidelines.*										
Substance often taken in larger amounts or over a longer period than subject intended.										
Present	1	1	1	1	1	1		1	1	1
Absent	2	2	2	2	2	2		2	2	2
Uncertain	3	3	3	3	3	3		3	3	3
Not Asked	4	4	4	4	4	4	4	4	4	4

CTP-Site ID	Participant ID	Assessment Date: ___ ___ / ___ ___ / ____ QSDTC
☐☐-☐☐	☐☐☐☐	QSEVLINT=-P12M m m d d y y y y

QSTESTCD/QSTEST

Place code for all drugs being evaluated. (D, A, or N) Use N for no use.

	A	B	C	D	E	F	G	H	I	J
	___	___	___	___	___	___	U	___	___	___
	Alcohol	Amphetamines	Cannabis	Cocaine	Hallucinogens	Inhalants	Nicotine *(Not Assessed)*	Opiates	PCP	Sedatives/Benzodiazepines
A.4 In the past 12 months, have you had times when you thought about cutting down or stopping your use of (DRUG)? If YES: Did you have thoughts like this for several weeks or longer? If NO TO EITHER: Have you unsuccessfully tried to cut down or stop using (DRUG) (attempted to but returned to same level of use within days, weeks, or months)? ** NOTE TO INTERVIEWER: If still uncertain how to code, provide example of symptom using operationally defined guidelines.*										
Persistent desire or one or more unsuccessful efforts to cut down or control substance use. Present	1	1	1	1	1	1		1	1	1
Absent	2	2	2	2	2	2		2	2	2
Uncertain	3	3	3	3	3	3		3	3	3
Not Asked	4	4	4	4	4	4	4	4	4	4
A.5 In the past 12 months, have you had times when you spent lots of time getting, using, and being affected by (DRUG) (i.e., about 6 hours or more, including periods where you were feeling desired effects, any hangover, or withdrawal symptoms)? If YES: Did this happen repeatedly for several weeks or longer? If NO: Have you used (DRUG) repeatedly throughout the day and evening hours for several weeks or longer? ** NOTE TO INTERVIEWER: If still uncertain how to code, provide example of symptom using operationally defined guidelines.*					QSORRES					
A great deal of time spent in activities necessary to get the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain smoking) or recover from its effects. Present	1	1	1	1	1	1		1	1	1
Absent	2	2	2	2	2	2		2	2	2
Uncertain	3	3	3	3	3	3		3	3	3
Not Asked	4	4	4	4	4	4	4	4	4	4
A.6 In the past 12 months, have you had times when you used (DRUG) instead of working, instead of spending time in other activities with family or friends, instead of doing hobbies, or other things you used to do (e.g., playing sports, exercising, traveling)? If YES: Did this happen repeatedly for several weeks or longer? ** NOTE TO INTERVIEWER: If still uncertain how to code, provide example of symptom using operationally defined guidelines.*										
Important social occupational, or recreational activities given up or reduced because of substance abuse. Present	1	1	1	1	1	1		1	1	1
Absent	2	2	2	2	2	2		2	2	2
Uncertain	3	3	3	3	3	3		3	3	3
Not Asked	4	4	4	4	4	4	4	4	4	4

CTP-Site ID	Participant ID	Assessment Date: ___ ___ / ___ ___ / ____ QSDTC
☐☐-☐☐	☐☐☐☐	QSEVLINT=-P12M m m d d y y y y

QSTESTCD/QSTEST

		A Alcohol	B Amphetamines	C Cannabis	D Cocaine	E Hallucinogens	F Inhalants	G Nicotine (Not Assessed)	H Opiates	I PCP	J Sedatives/Benzodiazepines
	Place code for all drugs being evaluated. (D, A, or N) Use N for no use.	___	___	___	___	___	___	U	___	___	___
A.7 In the past 12 months, have you had times when using (DRUG) either caused a psychological problem or made an existing problem worse (like feeling more sad, depressed, anxious, or paranoid after using it once or more times or days)? Has your use of (DRUG) ever caused a physical problem or made an existing physical problem or condition worse (like using despite having hepatitis, HIV, diabetes, hypertension, using during pregnancy)? If NO: Did a health care worker ever ask you to cut down or stop using because of a health problem or other medical condition? If YES TO ANY OF ABOVE: Did you continue using the (DRUG) anyway? ** NOTE TO INTERVIEWER: If still uncertain how to code, provide example of symptom using operationally defined guidelines.*	Present	1	1	1	1	1	1		1	1	1
Continued substance use despite knowledge of having persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the use of the substance.	Absent	2	2	2	2	2	2		2	2	2
	Uncertain	3	3	3	3	3	3		3	3	3
	Not Asked	4	4	4	4	4	4	4	4	4	4

QSORRES

A.8	Number of "Present" symptoms for each column. Dependence is indicated by a total of 3 or more.	___	___	___	___	___	___	0	___	___	___

If number of "Present" symptoms totals 3 or more, then DO NOT ASK OR COUNT abuse criteria for that substance: code B1-B4 as "Not Asked" for that substance.

SECTION B - ABUSE

Now I'd like to ask you a few more questions about your use of (DRUGS).
A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one (or more) of the following occurring within a 12-month period.

		A Alcohol	B Amphetamines	C Cannabis	D Cocaine	E Hallucinogens	F Inhalants	G Nicotine (Not Assessed)	H Opiates	I PCP	J Sedatives/Benzodiazepines
B.	*Place code for all drugs being evaluated. (D, A, or N) Use N for no use.*	___	___	___	___	___	___	U	___	___	___
B.1 In the past 12 months, have you had times when (DRUG) use interfered with responsibilities at work, school, or home (e.g., getting a job, keeping a job, or doing a job well; attending school, or completing school assignments; having enough money to provide food, clothing, housing for self or family members)? If YES: Did this happen repeatedly for at least several weeks or longer? ** NOTE TO INTERVIEWER: If still uncertain how to code, provide example of symptom using operationally defined guidelines.*	Present	1	1	1	1	1	1		1	1	1
Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school, neglect of children or household).	Absent	2	2	2	2	2	2		2	2	2
	Uncertain	3	3	3	3	3	3		3	3	3
	Not Asked	4	4	4	4	4	4	4	4	4	4

CTP-Site ID	Participant ID	Assessment Date: ___ ___ / ___ ___ / ____ QSDTC
☐☐-☐☐	☐☐☐☐	QSEVLINT=-P12M m m d d y y y y

QSTESTCD/QSTEST

		A Alcohol	B Amphetamines	C Cannabis	D Cocaine	E Hallucinogens	F Inhalants	G Nicotine (Not Assessed)	H Opiates	I PCP	J Sedatives/Benzodiazepines
Place code for all drugs being evaluated. (D, A, or N) Use N for no use.		___	___	___	___	___	___	U	___	___	___
B.2 In the past 12 months, have you had times when you used (DRUG) in situations where it might have been dangerous to use it (like driving, operating major equipment/machinery, cooking, smoking while lying in bed or on a couch, playing ball or other demanding sports)? If YES: Did this happen repeatedly for at least several weeks or longer? * *NOTE TO INTERVIEWER: If still uncertain how to code, provide example of symptom using operationally defined guidelines.*											
Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use).	Present	1	1	1	1	1	1		1	1	1
	Absent	2	2	2	2	2	2		2	2	2
	Uncertain	3	3	3	3	3	3		3	3	3
	Not Asked	4	4	4	4	4	4	4	4	4	4
B.3 In the past 12 months, have you had times your use of (DRUG) caused legal problems (e.g., charges for driving under the influence, charges for intoxication and disorderly conduct, charges for illegal possession, or sale of (DRUG)? * *NOTE TO INTERVIEWER: If still uncertain how to code, provide example of symptom using operationally defined guidelines.*					QSORRES						
Recurrent substance-related legal problems (e.g., driving under the influence, intoxication, disorderly conduct).	Present	1	1	1	1	1	1		1	1	1
	Absent	2	2	2	2	2	2		2	2	2
	Uncertain	3	3	3	3	3	3		3	3	3
	Not Asked	4	4	4	4	4	4	4	4	4	4
B.4 In the past 12 months, have you had times when your use of (DRUG) caused or worsened problems with other people (such as family members, friends, people at work)? If NO: What about getting into arguments about your using (DRUG), arguments over financial or other problems related to your use of (DRUG)? If YES TO EITHER: Did this happen repeatedly for at least several weeks or longer? If YES: Did you continue using the (DRUG) anyway? * *NOTE TO INTERVIEWER: If still uncertain how to code, provide example of symptom using operationally defined guidelines.*											
Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights).	Present	1	1	1	1	1	1		1	1	1
	Absent	2	2	2	2	2	2		2	2	2
	Uncertain	3	3	3	3	3	3		3	3	3
	Not Asked	4	4	4	4	4	4	4	4	4	4
B.5 Number of "Present" symptoms for each column. Abuse is indicated by a total of 1 or more.		___	___	___	___	___	___	0	___	___	___

SECTION C – Substance Dependence Questions A1-A7

CTP-Site ID	Participant ID	Assessment Date:
☐☐-☐☐	☐☐☐☐	___ ___ / ___ ___ / ____ (QSDTC)
		QSEVLINT=-P12M (m m d d y y y y)

C. ADDENDUM: SUBSTANCE DEPENDENCE QUESTIONS A1 – A7:

QSTESTCD/QSTEST

C.1 ___ Enter the substance with the highest number of items rated as "present" from Section A.8. This is the primary substance of abuse.

QSORRES

1 = Alcohol
2 = Amphetamines
3 = Cannabis
4 = Cocaine
5 = Hallucinogens
6 = Inhalants
7 = Nicotine *(7 is not a valid option for the CTN0009 Smoking Cessation Protocol)*
8 = Opiates
9 = PCP
10 = Sedative / Benzodiazepines

C.2 INTERVIEWER CONCURRENCE

QSTESTCD/QSTEST

a. ___ Interviewer concurrence
1 = Yes *(Skip to "d")*
0 = No; Must Specify: _____

QSORRES _____
_____

b. ___ Interviewer rated primary substance of abuse

1 = Alcohol
2 = Amphetamines
3 = Cannabis
4 = Cocaine
5 = Hallucinogens
6 = Inhalants
7 = Nicotine *(7 is not a valid option for the CTN0009 Smoking Protocol)*
8 = Opiates
9 = PCP
10 = Sedative/Benzodiazepine

c. ___ Interviewer rated total score for primary substance of abuse
(For the CTN0009 Smoking Cessation Protocol the score must be within the range of 3-7 for participant to be eligible)

d. Interviewer Signature: _____ Date Signed: __ __ / __ __ / __ __ __ __

DOMAIN: IE

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1

NODE: ☐☐ STUDYID

CTP-SITE ID: ☐☐-☐☐ STUDY WEEK: (circle one)

PARTICIPANT ID : ☐☐☐☐ USUBJID

EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

Assessment Date: __ __ / __ __ / __ __ __ __ IEDTC (mm / dd / yyyy) STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

IECAT

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

1. INCLUSION CRITERIA **If any of the Inclusion questions below are answered NO or UNKNOWN then the participant is not eligible and cannot be entered or randomized into the study.**

YES	NO	N/A	UNK		IETEST
1	0		9	1a.	Participant is male or female, at least 18 years of age.
1	0		9	1b.	Participant meets both of the following enrollment criteria:
					1. Enrollment and participation in a methadone or LAAM maintenance treatment program, or drug-free rehabilitation clinic, for 30 days or more prior to randomization, **AND**
					2. Scheduled to remain in treatment at the methadone or LAAM maintenance treatment program, or drug-free rehabilitation clinic, for 30 days or more after randomization.
1	0		9	1c.	Participant meets one of the following substance dependence criteria:
					1. Current drug dependence (other than nicotine or prescribed methadone or LAAM) according to DSM-IV checklist criteria, **OR**
					2. Current alcohol dependence plus current drug abuse disorder according to DSM-IV checklist criteria.
1	0		9	1d.	Participant has smoked cigarettes for at least 3 months, and is currently smoking 11 or more cigarettes/day, with exhaled CO levels greater than 10 ppm.
1	0		9	1e.	Is interested in quitting smoking and has a willingness to comply with all study procedures and medication instructions.
1	0	8	9	1f.	Participant, if female of child bearing potential, has a negative (urine) pregnancy test at screening and agrees to use at least one of the following birth control methods a. oral contraceptives b. barrier (diaphragm or cervical cap) with spermicide or condom c. intrauterine progesterone contraceptive system d. levonorgestrel implant e. medroxyprogesterone acetate contraceptive injection f. complete abstinence from sexual intercourse.

IEORRES

If any of the Inclusion questions above have been answered NO or UNKNOWN then the participant is not eligible. Please continue to question 2.

USUBJID

CTP-Site ID	Participant ID	Assessment Date:
☐☐-☐☐	☐☐☐☐	__ __ / __ __ / __ __ __ __ (m m / d d / y y y y) IEDTC

IECAT

2. EXCLUSION CRITERIA

If any of the Exclusion questions below are answered YES or UNKNOWN, the participant is not eligible and cannot be entered or randomized into the study.

YES	NO	N/A	UNK		IETEST
1	0		9	2a.	Participant has an acute, severe psychiatric condition in need of immediate treatment, or imminent suicide risk.
1	0		9	2b.	Participant uses tobacco products other than cigarettes.
1	0		9	2c.	Participant uses other smoking cessation counseling programs or medication treatments (eg. Zyban, Wellbutrin SR, or nicotine replacement therapy) currently, or within the last 2 months.
1	0		9	2d.	Participant uses, or has used, any investigational drug in the last 30 days.
1	0	8	9	2e.	Participant, if female of child bearing potential, is pregnant, lactating, or not using the acceptable modes of contraception during the study (see above methods of birth control).
IEORRES					**Evidence of a medical condition that in the opinion of the investigator would put the subject at risk through study participation, including but not limited to:**
1	0		9	2f.	Clinically significant uncontrolled hypertension. ***(Note: Evidence for hypertension: If subjects provide a blood pressure that is higher than 140 mm Hg (systolic) over 90 mm Hg (diastolic) then they will be evaluated by the study physician to determine if they have clinically significant hypertension that is not controlled.)***
1	0		9	2g.	History of clinically significant heart disease including arrhythmia, congestive heart failure, or unstable angina.
1	0		9	2h.	History of allergic or skin reactions to the use of transdermal products, adhesive tape and bandages, or skin disease.
1	0		9	2i.	Other clinically significant medical problem which precludes study participation (specify in 2j)
				2j.	Specify Other medical problem: _____

If any of the Exclusion questions above have been answered YES or UNKNOWN then the participant is not eligible.

3. ELIGIBILITY

SC.SCTEST

YES	NO	UNK		
1	0	9	3a.	Is the participant eligible for the study? ***If no or unknown, skip to 3c.***
SC.SCORRES			3b.	Date of eligibility: __ __ / __ __ / __ __ __ __ ***(mm / dd / yyyy)***
			3c.	Specify ineligibility: _____

4. CLINICIAN SIGNATURE: _____

Date Signed: __ __ / __ __ / __ __ __ __ ***(mm / dd / yyyy)***

DOMAIN: MH

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1
NODE: ☐☐	STUDYID	EPOCH Screening Baseline VISITNUM
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one)	-1 1 2 3 4 5 6 7 8 9 10 11 12 13
PARTICIPANT ID : ☐☐☐☐	USUBJID	14 15 16 17 18 19 20 21 22 23 24 25 26

Assessment Date: ___ ___ / ___ ___ / ___ ___ MHDTC (mm / dd / yyyy) STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify:)

USE THE FOLLOWING CODES FOR HISTORY ASSESSMENTS:

0 = No History
1 = Yes, history does not exclude
2 = Yes, history excludes
9 = Not Evaluated

QNAM=MHASSES
QLABEL=HISTORY ASSESSMENT
IDVAR=MHSEQ

MHTERM

MHOCCUR

If History (A) is Yes (1 or 2) then describe in Specify B.

Psychiatric/Neurological History Checklist *Have you ever been treated for:*		A History	B Specify
1.	Schizophrenia	___	
2.	Tourette's Syndrome	___	
3.	Major Depressive Disorder	___	
4.	Bipolar Disorder	___	
5.	Anxiety or Panic Disorder	___	
6.	Clinically Significant Neurological Damage	___	
7.	Attention Deficit Hyperactivity Disorder	___	
8.	Epilepsy or Seizure Disorder	___	
Medical Problem Checklist *Do you have now, or a history of:*			
9.	Head injury	___	
10.	Allergies *(including allergies to transdermal medications)*	___	
11.	Liver problems	___	
12.	Kidney problems	___	
13.	GI problems	___	
14.	Thyroid condition	___	
15.	Heart condition	___	
16.	Asthma	___	
17.	High Blood Pressure/Hypertension*	___	
18.	Any skin disease or problems with skin rashes	___	
19.a	Routine drug or methadone withdrawal symptoms	___	
19.b	Routine alcohol withdrawal symptoms	___	

QNAM=MHSPECIFY
QLABEL=HISTORY SPECIFIED
IDVAR=MHSEQ

** NOTE: Evidence for hypertension: If participant provides a blood pressure that is higher than 140 mm Hg (systolic) over 90 mm Hg (diastolic) then they will be evaluated by the study physician to determine if they have clinically significant hypertension that is not controlled.*

USUBJID

CTP - Site ID	Participant ID	Assessment Date:
☐☐-☐☐	☐☐☐☐	__ __ / __ __ / __ __ __ __ (m m d d y y y y)

MHDTC

If there are other medical conditions or psychiatric/neurological history not previously mentioned, then specify below.

USE THE FOLLOWING CODES FOR HISTORY ASSESSMENTS:

0 = No History
1 = Yes, history does not exclude
2 = Yes, history excludes
9 = Not Evaluated

QNAM=MHASSES
QLABEL=HISTORY ASSESSMENT
IDVAR=MHSEQ

MHTERM

MHOCCUR

If History (A) is Yes (1 or 2) then describe in Specify B.

		A History	B Specify
20.	Other 1 (specify): _____	___	
21.	Other 2 (specify): _____	___	
22.	Other 3 (specify): _____	___	
23.	Other 4 (specify): _____	___	

QNAM=MHSPECIFY
QLABEL=HISTORY SPECIFIED
IDVAR=MHSEQ

24. Clinician Signature: _____

Date Signed: __ __ / __ __ / __ __ __ __

25. Print Last Name, First Name: _____

THIS DATA NOT ENTERED

DOMAIN: RP

PREGNANCY ASSESSMENT (FOR FEMALE PARTICIPANTS ONLY)

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ___
NODE: ☐☐	STUDYID	EPOCH Screening Baseline VISITNUM
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one)	-1 1 2 3 4 5 6 7 8 9 10 11 12 13
PARTICIPANT ID : ☐☐☐☐	USUBJID	14 15 16 17 18 19 20 21 22 23 24 25 26
Assessment Date: ___ ___ / ___ ___ / ___ ___ RPDTC (mm / dd / yyyy)		STAFF ID: ☐☐☐☐☐
☐ FORM COMPLETION STATUS	1=Form completed as required 2=Participant refused 3=Responsible person did not complete	4=Not enough time at the visit 5=Participant did not attend visit 6=Other (specify: _____)

DO NOT COMPLETE IF MALE

Circle appropriate answer code

RPTEST

RPORRES

Yes	No		
1	0	1.a	Was a pregnancy test performed? ***IF NO, skip to question 2 & 3 and make a note.***

Pos	Neg		
1	0	1.b	What was the result?

Yes	No		
1	0	2.	Is the participant lactating?
1	0	3.	Does the participant agree to use an acceptable form of birth control?

Acceptable forms of birth control:

a. Oral contraceptives
b. Barrier (diaphram or cervical cap) with spermicide or condom
c. Intrauterine progesterone contraceptive system (IUD)
d. Levonorgestrel implant (Norplant®)
e. Medroxyprogesterone acetate contraceptive injection (Depo-provera)
f. Complete abstinence from sexual intercourse
g. Not of child-bearing potential

4. NOTES:

_____

_____

_____

_____

_____

_____

DOMAIN: CO

~~COVAL~~

DOMAIN=RP

IDVAR=VISITNUM or RPDTC

PRIOR AND CONCOMITANT MEDICATIONS (PCM)

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ____

NODE: ☐☐ STUDYID

CTP-SITE ID: ☐☐-☐☐ STUDY WEEK: (circle one)

PARTICIPANT ID : ☐☐☐☐ USUBJID

EPOCH Screening Baseline VISITNUM

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14 15 16 17 18 19 20 21 22 23 24 25 26

Assessment Date: __ __ / __ __ / __ __ CMDTC (mm / dd / yyyy) STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

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2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify:)

Yes	No		
1	0	1.	Has the participant taken any additional medications since the last visit/in the past 60 days? *(If YES, continue)* • *Enter all prescription and over-the-counter drugs. Use a single page per medication* • *Include vitamins and dietary supplements/alternative medications* • *Record prior medications only at screening visit* • *Number each new entry from 1 to n in the order they are reported to you.* • *Use generic names where possible.* • *Make a new entry when a dosage and/or frequency change occurs*
		2.a	CMTRT Medication Name *(Generic name if possible; otherwise brand name)* _____
		2.b	CMSPID Medication Number
		3.	Purpose/Indication: *(Why drug is being taken)* _____ CMINDC _____ _____
Yes	No		
1	0	4.a	Is the drug being given for the treatment of an AE? *(If YES, complete question 4b)*
		4.b	___ ___ ___ AE Number
		5.	__ __ __ __ CMDOSE Quantity *(Specify dose per administration)*
		6.a	CMDOSU Dosage *(Use codes on next page) (If other, specify in 6.b)*
		6.b	If Other, then specify: _____
		7.a	CMDOSFRM ___ ___ Dosage Form *(Use codes on next page) (If other, specify in 7.b)*
		7.b	If Other, then specify: _____
		8.a	CMROUTE Route of Administration *(Use codes on next page) (If other, specify in 8.b)*
		8.b	If Other, then specify: _____
		9.a	CMDOSFRQ ___ Frequency *(Use codes on next page) (If other, specify in 9.b)*
		9.b	If Other, then specify: _____
		10.	CMSTDTC __ __/__ __/__ __ __ __ (mm / dd / yyyy) Date added or dosage changed *(Enter date medication was first taken or date when dosage or frequency was modified)*
Yes	No		
1	0	11.a	CMENRF Is the medication continuing at the same dose and frequency? *(If NO, enter the date discontinued or dosage changed in 11b)*
		11.b	CMENDTC __ __/__ __/__ __ __ __ (mm / dd yyyy) Date discontinued/changed *(If the dosage or frequency was modified, enter date of termination and re-enter as a new medication with the new dosage and/or frequency)*

DATA NOT STORED

QNAM=CMFORAE
QLABEL=DRUG BEING GIVEN FOR TREATMENT OF AE
IDVAR=CMSEQ

QNAM=CMAENUM
QLABEL=MEDICATION AE NUMBER
IDVAR=CMSEQ

Site ID: ☐☐ - ☐☐ CTP Location	USUBJID Participant ID ☐☐☐☐	Visit Date: __ __ / __ __ / __ __ __ __ CMDTC m m d d y y y y

Routes of Administration (ICH-m2 Numeric Codes)

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

Dosage Form

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

Frequency

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

Dosage

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

12. Clinician Signature: THIS DATA NOT ENTERED

Date Signed: __ __ / __ __ / __ __ __ __

QNAM=CMSIG
QLABEL=MEDICATION SIGNATURE DATE
IDVAR=CMSEQ

13. Print Last Name, First Name: THIS DATA NOT ENTERED

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1
NODE: ☐☐	STUDYID	EPOCH Screening Baseline VISITNUM
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one)	-1 1 2 3 4 5 6 7 8 9 10 11 12 13
PARTICIPANT ID : ☐☐☐☐	USUBJID	14 15 16 17 18 19 20 21 22 23 24 25 26
		QSEVAL
Assessment Date: __ __ / __ __ / __QSDTC__ (mm / dd / yyyy)		STAFF ID: ☐ ☐ ☐ ☐ ☐
☐ FORM COMPLETION STATUS	1=Form completed as required 2=Participant refused 3=Responsible person did not complete	4=Not enough time at the visit 5=Participant did not attend visit 6=Other (specify: _____)

This assessment is to be administered by a Research Assistant.

QSTESTCD/QSTEST

__ __ 1. How old were you when you first smoked a cigarette?

__ __ 2. How old were you when you first started regular daily cigarette smoking?

__ __ __ 3. On average, how many cigarettes are you currently smoking per day?

__ __ __ 4. Over the past year how many cigarettes did you smoke per day?

__ __ __ 5. How many months have you been smoking?

6.a What brand of cigarettes or tobacco do you smoke most?

QSORRES

SPECIFY BRAND: _____

__ 6.b Length

1 = Regular
2 = 100's
3 = Other *(If other specify in 6.c)*

6.c If 6b = other (3), then specify other length: _____

__ 6.d Pack style

1 = Hard pack
2 = Soft pack

__ 7. Among your close friends and family, what percentage would you say smoke cigarettes?

0 = None
1 = Few
2 = Approximately 25%
3 = Approximately 50%
4 = Approximately 75%
5 = Approximately 100%

__ 8. Among the people that you use drugs or alcohol with currently, what percentage would you say smoke cigarettes?

0 = None
1 = Few
2 = Approximately 25%
3 = Approximately 50%
4 = Approximately 75%
5 = Approximately 100%

__ 9.a Are there any other cigarette smokers in your household/living arrangements?

1 = Yes *(if yes, then answer 9.b)*
0 = No

__ __ 9.b **IF YES, How many?**

__ 10. How much do the people closest to you want you to stop smoking? *(Choose one answer)*

0 = Not at all
1 = Not much
2 = Neutral
3 = Somewhat
4 = Very much

CTP - Site ID	USUBJID Participant ID	Visit Date: __ __ / __ __ / __ __ __ __ QSDTC
☐☐ - ☐☐	☐☐☐☐	m m d d y y y y

QSTESTCD/QSTEST

__ 11. If you were to stop, how helpful would the people closest to you be?

QSORRES

0 = Not helpful
1 = Not much help
2 = Neutral
3 = Somewhat helpful
4 = Very helpful

Yes	No		
1	0	12.a	Have you ever used non-cigarette tobacco products?
			If 12.a is yes, then circle an answer for each of the following:
1	0	12.b	Cigars
1	0	12.c	Pipes
1	0	12.d	Bidis (tobacco wrapped in a temburni leaf)
1	0	12.e	Smokeless tobacco (pan, chewing tobacco, snuff)

__ __ __ 13. How many times have you *attempted* to quit smoking?
(IF ZERO times, enter 000 and then answer questions 14 & 15, then stop.)

__ 14. Since you started smoking regularly, what is the longest time that you have gone without smoking any cigarettes? ***(Choose one answer)***

0 = Never gone without smoking
1 = Less than a day
2 = At least one day, but less than a week
3 = At least one week, but less than a month
4 = At least one month, but less than one year
5 = One year or more

__ 15.a Have you ever experienced uncomfortable symptoms when you stopped smoking?
(Choose one below)

0 = Does not apply – I have never stopped smoking
1 = I have stopped smoking in the past but never experienced uncomfortable symptoms
2 = I have stopped smoking in the past and have experienced uncomfortable symptoms

If yes, what symptoms did you experience when you stopped smoking?
(Circle an answer choice for each symptom)

Yes	No		
1	0	15.b	Craving
1	0	15.c	Decreased heart rate
1	0	15.d	Irritability
1	0	15.e	Anxiety
1	0	15.f	Increased eating
1	0	15.g	Restlessness
1	0	15.h	Difficulty concentrating
1	0	15.i	Other ***(If other, then specify in question 15.j)***
		15.j	Other SPECIFY: _____

Enter the number of times you have tried the following methods to stop smoking.
(If zero enter 000)

__ __ __ 16.a Self-help material (for example American Lung Association material, materials from your doctor, etc…)
__ __ __ 16.b A formal cessation program (for example with classes, group discussions, etc…)
__ __ __ 16.c A private consultation with your doctor or mental health physician
__ __ __ 16.d Hypnosis/Acupuncture
__ __ __ 16.e Nicotine medicated gum
__ __ __ 16.f Zyban
__ __ __ 16.g On your own (cold turkey)
__ __ __ 16.h Other ***(If other, then specify in question 16.i)***
16.i If 16h is chosen then please describe other: _____

CTP - Site ID	USUBJID Participant ID	Visit Date: __ __ / __ __ / __ __ __ __ (QSDTC)
☐☐ - ☐☐	☐☐☐☐	m m d d y y y y

QSTESTCD/QSTEST

__ 17.a Have you ever used nicotine skin patches?

1 = Yes *(IF Yes, complete 17.b through 17.d)*
0 = No

QSORRES
__ __ __ 17.b If you have used nicotine skin patches, how many times?

__ 17.c If you have used nicotine skin patches, did you have any problems with the patch?

1 = Yes
0 = No

17.d If 17.c was yes, please describe: _____

__ 18.a When was your last attempt to stop/quit smoking?

0 = Never attempted *(IF NEVER ATTEMPTED, stop)*
1 = Hours ago
2 = Days ago
3 = Weeks ago
4 = Months ago
5 = Years ago

18.b When was the date of the last attempt to quit smoking? __ __ / __ __ / __ __ __ __ *(mm / dd / yyyy)*

__ 18.c For how long did you go without smoking at that time?

0 = Never stopped
1 = Hours
2 = Days
3 = Weeks
4 = Months
5 = Years

18.d How did you stop? Please describe *(maximum of 200 characters)*:

_____

_____

18.e Why did you start again? Please describe *(maximum of 200 characters)*:

_____

_____

__ 19. What is the longest period of time you have gone without smoking?

1 = Hours
2 = Days
3 = Weeks
4 = Months
5 = Years

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ___

NODE: ☐☐

CTP-SITE ID: ☐☐-☐☐

PARTICIPANT ID : ☐☐☐☐

STUDYID

USUBJID

STUDY WEEK: *(circle one)*

EPOCH Screening Baseline VISITNUM

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QSEVAL

Assessment Date: ___ ___ / ___ ___ / ___ ___ ___ ___ *(mm / dd / yyyy)* QSDTC

STAFF ID: ☐ ☐ ☐ ☐ ☐

☐ FORM COMPLETION STATUS

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6=Other (specify: _____)

SMOKING ASSESSMENTS: QSTESTCD/QSTEST

___ 1. Exhaled air CO measurement (ppm): Measurement #1

___ 2. Exhaled air CO measurement (ppm): Measurement #2

___ . ___ 3. Average of Measurement #1 & #2

___ 4. Has the subject been continuously abstinent since the last visit?
(For Screening assessment, answer no. There is no prior visit)

QSORRES

0 = No
1 = Yes

___ . ___ 5. If question 4 is NO, indicate the average number of cigarettes smoked per day

___ 6. Has Participant used any other non-cigarette tobacco product? ***(If no, then stop)***

0 = No
1 = Yes

If the Participant answered yes to question 6, then indicate for each type of tobacco product below (7a thru 7d), indicate the average number per day.
(if, none, enter 00.00)

___ . ___ 7.a Cigars

___ . ___ 7.b Pipes

___ . ___ 7.c Bidis (tobacco wrapped in a temburni leaf)

___ . ___ 7.d Smokeless tobacco (pan, chewing tobacco, snuff)

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ___
NODE: ☐☐	STUDYID	EPOCH Screening Baseline VISITNUM
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one)	-1 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26
PARTICIPANT ID : ☐☐☐☐	USUBJID	
Assessment Date: __ __ / __ __ / __SCDTC__ (mm / dd / yyyy)		STAFF ID: ☐☐☐☐☐
☐ FORM COMPLETION STATUS	1=Form completed as required 2=Participant refused 3=Responsible person did not complete	4=Not enough time at the visit 5=Participant did not attend visit 6=Other (specify:)

1. **Date informed consent was signed:** __ __ / __ __ / __ __ __ __ (mm / dd/ yyyy)
   SCTEST SCORRES

2. **Clinician Signature:** THIS DATA NOT ENTERED _____

   Date Signed: __ __ / __ __ / __ __ __ __
   SCTEST SCORRES

3. **Print Last Name, First Name:** THIS DATA NOT ENTERED _____

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ____

NODE: ☐☐ STUDYID

CTP-SITE ID: ☐☐-☐☐ STUDY WEEK: (circle one)

PARTICIPANT ID : ☐☐☐☐ USUBJID

EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

Assessment Date: __ __ / __ __ / __ __ __ __ VSDTC (mm / dd / yyyy) STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

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4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

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

VSTEST
VSORRES __ __ __ . __ 2.a Temperature (*oral*)

__ 2.b Measure VSORRESU

1 = Degrees Fahrenheit
2 = Degrees Celsius

__ __ __ / __ __ __ 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=VSDTC or VISITNUM

8. Clinician Signature: THIS DATA NOT ENTERED

Date Signed: __ __ / __ __ / __ __ __ __

QNAM=VSSIG
QLABEL=VITALS SIGNATURE DATE
IDVAR=VISITNUM

9. Print Last Name, First Name: THIS DATA NOT ENTERED

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs
NODE: ☐☐	STUDYID
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one)
PARTICIPANT ID : ☐☐☐☐	USUBJID

EPOCH Screening Baseline VISITNUM

-1 1 2 3 4 5 6 7 8 9 10 11 12 13
14 15 16 17 18 19 20 21 22 23 24 25 26

Assessment Date: ___ ___ / ___ ___ / ___BRDTC___ (mm / dd / yyyy) STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

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

2. 0.__ __ __ BrAC Alcohol Breathalyzer result
   BRORRESU

3. COMMENTS:

DOMAIN: CO
COVAL
RDOMAIN=BR
IDVAR=VISITNUM

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ___

NODE: ☐☐ STUDYID

CTP-SITE ID: ☐☐-☐☐ STUDY WEEK: (circle one) EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

PARTICIPANT ID : ☐☐☐☐ USUBJID QSEVAL

Assessment Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy) QSDTC STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

Composite Scores

(for site use only):

Medical:	_____	Legal:	_____
Employment:	_____	Family:	_____
Drug:	_____	Psychiatric:	_____
Alcohol:	_____		

KEY:

Patient Rating Scale
0 = Not at all
1 = Slightly
2 = Moderately
3 = Considerably
4 = Extremely

Interviewer Severity Ratings
0-1 = No real problem, treatment not necessary
2-3 = Slight problem, treatment probably not necessary
4-5 = Moderate problem, treatment probably necessary
6-7 = Considerable problem, treatment necessary
8-9 = Extreme problem, treatment absolutely necessary

Hollingshead Categories	
1 =	Higher Executive, Doctoral Level Professional, Owner of Large Business
2 =	Business Manager, Owner (medium sized business), Other Professional (nurse, optician, pharmacist, social worker, teacher)
3 =	Administrative Personnel, Manager, Owner/Proprietor of Small Business (bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent)
4 =	Clerical and Sales, Technician, Owner of Small Business (bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary, car salesperson)
5 =	Skilled Manual—usually having had training (baker, barber, brakeman, chef, electrician, fireman, lineman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, police officer, plumber)
6 =	Semi-skilled (hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator)
7 =	Unskilled (attendant, janitor, construction help, unspecified labor, porter). Include unemployed.
8 =	Homemaker
9 =	Student/No occupation/disabled

Throughout the ASI, when noted:

Use X when question not answered.
Use N when question is not applicable

CTP - Site ID	USUBJID Participant ID	Assessment Date: __ __ / __ __ / __ __ __ __ (QSDTC)
☐☐-☐☐	☐☐☐☐	m m / d d / y y y y

GENERAL INFORMATION =QSSCAT

QSTEST

__ __/__ __/__ __ __ __ 4. Date of Admission
m m d d y y y y

_____ 8. Class:
QSORRES
1=Intake
2=Follow up

_____ 9. Contact code:
1=In person
2=Telephone (Intake ASI must be in person)
3=Mail
X=Not Answered

_____ 10. Gender:
1=Male
2=Female
X=Not Answered

_____ 12. Special:
1=Patient terminated
2=Patient refused
3=Patient unable to respond
N=Not Applicable

QSORRESU=YEAR / QSORRESU=MONTH

____/____ 14. How long have you lived at your current address? *(XX/XX=Not Answered)*
a. Yrs. b. Mos.

_____ 17. Of what race do you consider yourself?
1=White (Not Hispanic)
2=Black (Not Hispanic)
3=American Indian
4=Alaskan Native
5=Asian/Pacific
6=Hispanic-Mexican
7=Hispanic-Puerto Rican
8=Hispanic-Cuban
9=Other Hispanic
X=Not Answered

_____ 18. Do you have a religious preference?
1=Protestant
2=Catholic
3=Jewish
4=Islamic
5=Other (specify_____)
6=None
X=Not Answered

_____ 19. Have you been in a controlled environment in the past 30 days?
A place, theoretically, without access to drugs/alcohol.
1=No
2=Jail
3=Alcohol or Drug Treatment
4=Medical Treatment
QSEVLINT=-P30D
5=Psychiatric Treatment
6=Other (specify_____)
X=Not Answered

__ __ 20. How many days? QSEVLINT=-P30D QSORRESU=DAY
"NN" if question 19 is "No". Refers to total number of days detained in the past 30 days. *(XX=Not Answered)*

Comments:

THIS DATA NOT ENTERED

CTP - Site ID	Participant ID (USUBJID)	Assessment Date: __ __ / __ __ / __ __ __ __ (QSDTC)
☐☐-☐☐	☐☐☐☐	m m / d d / y y y y

MEDICAL STATUS =QSSCAT

QSTEST

___ ___ 1. How many times in your life have you been hospitalized for medical problems?

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

QSORRES

_____ 3. Do you have any chronic medical problems which continue to interfere with your life?

0=No, 1=Yes

A chronic medical condition is a serious physical or medical condition that requires regular care, (i.e., medication, dietary restriction) preventing full advantage of their abilities. *(X=Not Answered)*

If "Yes," specify: _____

_____ 4. Are you taking any prescribed medication on a regular basis for a physical problem?

0=No, 1=Yes

Medication prescribed by a MD for medical conditions; not psychiatric medicines. Include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems. *(X= Not Answered)*

If "Yes," specify: _____

_____ 5. Do you receive a pension for a physical disability? *(X= Not Answered)*

0=No, 1=Yes

Include Workers' compensation, exclude psychiatric disability.

If "Yes," specify: _____

___ ___ 6. How many days have you experienced medical problems in the past 30 days?

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

QSORRESU=DAY QSEVLINT=-P30D

For Questions 7 & 8, please ask the patient to use the Patient Rating scale.

_____ 7. How troubled or bothered have you been by these medical problems in the past 30 days?

Restrict response to problem days of Question 6. *(X=Not Answered)*

QSEVLINT=-P30D

_____ 8. How important to you now is treatment for these medical problems?

Refers to the need for new or additional medical treatment by the patient. *(X=Not Answered)*

CONFIDENCE RATINGS

Is the above information significantly distorted by:

_____ 10. Patient's misrepresentation?

0=No, 1=Yes

_____ 11. Patient's inability to understand?

0=No, 1=Yes

COMMENTS:

THIS DATA NOT ENTERED

CTP - Site ID	Participant ID	Assessment Date:
☐☐-☐☐	USUBJID ☐☐☐☐	QSDTC __ __ / __ __ / __ __ __ __ (m m / d d / y y y y)

EMPLOYMENT/SUPPORT STATUS =QSSCAT

QSORRESU=YEAR / QSORRESU=MONTH

__ __ / __ __ a. Yrs. / b. Mos.

1. Education completed? QSTEST

GED = 12 years. Include formal education only. *(XX/XX=Not Answered)*

QSORRESU=MONTH

__ __ Mos.

2. Training or technical education completed:

Formal/organized training only. For military training, only include training that can be used in civilian life (i.e., electronics or computers). *(XX=Not Answered)*

QSORRES

4. Do you have a valid driver's license? Valid license; not suspended/revoked. *(X=Not Answered)*

_____ 0=No, 1=Yes

5. Do you have an automobile available? (If answer to Q4 is "No", then Q5 must be "No")

_____ 0=No, 1=Yes

Does not require ownership, only requires availability on a regular basis. *(X=Not Answered)*

QSORRESU=YEAR / QSORRESU=MONTH

__ __ / __ __ a. Yrs. / b. Mos.

6. How long was your longest full time job?

Full time = 35+ hours weekly; does not necessarily mean most recent job. *(XX/XX=Not Answered)*

_____

7. Usual (or last) occupation? (specify): _____

(use Hollingshead Categories Reference Sheet) *(X=Not Answered)*

_____ 0=No, 1=Yes

9. Does someone contribute the majority of your support?

Is patient receiving any regular support (i.e., cash, food, housing) from family/friend? Include spouse's contribution; exclude support by an institution. *(X=Not Answered)*

_____

10. Usual employment pattern, past three years?

QSEVLINT=-P3Y

1 = Full time (35+ hrs/wk)	4 = Student	7 = Unemployed
2 = Part time (regular hours)	5 = Military Service	8 = In controlled environment
3 = Part time (irreg., daywork)	6 = Retired/Disability	*(X=Not Answered)*

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

QSORRESU=DAY

__ __ __

QSEVLINT=-P30D

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

Include "under the table" work, paid sick days, and vacation. *(XX=Not Answered)*

Max=$99999

For questions 12-17: How much money did you receive from the following sources in the past 30 days?

$ __ __ __ __ __

12. Employment (net income)? (Net or "take home" pay, include any "under the table" money.) *(XXXXX=Not Answered)*

$ __ __ __ __ __

13. Unemployment Compensation? *(XXXXX=Not Answered)*

$ __ __ __ __ __

14. Welfare? (Include food stamps, transportation money provided by an agency to go to and from treatment.) *(XXXXX=Not Answered)*

QSEVLINT=-P30D

QSORRESU=DOLLAR

$ __ __ __ __ __

15. Pensions, benefits or Social Security? (Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.) *(XXXXX=Not Answered)*

$ __ __ __ __ __

16. Mate, family or friends? (Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g., gambling). Record cash payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.). *(XXXXX=Not Answered)*

CTP - Site ID	Participant ID	Assessment Date:
☐☐-☐☐	USUBJID ☐☐☐☐	QSDTC __ __ / __ __ / __ __ __ __ (m m / d d / y y y y)

QSTEST

$ QSORRES __ __ __ __ __ 17. Illegal? *(XXXXX=Not Answered)*

___ ___ Max = 99

18. How many people depend on you for the majority of their food, shelter, etc.?
Must be regularly depending on patient, do include alimony/child support, do not include the patient or self-supporting spouse, etc. *(X=Not Answered)*

___ ___

19. How many days have you experienced employment problems in the past 30 days?
Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized. *(XX=Not Answered)* QSEVLINT=-P30D QSORRESU=DAY

For Questions 20 & 21, ask the patient to use the Patient's Rating scale.

The patient's ratings in Questions 20 & 21 refer to Question 19. Stress help in finding or preparing for a job, not giving them a job.

_____

20. How troubled or bothered have you been by these employment problems in the past 30 days? QSEVLINT=-P30D
If the patient has been incarcerated or detained during the past 30 days, they cannot have employment problems. *(X=Not Answered)*

_____

21. How important to you now, is counseling for these employment problems? *(X=Not Answered)* QSEVLINT=-P30D

CONFIDENCE RATINGS

Is the above information significantly distorted by:

_____ 0=No, 1=Yes

23. Patient's misrepresentation?

_____ 0=No, 1=Yes

24. Patient's inability to understand?

COMMENTS:

THIS DATA NOT ENTERED

CTP - Site ID	Participant ID (USUBJID)	Assessment Date: __ __ / __ __ / __ __ __ __ (QSDTC)
☐☐-☐☐	☐☐☐☐	m m d d y y y y

DRUG/ALCOHOL USE =QSSCAT

Route of Administration Types:

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

Note the usual or most recent route. For more than one route, choose the most severe. The routes are listed from least severe to most severe. If Past 30 Days and Lifetime Use are zero, route should be coded as "N." *(XX=Not Answered)*

Substance (QSTEST)	a. Past 30 Days (QSEVLINT=-P30D; QSORRES)	b.Lifetime Use (Years)	c. Route of Admin.
01. Alcohol (any use at all)	__ __	__ __	
02. Alcohol (to intoxication)	__ __	__ __	
03. Heroin	__ __	__ __	_____
04. Methadone	__ __	__ __	_____
05. Other Opiates/Analgesics	__ __	__ __	_____
06. Barbiturates	__ __	__ __	_____
07. Other Sedatives/Hypnotics/Tranquilizers	__ __	__ __	_____
08. Cocaine	__ __	__ __	_____
09. Amphetamines	__ __	__ __	_____
10. Cannabis	__ __	__ __	_____
11. Hallucinogens	__ __	__ __	_____
12. Inhalants	__ __	__ __	_____
13. More than 1 substance per day (including alcohol)	__ __	__ __	

How many times have you: (QSTEST)

__ __ (QSORRES) 17. Had Alcohol DT's? Delirium Tremens (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake. Characterized by shaking, severe disorientation, fever, hallucinations, they usually require medical attention. *(XX=Not Answered)*

How many times in your life have you been treated for: Include detoxification, halfway houses, in/outpatient counseling, and AA or NA (if 3+ meetings within one month period). *(XX=Not Answered)*

__ __ 19. Alcohol abuse?

__ __ 20. Drug abuse?

How many of these were detox only?

__ __ 21. Alcohol? If Q19 ="00", then question Q21 is "NN" *(XX=Not Answered)*

__ __ 22. Drugs? If Q20 ="00", then question Q22 is "NN" *(XX=Not Answered)*

CTP - Site ID	USUBJID Participant ID	Assessment Date: __ __ / __ __ / __ __ __ __ QSDTC
☐☐-☐☐	☐☐☐☐	m m d d y y y y

QSORRES QSTEST

Max =$99999

How much money would you say you spent during the past 30 days on:
Only count actual money spent. What is the financial burden caused by drugs/alcohol? *(XXXXX=Not Answered)*

$ __ __ __ __ __ 23. Alcohol? QSEVLINT=-P30D QSORRESU=DOLLAR

$ __ __ __ __ __ 24. Drugs? QSEVLINT=-P30D QSORRESU=DOLLAR

___ ___ 25. How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days? *(Include AA/NA) (XX=Not Answered)*
QSEVLINT=-P30D QSORRESU=DAY

How many days in the past 30 have you experienced:
Include only: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to. *(XX=Not Answered)*

___ ___ 26. Alcohol problems? QSEVLINT=-P30D QSORRESU=DAY

___ ___ 27. Drug problems? QSEVLINT=-P30D QSORRESU=DAY

For questions 28 - 31, please ask the patient to use the Patient's Rating scale.
The Patient is rating the need for additional substance abuse treatment. *(X=Not Answered)*

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

_____ 28. Alcohol problems? QSEVLINT=-P30D

_____ 29. Drug problems? QSEVLINT=-P30D

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

_____ 30. Alcohol problems?

_____ 31. Drug problems?

CONFIDENCE RATINGS

Is the above information significantly distorted by:

_____ 0=No, 1=Yes 34. Patient's misrepresentation?

_____ 0=No, 1=Yes 35. Patient's inability to understand?

COMMENTS:

THIS DATA NOT ENTERED

CTP - Site ID	USUBJID Participant ID	Assessment Date: __ __ / __ __ / __ __ __ __ QSDTC
☐☐-☐☐	☐☐☐☐	m m d d y y y y

LEGAL STATUS =QSSCAT

QSORRES QSTEST

_____ 1. Was this admission prompted by the criminal justice system?
0=No, 1=Yes
Judge, probation/parole officer, etc. *(X=Not Answered)*

_____ 2. Are you on parole or probation?
0=No, 1=Yes
Note duration and level in comments. *(X=Not Answered)*

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

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

___ ___	3. Shoplifting/Vandalism	___ ___	10. Assault
___ ___	4. Parole/Probation Violations	___ ___	11. Arson
___ ___	5. Drug Charges	___ ___	12. Rape
___ ___	6. Forgery	___ ___	13. Homicide/Manslaughter
___ ___	7. Weapons Offense	___ ___	14. Prostitution
___ ___	8. Burglary/Larceny/B&E	___ ___	15. Contempt of court
___ ___	9. Robbery	___ ___	16. Other: (specify_____)

___ ___ 17. How many of these charges resulted in convictions?
If Q3-16="00", then Q17="NN". Do not include misdemeanor offenses from questions 18-20 below. Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas. *(XX=Not Answered)*

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

Do not include misdemeanor offenses.

___ ___ 18. Disorderly conduct, vagrancy, public intoxication? *(XX=Not Answered)*

___ ___ 19. Driving while intoxicated (DWI)? *(XX=Not Answered)*

___ ___ 20. Major driving violations?
Moving violations: speeding, reckless driving, no license, etc. *(XX=Not Answered)*

QSORRESU=MONTH

___ ___ 21. How many months were you incarcerated in your life? *(XX=Not Answered)*
Mos.
If incarcerated 2 weeks or more, round this up to 1 month. List total number of months incarcerated.

_____ 24 Are you presently awaiting charges, trial, or sentence? *(X=Not Answered)*
0=No, 1=Yes

___ ___ 25 What for? (Refers to Q24.) Use code 03-16, 18-20. If more than one, choose most severe.
Don't include civil cases, unless a criminal offense is involved. *(XX=Not Answered, NN= Not Applicable)*

03 = Shoplifting	09 = Robbery	15 = Contempt
04 = Probation violation	10 = Assault	16 = Other
05 = Drug	11 = Arson	18 = Disorderly conduct
06 = Forgery	12 = Rape	19 = DWI
07 = Weapons	13 = Homicide	20 = Major driving violation
08 = Burglary	14 = Prostitution	

CTP - Site ID	USUBJID Participant ID	QSDTC Assessment Date: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
☐☐-☐☐	☐☐☐☐	

QSORRES QSTEST QSEVLINT=-P30D QSORRESU=DAY

___ ___ 26. How many days in the past 30, were you detained or incarcerated?
Include being arrested and released on the same day. *(XX=Not Answered)*

QSEVLINT=-P30D QSORRESU=DAY

___ ___ 27. How many days in the past 30, have you engaged in illegal activities for profit?
Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross- checked with Question 17 under Employment/Family Support Section. *(XX=Not Answered)*

For questions 28 & 29, ask the patient to use the Patient's Rating scale.

_____ 28. How serious do you feel your present legal problems are? Exclude civil problems. *(X=Not Answered)*

_____ 29. How important to you now is counseling or referral for these legal problems?
Patient is rating a need for additional referral to legal counsel for defense against criminal charges. *(X=Not Answered)*

CONFIDENCE RATINGS

Is the above information significantly distorted by:

_____ 0=No, 1=Yes 31. Patient's misrepresentation?

_____ 0=No, 1=Yes 32. Patient's inability to understand?

COMMENTS:

THIS DATA NOT ENTERED

CTP - Site ID	USUBJID Participant ID	Assessment Date: __ __ / __ __ / __ __ __ __ (QSDTC)
☐☐-☐☐	☐☐☐☐	m m / d d / y y y y

FAMILY/SOCIAL RELATIONSHIPS =QSSCAT

QSORRES _____ QSTEST

1. Marital Status

   1 = Married 3 = Widowed 5 = Divorced
   2 = Remarried 4 = Separated 6 = Never Married
   Common-law marriage = "1." (Specify in comments) (X=Not Answered)

_____ 3. Are you satisfied with this situation? (Refers to Question 1)
0=No, 2=Yes, 1=Indifferent
Satisfied = generally liking the situation. *(X=Not Answered)*

_____ 4. Usual living arrangements (past 3 years):

QSEVLINT=-P3Y

1 = With sexual partner & children 4 = With parents 7 = Alone
2 = With sexual partner alone 5 = With family 8 = Controlled Environment
3 = With children alone 6 = With friends 9 = No stable arrangement

Choose arrangements most representative of the past 3 years. If there is an even split in time between these arrangements, choose the most recent arrangement. *(X=Not Answered)*

_____ 6. Are you satisfied with these arrangements?
0=No, 2=Yes, 1=Indifferent
Refers to response in Question 4. *(X=Not Answered)*

Do you live with anyone who:

_____ 7. Has a current alcohol problem? *(X=Not Answered)*
0=No, 1=Yes

_____ 8. Uses non-prescribed drugs? *(X=Not Answered)*
0=No, 1=Yes

_____ 9. With whom do you spend most of your free time?
1=Family, 2=Friends, 3=Alone
If a girlfriend/boyfriend is considered as a family by patient, then they must refer to them as family throughout this section, not a friend. Family is not to be referred to as "friend." *(X=Not Answered)*

_____ 10. Are you satisfied with spending your free time this way? (Refers to Question 9.)
0=No, 2=Yes, 1=Indifferent
A satisfied response must indicate that the person generally likes the situation. *(X=Not Answered)*

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

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

QSEVLINT=-P30D

a. Past 30 Days	b. Lifetime	0= No, 1= Yes, *(X= Not Answered, N= Not Applicable)*
_____	_____	18. Mother
_____	_____	19. Father
_____	_____	20. Brothers/Sisters
_____	_____	21. Sexual Partner/Spouse
_____	_____	22. Children
_____	_____	23. Other Significant Family (Specify) _____
_____	_____	24. Close Friends
_____	_____	25. Neighbors
_____	_____	26. Co-workers

CTP - Site ID	USUBJID Participant ID	Assessment Date: QSDTC
☐☐-☐☐	☐☐☐☐	___ ___ / ___ ___ / ___ ___ ___ ___ (m m / d d / y y y y)

a. Past 30 Days b. Lifetime — 0= No, 1= Yes *(X=Not Answered)*

QSEVLINT=-P30D QSTEST

Did any of these people (Question 18 - 26) abuse you?

QSORRES

_____ _____ 28. Physically? (Caused you physical harm.)

_____ _____ 29. Sexually? (Forced sexual advances/acts.)

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

___ ___ 30. With your family? *(XX= Not Answered)* QSEVLINT=-P30D QSORRESU=DAY

___ ___ 31. With other people (excluding family)? *(XX= Not Answered)* QSEVLINT=-P30D QSORRESU=DAY

For Questions 32-35, ask the patient to use the Patient Rating scale.

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

_____ 32. Family problems *(X= Not Answered)* QSEVLINT=-P30D

_____ 33. Social problems *(X= Not Answered)* QSEVLINT=-P30D

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

_____ 34. Family problems

Patient is rating his family's need for counseling for family problems, not whether they would be willing to attend. *(X= Not Answered)*

_____ 35. Social problems

Include patient's need to seek treatment for such social problems as loneliness, inability to socialize, and dissatisfaction with friends. Patient rating should refer to dissatisfaction, conflicts, or other serious problems. Exclude problems that would be eliminated if patient had no substance abuse. *(X= Not Answered)*

CONFIDENCE RATING

Is the above information significantly distorted by:

_____ 37. Patient's misrepresentation?
0=No, 1=Yes

_____ 38. Patient's inability to understand?
0=No, 1=Yes

COMMENTS: THIS DATA NOT ENTERED

CTP - Site ID	USUBJID Participant ID	Assessment Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (m m / d d / y y y y) QSDTC
☐☐-☐☐	☐☐☐☐	

PSYCHIATRIC STATUS=QSSCAT

QSTEST

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

Do not include substance abuse, employment, or family counseling. Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days. Enter diagnosis in comments if known.

QSORRES

___ ___ 1. In a Hospital or inpatient setting? *(XX= Not Answered)*

___ ___ 2. Outpatient/private patient? *(XX= Not Answered)*

_____ 0=No, 1=Yes 3. Do you receive a pension for a psychiatric disability? *(X=Not Answered)*

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

a. Past 30 Days	b. Lifetime	0=No, 1=Yes, (*X= Not Answered*)
QSEVLINT=-P30D _____	_____	4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?
_____	_____	5. Experienced serious anxiety/tension-uptight, unreasonably worried, inability to feel relaxed?
_____	_____	6. Experienced hallucinations-saw things or heard voices that were not there?
_____	_____	7. Experienced trouble understanding, concentrating, or remembering?

For questions 8-10, patient could have been under the influence of alcohol/drugs.

_____	_____	8. Experienced trouble controlling violent behavior including episodes of rage, or violence? (Patient can be under the influence of alcohol/drugs.)
_____	_____	9. Experienced serious thoughts of suicide? Patient seriously considered a plan for taking his/her life.
_____	_____	10. Attempted suicide? (Include actual suicidal gestures or attempts.)
_____	_____	11. Been prescribed medication for any psychological or emotional problems? (Prescribed for the patient by MD. Record "Yes" if a medication was prescribed even if the patient is not taking it.)

___ ___ 12. How many days in the past 30 have you experienced these psychological or emotional problems? (This refers to problems noted in Questions 4-10.) *(XX= Not Answered)*

QSEVLINT=-P30D QSORRESU=DAY

CTP - Site ID	USUBJID Participant ID	Assessment Date: QSDTC
☐☐-☐☐	☐☐☐☐	___ ___ / ___ ___ / ___ ___ ___ ___ (m m / d d / y y y y)

QSTEST

For Question 13 & 14, ask the patient to use the Patient Rating scale.

QSORRES

_____ 13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days? (Patient should be rating the problem days from Question 12.) *(X= Not Answered)* QSEVLINT=-P30D

_____ 14. How important to you now is treatment for these psychological or emotional problems? *(X= Not Answered)*

CONFIDENCE RATING

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

_____ 22. Patient's misrepresentation?
0=No, 1=Yes

_____ 23. Patient's inability to understand?
0=No, 1=Yes

COMMENTS:

THIS DATA NOT ENTERED

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ____
NODE: ☐☐	STUDYID	EPOCH Screening Baseline VISITNUM
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one)	-1 1 2 3 **4** 5 6 7 **8** 9 10 11 12 **13**
PARTICIPANT ID : ☐☐☐☐	USUBJID	14 15 16 17 18 19 20 21 22 23 24 25 **26** QSEVAL
Assessment Date: ___ ___ / ___ ___ / ___QSDTC___ (mm / dd / yyyy)		STAFF ID: ☐☐☐☐☐
☐ FORM COMPLETION STATUS	1=Form completed as required 2=Participant refused 3=Responsible person did not complete	4=Not enough time at the visit 5=Participant did not attend visit 6=Other (specify:)

The Research Assistant is to complete the Header information on this Study Cover Sheet.

The Research Assistant is to complete the header information on the attached form in the following manner:

1. No identifying information may be collected on this study instrument.
2. Enter the date the assessment is being completed in the instrument's header.
3. Only the Participant's ID number are entered on the instrument's header
4. NO other header information should be entered on this instrument.

Once the Research Assistant has completed both the Cover Sheet & the Instruments header information he/she should hand the purchased form to the participant for completion.

Following the manuals instructions for the administration of this form, keep in mind that:

1. Respondents are to use the purchased form and choose only one statement for each question, including Item 16 (Changes in Sleeping Pattern) and Item 18 (Changes in Appetite).
2. If a participant has made multiple choices for an item, the choice with the highest rating is used and should be noted on the original form as the value to be entered into the data acquisition system.
3. For Items 16 & 18: Each of these items contains seven options rated, in order, as 0, 1a, 1b, 2a, 2b, 3a, 3b, to differentiate between increases and decreases in behavior or motivation. If a higher rated option is chosen by the respondent (1*x*, 2*x*, 3*x*), the presence of an increase or decrease in either symptom should be clinically noted.

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1
NODE: ☐☐	STUDYID	EPOCH Screening Baseline VISITNUM
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one)	-1 1 2 3 4 5 6 7 8 9 10 11 12 13
PARTICIPANT ID : ☐☐☐☐	USUBJID	14 15 16 17 18 19 20 21 22 23 24 25 26
Assessment Date: __ __ / __ __ / QSDTC __ __ (mm / dd / yyyy)		QSEVAL STAFF ID: ☐☐☐☐☐
☐ FORM COMPLETION STATUS	1=Form completed as required 2=Participant refused 3=Responsible person did not complete	4=Not enough time at the visit 5=Participant did not attend visit 6=Other (specify: _____)

QSTEST Please read each question below.
For each question enter the answer choice which best describes your responses.

__ 1. How soon after you wake up do you smoke your first cigarette?

QSORRES

(a) Within 5 minutes
(b) Within 6 – 30 minutes
(c) Within 31 – 60 minutes
(d) After 60 minutes

__ 2. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g., in church, at the library, at the movies, etc.?

(a) Yes
(b) No

__ 3. Which cigarette would you hate most to give up?

(a) The first one in the morning
(b) All others

__ 4. How many cigarettes per day do you smoke?

(a) 10 or less
(b) 11 –20
(c) 21 - 30
(d) 31 or more

__ 5. Do you smoke more frequently during the first hours after waking than during the rest of the day?

(a) Yes
(b) No

__ 6. Do you smoke if you are so ill that you are in bed most of the day?

(a) Yes
(b) No

DOMAIN: SC, DM, DS

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1

NODE: ☐☐ STUDYID

CTP-SITE ID: ☐☐-☐☐ STUDY WEEK: (circle one)

PARTICIPANT ID : ☐☐☐☐ USUBJID

EPOCH VISITNUM

Screening Baseline

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

14 15 16 17 18 19 20 21 22 23 24 25 26

Assessment Date: __ __ / __ __ / __ __ __ __ (mm / dd / yyyy) SCDTC/DSDTC

STAFF ID: ☐ ☐ ☐ ☐ ☐

☐ FORM COMPLETION STATUS

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5=Participant did not attend visit
6=Other (specify: _____)

YES	NO		SC.SCORRES SC.SCTEST
1	0	A.	Does the Participant continue to meet eligibility criteria? *If no, answer Question1 and then jump to Question 4 (skipping Questions 2 & 3).*

RANDOMIZATION

YES	NO		SC.SCORRES SC.SCTEST
1	0	1.	Was Participant randomized? *If no, skip to question 4. If yes, continue to question 2.*
2.a	__ __ __ __		Randomization number.
2.b	___		Randomization Group Assignment? 1 = Group 1 (Smoking Cessation) 2 = Group 2 (Treatment As Usual) DM.ARM
3.			Date of randomization: __ __ / __ __ / __ __ __ __ (mm / dd / yyyy) DM.RFSTDTC

If not randomized, reasons not randomized:

YES	NO		DS.DSOCCUR DS.DSTERM
1	0	4.a	Failed to return to clinic
1	0	4.b	Declined study participation (specify in comments below) DS.DSCAT=DISPOSITION EVENT
1	0	4.c	Moved from area (current or pending)
1	0	4.d	Incarceration (current or pending)
1	0	4.e	Death
1	0	4.f	Failed to meet inclusion criteria or met exclusion criteria
1	0	4.g	Other (if other, then specify in 4h)
		4.h	Specify Other: _____

5. Comments:

DOMAIN: CO
Variables COVAL-COVALN
RDOMAIN=DS
IDVAR=VISITNUM

FOR STAFF USE ONLY

		SC.SCTEST	SC.SCORRES
6.a	Initial Target Quit Date (TQD-01):		__ __ / __ __ / __ __ __ __
6.b	Initial Target Quit Day:		__ __ __
6.c	Start Date*:		__ __ / __ __ / __ __ __ __
6.d	Start Day:		__ __ __

*Start Date (& Study Day) is the date of 1First Smoking First Smoking Cessation Counseling Session for Group 1, OR the date the TAU group (Group 2) would have started Smoking Cessation Counseling if they HAD been randomized to Group 1. Start Day is the day number corresponding to the start date.

7. Signature:
(Study Clinician / Study Physician) _____ THIS DATA NOT ENTERED

Date signed: __ __ / __ __ / __ __ __ __ SC.SCTEST SC.SCORRES

QSCAT=RISK BEHAVIORS SURVEY

DOMAIN: QS

RISK BEHAVIORS SURVEY (RBS)

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1

STUDYID

NODE: ☐☐

CTP-SITE ID: ☐☐-☐☐ USUBJID

PARTICIPANT ID : ☐☐☐☐

STUDY WEEK: (circle one)

EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

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

STAFF ID: ☐☐☐☐☐ QSEVAL

☐ FORM COMPLETION STATUS

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4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

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.

QSSCAT = DRUG USE

A. DRUG USE

QSEVLINT=-P3OD →

QSTEST: 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. Have you ever used? (If no use, skip to next drug) QSORRES				b. How many days did you use ___ in the last 30 days? (If 00, do not ask parts c-f, and skip to next drug)	c. How many days did you inject ___ in the last 30 days? (If 00, skip to part e)	d. How many times a day did you inject ___? (Average # of injections/day)	e. How many days did you use ___ without injecting (smoking, snorting, swallowing) in the last 30 days? (If 00, then skip to next drug class)	f. How many times a day did you use ___without injecting?
		NO	YES	UNK	REF	QSORRESU=DAY			QSORRESU=DAY	
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	___ ___	___ ___	___ ___	___ ___	___ ___

Site ID: ☐☐ - ☐☐ (CTP / Location)	USUBJID Participant ID ☐☐☐☐	Visit Date: __ __ / __ __ / __ __ __ __ (m m / d d / y y y y) QSDTC

QSSCAT=DRUG INJECTION

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

QSTEST QSEVLINT=-P30D

__ __ __ 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? QSORRES
(If 0, then skip to B3)

__ __ __ 2. Of the times you injected after someone, how many times did you clean the works with full-strength bleach? *(Number cannot exceed total number of times used after a friend (qB1).*

__ __ __ 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 (through use of the same cooker/spoon or through front or back loading)?

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?

(IF NONE, ENTER 000 AND THE QUESTIONNAIRE IS COMPLETED)

__ __ __ 2. How many of your partners were female? *Number cannot exceed total number of people (qC1)*

__ __ __ 3. How many of your partners were male? *Number cannot exceed total number of people (qC1)*

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

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		

___ 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=SEXUAL ACTIVITY – CLIENT WITH FEMALE PARTNER

D. Ask Male/Female Clients who had Female Partners

__ __ __ 1.a How many women performed oral sex ("went down") on you?
(If 0, then skip to question 2a. Number cannot exceed total number of female partners (qC2))

__ __ 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?
(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 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)?

Site ID: ☐☐ - ☐☐ (CTP / Location) USUBJID Participant ID ☐☐☐☐ Visit Date: __ __ / __ __ / __ __ __ __ (m m / d d / y y y y) QSDTC

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=SEXUAL ACTIVITY – MALE CLIENT WITH FEMALE PARTNER

QSEVLINT=-P30D

E. Ask Male Clients who had Female Partners:

__ __ __ 1.a How many women did you have vaginal sex with? QSTEST

(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?

__ 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?

QSSCAT=SEXUAL ACTIVITY – MALE CLIENT WITH MALE PARTNER

F. Ask Male Clients who had 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=SEXUAL ACTIVITY – CLIENT WITH MALE PARTNER

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)?

QSSCAT=SEXUAL ACTIVITY – FEMALE CLIENT WITH MALE PARTNER

H. Ask Female Clients who had 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=SEXUAL ACTIVITY – CLIENT WITH MALE PARTNER

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?

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ____

NODE: ☐☐

CTP-SITE ID: ☐☐-☐☐ STUDYID

PARTICIPANT ID : ☐☐☐☐ USUBJID

STUDY WEEK: *(circle one)*

EPOCH Screening Baseline VISITNUM

-1 1 2 3 4 5 6 7 **8** 9 10 11 12 **13**

14 15 16 17 18 19 20 21 22 23 24 25 **26**

QSEVAL

Assessment Date: __ __ / __ __ / __QSDTC__ *(mm / dd / yyyy)* STAFF ID: ☐ ☐ ☐ ☐ ☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

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

QSTEST

_____ 1. In general, would you say your health is:

QSORRES

1=Excellent
2=Very good
3=Good
4=Fair
5=Poor

_____ 2. Compared to one year ago, how would you rate your health in general now?

1=Much better now than one year ago
2=Somewhat better now than one year ago
3=About the same as one year ago
4=Somewhat worse now than one year ago
5=Much worse now than one year ago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

1=Yes, limited a lot
2=Yes, limited a little
3=No, not limited at all

_____ a. Vigorous activities such as running, lifting heavy objects, participating in strenuous sports

_____ b. Moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

_____ c. Lifting or carrying groceries

_____ d. Climbing several flights of stairs

_____ e. Climbing one flight of stairs

_____ f. Bending, kneeling, or stooping

_____ g. Walking more than a mile

_____ h. Walking several blocks

_____ i. Walking one block

_____ j. Bathing or dressing yourself

4. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(2=No, 1=Yes)* QSEVLINT=-P4W

_____ a. Cut down the amount of time you spent on work or other activities

_____ b. Accomplished less than you would like

_____ c. Were limited in the kind of work or other activities

_____ d. Had difficulty performing the work or other activities (for example, it took extra effort)

DOMAIN: QS

SF-36 =QSCAT

CTP - Site ID	USUBJID Participant ID	Visit Date: __ __ / __ __ / __ __ __ __ QSDTC
☐☐ - ☐☐	☐☐☐☐	m m d d y y y y

5. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)? *(2=No, 1=Yes)* QSTEST

QSORRES_____ a. Cut down the amount of time you spent on work or other activities

_____ b. Accomplished less than you would like

_____ c. Didn't do work or other activities as carefully as usual

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

1=Not at all
2=Slightly
3=Moderately
4=Quite a bit
5=Extremely

_____ 7. How much **bodily** pain have you had during the **past 4 weeks**?

1=None
2=Very mild
3=Mild
4=Moderate
5=Severe
6=Very severe

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

1=Not at all
2=A little bit
3=Moderately
4=Quite a bit
5=Extremely

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

1=All of the time
2=Most of the time
3=A good bit of the time
4=Some of the time
5=A little of the time
6=None of the time

QSEVLINT=-P4W

How much of the time during the **past 4 weeks**...

_____ a. did you feel full of pep?

_____ b. have you been a very nervous person?

_____ c. have you felt so down in the dumps that nothing could cheer you up?

_____ d. have you felt calm and peaceful?

_____ e. did you have a lot of energy?

_____ f. have you felt downhearted and blue?

_____ g. did you feel worn out?

_____ h. have you been a happy person?

_____ i. did you feel tired?

CTP - Site ID	USUBJID Participant ID	Visit Date: __ __ / __ __ / __ __ __ __ QSDTC
☐☐ - ☐☐	☐☐☐☐	m m d d y y y y

QSORRES QSTEST

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

    1=All of the time
    2=Most of the time
    3=Some of the time
    4=A little of the time
    5=None of the time

QSEVLINT=-P4W

11. How **true** or **false** is **each** of the following statements for you?

    1=Definitely true
    2=Mostly true
    3=Don't know
    4=Mostly false
    5=Definitely false

_____ a. I seem to get sick a little easier than other people.

_____ b. I am as healthy as anybody I know.

_____ c. I expect my health to get worse.

_____ d. My health is excellent.

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1

NODE: ☐☐ STUDYID

CTP-SITE ID: ☐☐-☐☐

PARTICIPANT ID : ☐☐☐☐ USUBJID

STUDY WEEK: (circle one) EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

QSEVAL

Assessment Date: __ __ / __ __ / __ __ __ __ QSDTC (mm / dd / yyyy) STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

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Smoker's Belief Questionnaire

QSTEST

QSORRES

____ 1. Please record the statement below that best agrees with your beliefs about smoking:

a) It is not possible to be addicted to cigarettes.
b) It is possible to be addicted to cigarettes but I, personally, am not addicted.
c) I am addicted to cigarettes, but less so than the average smoker.
d) I am addicted to cigarettes about as much as the average smoker.
e) I am addicted to cigarettes but more so than the average smoker.

____ 2. If I were to attempt to quit smoking for good, I think that: (Record one)

a) I would have a much easier time than most people who try to quit.
b) I would have an easier time than most people who try to quit.
c) I would do about as well as most people who try to quit.
d) I would have a more difficult time than most people who try to quit.
e) I would have a much more difficult time than most people who try to quit.

 DOMAIN: SU

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ___

NODE: ☐☐ STUDYID

CTP-SITE ID: ☐☐-☐☐ STUDY WEEK: (circle one)

PARTICIPANT ID : ☐☐☐☐ USUBJID

EPOCH Screening Baseline VISITNUM

-1 **1** 2 3 4 5 6 7 8 9 10 11 12 **13**

14 15 16 17 18 19 20 21 22 23 24 25 **26**

Assessment Date: ___ ___ / ___ ___ / ___SUDTC___ (mm / dd / yyyy) STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
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4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

There must be one Substance Use Report form completed for each day in the study. If the participant misses visits for more than one week the Research Assistant should complete all forms up to today's visit. This may require filling in forms for prior weeks, and possibly for a part of a current week.

For each day, circle an answer choice for each substance.

SUCAT=SUBSTANCE USE REPORT

SUTRT

SUOCCUR

Indicate which days drug use occurred for this study week.

Write Day corresponding to the date in this column. However, Only "day" 1 is entered into your data acquisition system	(A) DATE	(B) Alcohol	(C) Amphetamines	(D) Barbiturates	(E) Benzodiazepines	(F) Cannabinoids (THC)	(G) Cocaine	(H) Methadone (non-prescribed)	(I) Methamphetamines	(J) Opiates	(K) Phencyclidine (PCP)	(L) Hallucinogens	(M) Inhalants
		no yes	no yes	no yes	no yes	no yes	no yes	no yes	no yes	no yes	no yes	no yes	no yes
1.	_____	__/__SUSTDTC__	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1
2.	_____	__/__/____	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1
3.	_____	__/__/____	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1
4.	_____	__/__/____	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1
5.	_____	__/__/____	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1
6.	_____	__/__/____	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1
7.	_____	__/__/____	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1	0 1

8. COMMENTS: _____

DOMAIN: CO

~~COVAL~~

RDOMAIN=SU

IDVAR=VISITNUM

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ____

NODE: ☐☐ STUDYID

CTP-SITE ID: ☐☐-☐☐ STUDY WEEK: (circle one)

PARTICIPANT ID : ☐☐☐☐ USUBJID

EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

QSEVAL

Assessment Date: ___ ___ / ___ ___ / ___ QSDTC ___ (mm / dd / yyyy) STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify:)

Instructions: Each statement describes how a person might feel when starting therapy or approaching problems in their lives. Please indicate the extent to which you tend to agree or disagree with each statement by circling the corresponding number. In each case, make your choice in terms of **how you feel right now**, not what you have felt in the past or would like to feel. For all the statements that refer to your "problem", answer in terms of problems related to your drug or alcohol use. The words "here" and "this place" refers to this substance abuse treatment program.

QSORRES

	QSTEST	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1.	As far as I'm concerned, I don't have any problems that need changing.	1	2	3	4	5
2.	I think I might be ready for some self-improvement.	1	2	3	4	5
3.	I am doing something about the problems that had been bothering me.	1	2	3	4	5
4.	It might be worthwhile to work on my problem	1	2	3	4	5
5.	I'm not the problem one. It doesn't make much sense for me to be here.	1	2	3	4	5
6.	It worries me that I might slip back on a problem I have already changed, so I am here to seek help.	1	2	3	4	5
7.	I am finally doing some work on my problem.	1	2	3	4	5
8.	I've been thinking that I might want to change something about myself.	1	2	3	4	5
9.	I have been successful in working on my problem but I'm not sure I can keep up the effort on my own.	1	2	3	4	5
10.	At times my problem is difficult, but I'm working on it.	1	2	3	4	5
11.	Being here is pretty much a waste of time for me because the problem doesn't have to do with me.	1	2	3	4	5
12.	I am hoping this place will help me to better understand myself.	1	2	3	4	5
13.	I guess I have faults, but there's nothing that I really need to change.	1	2	3	4	5
14.	I'm really working hard to change.	1	2	3	4	5

CTP - Site ID	USUBJID Participant ID	Assessment Date: QSDTC
☐☐ - ☐☐	☐☐☐☐	___ ___ / ___ ___ / ___ ___ ___ ___ (m m d d y y y y)

QSORRES

	QSTEST	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
15.	I have a problem and I really think I should work on it.	1	2	3	4	5
16.	I'm not following through with what I had already changed as well as I had hoped, and I'm here to prevent a relapse of the problem.	1	2	3	4	5
17.	Even though I'm not always successful in changing, I am at least working on my problem.	1	2	3	4	5
18.	I thought once I had resolved the problem I would be free of it, but sometimes I still find myself struggling with it.	1	2	3	4	5
19.	I wish I had more ideas on how to solve my problem.	1	2	3	4	5
20.	I have started working on my problem but I would like help.	1	2	3	4	5
21.	Maybe this place will be able to help me.	1	2	3	4	5
22.	I may need a boost right now to help me maintain the changes I've already made.	1	2	3	4	5
23.	I may be part of the problem, but I don't really think I am.	1	2	3	4	5
24.	I hope that someone here will have some good advice for me.	1	2	3	4	5
25.	Anyone can talk about changing; I'm actually doing something about it.	1	2	3	4	5
26.	All this talk about psychology is boring. Why can't people just forget about their problems?	1	2	3	4	5
27.	I'm here to prevent myself from having a relapse of my problem.	1	2	3	4	5
28.	It is frustrating, but I feel I might be having a recurrence of a problem I thought I had resolved.	1	2	3	4	5
29.	I have worries but so does the next guy. Why spend time thinking about them?	1	2	3	4	5
30.	I am actively working on my problem.	1	2	3	4	5
31.	I would rather cope with my faults than try to change them.	1	2	3	4	5
32.	After all I had done to try and change my problems, every now and again it comes back to haunt me.	1	2	3	4	5

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ___

NODE: ☐☐ STUDYID

CTP-SITE ID: ☐☐-☐☐ STUDY WEEK: (circle one)

PARTICIPANT ID : ☐☐☐☐ USUBJID

EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

Assessment Date: __ __ / __ __ / __ __ __ __ (mm / dd / yyyy) STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

QNAM=LBVISDTC
QLABEL=LAB VISIT DATE
IDVAR = LBSEQ

__ 1a. Was sample collected? *(If no, 1b must be answered)*
0 = No
1 = Yes

__ 1b. Why was a sample not collected?
1 = Participant did not attend
2 = Participant refused
3 = Other *(If other specify in 2c)*

LBSTAT/LBREASND

1c. If other, specify: _____

__ __ / __ __ / __ __ __ __ 2. Collection date *(mm / dd / yyyy)*

LBDTC

__ __ : __ __ 3. Collection time *(24 hours, hh:mm)*

LBSPID

__ __ __ __ __ __ __ __ 4. Northwest Toxicology number *(NWT barcode)*

QNAM = LBSHIP
QLABEL = SAMPLE SHIPPED
IDVAR=LBSEQ

THIS DATA NOT ENTERED __ __ 5. Subject Name Code

__ 6a. Was the sample shipped? *(If no, 6b must be answered; if Yes skip to question 6c)*
0 = No
1 = Yes

QNAM = SHIPDTC
QLABEL = DATE URINE SHIPPED
IDVAR=LBSEQ

__ 6b. If sample was not shipped, why?
1 = Sample invalid
2 = Urine lost
3 = Too little urine collected

QNAM = LBNOSHIP
QLABEL = REASON URINE NOT SHIPPED
IDVAR=LBSEQ

__ __ / __ __ / __ __ __ __ 6c. Date sample was shipped. *(mm / dd / yyyy)*

__ __ __ __ __ 7. Who shipped the sample? *(Staff ID)*

QNAM = LBSHIPBY
QLABEL = SHIPPED BY
IDVAR=LBSEQ

Additional values captured from the Northwest Toxicology Urinalysis lab file.

URINE DRUG SCREEN (UDS) LBCAT=DRUG SCREEN **DOMAIN: LB**

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ___

NODE: ☐☐ STUDYID

CTP-SITE ID: ☐☐-☐☐ STUDY WEEK: (circle one)

PARTICIPANT ID : ☐☐☐☐ USUBJID

EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

Assessment Date: ___ ___ / ___ ___ / _____ ___ ___ (mm / dd / yyyy) STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

QNAM=LBVISDTC
QLABEL=LAB VISIT DATE
IDVAR = LBSEQ

1. ___ ___ / ___ ___ / ___ ___ LBDTC Date urine collected (mm/dd/yyyy)

2. _____ Urine temperature within expected range?
0 = No
1 = Yes
9 = Unknown
(Temperature 92°F ≤ X ≤ 96°F OR ≥ 33.3°C)

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

LBORRES

(Circle number for each question) LBTEST	Negative	Positive	Unclear or Equivocal	Results Not Valid	Not Assessed
3. Amphetamines	0	1	2	3	8
4. Barbiturates	0	1	2	3	8
5. Benzodiazepines	0	1	2	3	8
6. Cocaine metabolites	0	1	2	3	8
7. Methamphetamines	0	1	2	3	8
8. Methadone	0	1	2	3	8
9. Opiates/Morphine	0	1	2	3	8
10. Phencyclidine (PCP)	0	1	2	3	8
11. Tricyclic Antidepressants	0	1	2	3	8
12. Cannabinoids (THC)	0	1	2	3	8

13. _____ Was this urine collection supervised?
0 = No
1 = Yes
9 = Unknown

QNAM = LBSUPER
QLABEL = URINE COLLECTION SUPERVISED
IDVAR = LBSEQ

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ___
NODE: ☐☐	STUDYID	EPOCH Screening Baseline VISITNUM
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one)	-1 1 2 3 4 5 6 7 8 9 10 11 12 13
PARTICIPANT ID : ☐☐☐☐	USUBJID	14 15 16 17 18 19 20 21 22 23 24 25 26
Assessment Date: ___ ___ / ___ ___ / AEDTC ___ (mm / dd / yyyy)		STAFF ID: ☐☐☐☐☐
☐ FORM COMPLETION STATUS	1=Form completed as required 2=Participant refused 3=Responsible person did not complete	4=Not enough time at the visit 5=Participant did not attend visit 6=Other (specify: _____)

	Yes	No		
AESEQ	1	0	1.	Did the participant have any new adverse events since the last visit? *If YES, continue.* IF NO, THEN NO RECORD EXISTS IN SDTM AE FILE *If NO, skip to question 16 and sign and Date.*
			AESPID__ 2.a	Adverse Event Number
			2.b	Adverse Event Term: AETERM (AEDECOD, AEBODSYS)
			2.c	Adverse Event Description: *(Max 200 characters. One adverse event per form. List syndrome components on separate forms)* QNAM = AEDESC QLABEL = AE DESCRIPTION IDVAR = AESEQ
			__ 3.	Type of Report: 1 = New Adverse Event 2 = Change in severity of an existing Adverse Event QNAM = AETYPE QLABEL = AE TYPE OF REPORT IDVAR = AESEQ
			AESTDTC __ __ - __ __ - __ __ __ __ 4.a	Date of onset (or change) of event *(mm / dd / yyyy)*
			AESTDTC __ __ : __ __ 4.b	Time of onset of event *(hh:mm Use 24 hour clock)*
			AEREL__ 5.	Study Drug Related 1=Definitely 2=Possibly 3=Definitely Not 9=Unknown
			AESEV__ 6.	Severity 1 = Mild 2 = Moderate 3 = Severe 4 = Life Threatening
			AEACN__ 7.	Action Taken Regarding Study Drug 1 = None 2 = Discontinued Permanently 3 = Discontinued Temporarily 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose 8 = Not Applicable 9 = Unknown

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

Site ID: ☐☐ - ☐☐ CTP Location	USUBJID Participant ID ☐☐☐☐	Visit Date: __ __ / __ __ / __ __ __ __ AEDTC (m m d d y y y y)

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

AECONTRT

QNAM = AEMED1-3
QLABEL = AE MEDICATION NUMBER 1-3
IDVAR = AESEQ

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

AEACNOTH

AEOUT __

10. Outcome
1 = Resolved
2 = Resolved with sequelae
3 = Not resolved
4 = Death*
9 = Unknown

Yes	No		
AESER 1	0	11.	Was the Adverse Event Serious? *
AEENRF 1	0	12.	Is the Adverse Event continuing? (Same event, same severity) ***If YES, skip to question 16 and sign and Date.*** ***If NO, continue to question 13.***
1	0	13.	Did the Adverse Event resolve or change in severity? ***If YES, continue to 14.*** ***If NO, continue to 16 and sign and Date.***

QNAM = AESEVCHG
QLABEL = AE SEVERITY CHANGE
IDVAR = AESEQ

If an Adverse Event has resolved or changed in severity then either question 14 (duration) OR questions 15.a and 15.b (date & time of change) 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 __ __ __ - __ __ - __ __	14.	If the Adverse Event has resolved or the severity has changed, then estimate the duration to the best of your ability. ***(days – hours-- minutes)***
__ __ / __ __ / __ __ __ __	15.a	Date of resolution or change in severity? ***(mm / dd / yyyy)***
__ __ : __ __	15.b	Time of resolution or change in severity? ***(hh:mm, 24 hour clock)***
	16.	**STUDY CLINICIAN'S SIGNATURE:** _____ **DATE SIGNED:** __ __ / __ __ / __ __ __ __

THIS DATA NOT ENTERED

QNAM = AESIGDTC
QLABEL = AE SIGNATURE DATE
IDVAR = AESEQ

QNAM = AECHGDTC
QLABEL = AE INTENSITY CHANGE DATE
IDVAR = AESEQ

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

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

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ___

NODE: ☐☐

CTP-SITE ID: ☐☐-☐☐

PARTICIPANT ID : ☐☐☐☐

STUDY WEEK: *(circle one)*

Screening Baseline

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

14 15 16 17 18 19 20 21 22 23 24 25 26

Date of this Report: __ __ / __ __ / __ __ __ __ *(mm / dd / yyyy)*

STAFF ID: ☐ ☐ ☐ ☐ ☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify:)

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

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

_____ 3. **Group Assignment**

__ __ / __ __ / __ __ __ __ 4. **Date of First Study Treatment**

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

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

EVENT CONTACT PERSON

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

(_ _ _) _ _ _ - _ _ _ _ x _ _ _ _ 6.b **Phone Number of Person to whom SAE questions should be addressed.**

PARTICIPANT DATA

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

__ __ 8. **Age**

___ 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_____)

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

___ 10.b **Units**
1=pounds
2=kilograms

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: _____)

__ __ __ 12.a **Adverse Event Number**

_____ 12.b **Adverse Event Term**

Site ID	Participant ID	Report Date:
☐☐☐☐	☐☐☐☐	__ __ / __ __ / __ __ __ __ (m m / d d / y y y y)

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

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

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)*

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)* _____

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?

NO	YES		STUDY DRUG INFORMATION
0	1	23.	Is Study Drug information known?
0	1	24.	Are there more than 4 Study Drugs or other concomitant medications for which information is known? If yes, please fill out the Serious Adverse Events Addendum.

Site ID	Participant ID	Report Date:
☐☐☐☐	☐☐☐☐	__ __ / __ __ / __ __ __ __ (m m d d y y y y)

For Route, Frequency, Dosage & Dosage Form, use Dosage Administration Coding Sheet page 5. For all codes marked other, specify in the shaded spaces provided.

COMPLETE FOR STUDY DRUG

Study Drug Name	b. Lot #	c. Expiration Date	d. Route	e. Frequency	f. Quantity	g. Dosage	h. Dosage Form	i. Start Date	j. Stop Date	k. Continuing No	k. Continuing Yes
25.a (max. 50 char.)		__/__/____ Other:						__/__/____	__/__/____	0	1
26.a (max. 50 char.)		__/__/____ Other:						__/__/____	__/__/____	0	1
27.a (max. 50 char.)		__/__/____ Other:						__/__/____	__/__/____	0	1
28.a (max. 50 char.)		__/__/____ Other:						__/__/____	__/__/____	0	1

Lot Number and Expiration Date, if unknown, are not necessary for concomitant medications.

COMPLETE FOR CONCOMITANT DRUGS

Concomitant Drug Name	b. Lot #	c. Expiration Date	d. Route	e. Frequency	f. Quantity	g. Dosage	h. Dosage Form	i. Start Date	j. Stop Date	k. Continuing No	k. Continuing Yes
29.a (max. 50 char.)		__/__/____ Other:						__/__/____	__/__/____	0	1
30.a (max. 50 char.)		__/__/____ Other:						__/__/____	__/__/____	0	1
31.a (max. 50 char.)		__/__/____ Other:						__/__/____	__/__/____	0	1
32.a (max. 50 char.)		__/__/____ Other:						__/__/____	__/__/____	0	1

NO DATA IN DATABASE

Site ID	Participant ID	Report Date: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
☐☐☐☐	☐☐☐☐	

ASSESSMENT OF SAE

___ 33. **Severity**
1 = Mild
2 = Moderate
3 = Severe
4 = Life Threatening

___ 34. **Expectedness**
1 = Expected
2 = Unexpected

___ 35.a **Outcome**
1 = Resolved
2 = Resolved with sequelae
3 = Not resolved
4 = Death* *(if Death, continue 35.b thru 35.d)*
9 = Unknown

__ __ / __ __ / __ __ __ __ 35.b **Date of Death**

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

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

_____

_____

___ 36. **Study Drug Related**
1 = Definitely
2 = Possibly
3 = Definitely not
9 = Unknown

ACTIONS RESULTING FROM SAE

___ 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): _____

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

PHYSICIAN SIGNATURE REQUIRED FOR MEDICATION TRIALS

40. NAME OF PHYSICIAN (please print): _____

SIGNATURE: _____ 41. Date signed: __ __/ __ __/ __ __ __ __

Site ID	Participant ID	Report Date: __ __ / __ __ / __ __ __ __ (m m d d y y y y)
☐☐☐☐	☐☐☐☐	

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

Dosage Administration Coding Sheet

Routes of Administration (ICH-m2 Numeric Codes)

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

Dosage Form

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

Frequency

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

Dosage

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

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: ___
NODE: ☐☐	STUDY WEEK: (circle one)	Screening: -1 1 2 3 4 5 6 7 — Baseline: 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26
CTP-SITE ID: ☐☐-☐☐		
PARTICIPANT ID : ☐☐☐☐		
Date of this Report: __ __ / __ __ / __ __ __ __ (mm / dd / yyyy)		STAFF ID: ☐ ☐ ☐ ☐ ☐
☐ FORM COMPLETION STATUS	1=Form completed as required 2=Participant refused 3=Responsible person did not complete	4=Not enough time at the visit 5=Participant did not attend visit 6=Other (specify: _____)

If you have answered yes to question 24 on the Serious Adverse Events form ***(Are there more than 4 Study Drugs or other concomitant medications for which information is known? If yes, please fill out the Serious Adverse Events Addendum.)*** then these drugs must be listed below.

Refer to the Serious Adverse Events form Dosage Administration Coding Sheet (page 5) for Route, Frequency, Dosage & Dosage Form. For all codes marked other, specify in the shaded spaces provided. *Lot Number and Expiration Date, if unknown, are not necessary for concomitant medications.*

	a. Drug Name (max. 50 char.)	b. Drug Type: Study	b. Drug Type: Con	c. Lot #	d. Expiration Date	e. Route	f. Frequency	g. Quantity	h. Dosage	i. Dosage Form	j. Start Date	k. Stop Date	l. Continuing: No	l. Continuing: Yes
1.		1	2	_____	__/____	___	___	___	___	___	__/__/____	__/__/____	0	1
				Other:		_____	_____	_____	_____	_____				
2.		1	2	_____	__/____	___	___	___	___	___	__/__/____	__/__/____	0	1
				Other:		_____	_____	_____	_____	_____				
3.		1	2	_____	__/____	___	___	___	___	___	__/__/____	__/__/____	0	1
				Other:		_____	_____	_____	_____	_____				
4.		1	2	_____	__/____	___	___	___	___	___	__/__/____	__/__/____	0	1
				Other:		_____	_____	_____	_____	_____				

NO DATA IN DATABASE

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1

NODE: ☐☐

CTP-SITE ID: ☐☐-☐☐ STUDYID

PARTICIPANT ID: ☐☐☐☐ USUBJID

STUDY WEEK: *(circle one)*

EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

QSEVAL

Assessment Date: ___ ___ / ___ ___ / ____ QSDTC ___ *(mm / dd / yyyy)* STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify:)

QSORRES

Staff Use Only

A. ___		Identify the primary substance of dependence as determined by DSM-IV checklist & addendum.
	1	= Alcohol
	2	= Amphetamine QSTEST
	3	= Cannabis
	4	= Cocaine
	5	= Hallucinogens
	6	= Inhalants
	7	~~= Nicotine~~
	8	= Opiates
	9	= PCP
	10	= Sedatives – Benzodiazepines
	11	= Other (specify: _____)

Please answer the following questions with regard to your Craving for the primary drug.

1.	___		The INTENSITY of my craving, that is, how much I desired this drug in the past 24 hours was:
		0	= None at all
		1	= Slight
		2	= Moderate
		3	= Considerable
		4	= Extreme
2.	___		The FREQUENCY of my craving, that is, how often I desired this drug in the past 24 hours was:
		0	= Never
		1	= Almost Never
		2	= Several Times
		3	= Regularly
		4	= Almost Constantly
3.	___		The LENGTH of time I spent in craving this drug during the past 24 hours was:
		0	= None at all
		1	= Very Short
		2	= Short
		3	= Somewhat Long
		4	= Very Long
4.	__ __		Write in the NUMBER of times you think you had craving for this drug during the past 24 hours.

CTP-Site ID	USUBJID Participant ID	Assessment Date: QSDTC
☐☐-☐☐	☐☐☐☐	__ __ / __ __ / __ __ __ __ (m m d d y y y y)

QSORRES QSTEST

B.	___	A second Craved substance during the past 24 hours was (choose only ONE from the following)	
		0	= None **(STOP)**
		1	= Alcohol
		2	= Amphetamine
		3	= Cannabis (Marijuana)
		4	= Cocaine
		5	= Hallucinogens (including ecstasy)
		6	= Inhalants
		7	= ~~Nicotine~~
		8	= Opiates (Heroine, Morphine, etc.)
		9	= PCP
		10	= Sedatives – Benzodiazepines (Barbiturates, downers, Valium, and Xanex)
		11	= Other (specify: _____)
Please answer the following questions with regard to a second craved drug:			
5.	___	The INTENSITY of my craving, that is, how much I desired this drug in the past 24 hours was:	
		0	= None at all
		1	= Slight
		2	= Moderate
		3	= Considerable
		4	= Extreme
6.	___	The FREQUENCY of my craving, that is, how often I desired this drug in the past 24 hours was:	
		0	= Never
		1	= Almost Never
		2	= Several Times
		3	= Regularly
		4	= Almost Constantly
7.	___	The LENGTH of Time I spent in craving this drug during the past 24 hours was:	
		0	= None at all
		1	= Very Short
		2	= Short
		3	= Somewhat Long
		4	= Very Long
8.	__ __	Write in the NUMBER of times you think you had craving for this drug during the past 24 hours.	

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1

NODE: ☐☐

CTP-SITE ID: ☐☐-☐☐ STUDYID

STUDY WEEK: (circle one)

PARTICIPANT ID : ☐☐☐☐ USUBJID

EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

Assessment Date: ___ ___ / ___ ___ / ___ ___ TUDTC (mm / dd / yyyy) STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

TUORRES TUTEST/TUTESTCD

___ 1. How many substance abuse counseling sessions were scheduled for the participant? *(0, 1, 2, 3, 4, 5)*
If zero sessions scheduled skip to question 7.a.

TUTEST/TUTESTCD

Circle answer choice for b thru d.
If Other is chosen for section d, then this must be specified in section e.

	(a) Scheduled Session Date	(b) Type		(c) Attended		TUORRES (d) If Not Attended, Why?				(e) If Other for Not Attended Specify
	TUSPID TUSTDTC	Individual	Group	No	Yes	Counselor cancelled	Participant cancelled	Other	Unk	
2.	__ __/__ __/__ __ __ __	1	2	0	1	1	2	3	9	_____
3.	__ __/__ __/__ __ __ __	1	2	0	1	1	2	3	9	_____
4.	__ __/__ __/__ __ __ __	1	2	0	1	1	2	3	9	_____
5.	__ __/__ __/__ __ __ __	1	2	0	1	1	2	3	9	_____
6.	__ __/__ __/__ __ __ __	1	2	0	1	1	2	3	9	_____

QNAM = TUEOTHER
QLABEL = NOT ATTENDED FOR OTHER REASON
IDVAR = TUSEQ

___ 7.a Is the participant still enrolled as a client at the CTP? ~~*(If No, then continue to 7.b, If Yes, then stop)*~~
0 = No
1 = Yes

___ 7.b During which study week was the participant dropped as a CTP client?
(Screening, Baseline, -1, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26)

___ 7.c If the participant is NOT still enrolled as a client at the CTP, WHY?
1 = Client completed program successfully
2 = Administratively discontinued
3 = Participant failed to adhere to CTP policy
4 = Self-withdrawal
5 = Referral
6 = Other *(if other reason, specify in 7.d)*

7.d If the participant is not still enrolled as a client at the CTP for "Other" reason, specify:

_____
_____

QNAM = TUENROTH
QLABEL = NOT ENROLLED FOR OTHER REASON
IDVAR = TUSEQ

WITHDRAWAL SCALE FOR TOBACCO =QSCAT

DOMAIN: QS

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: __ __

NODE: ☐☐

CTP-SITE ID: ☐☐ - ☐☐

PARTICIPANT ID : ☐☐☐☐

STUDYID

STUDY WEEK: *(circle one)*

USUBJID

EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 26

QSEVAL

Assessment Date: __ __ / __ __ / __ __ __ __ QSDTC *(mm / dd / yyyy)*

STAFF ID: ☐☐☐☐☐

☐ **FORM COMPLETION STATUS**

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

Please rate the following items based on how you have felt or what you have noticed over the last 24 hours.

Rate the items by circling the number that best reflects how you have generally felt during this time.

QSORRES

QSTEST		NONE	SLIGHT	MILD	MODERATE	SEVERE
1.	Craving for a cigarette	0	1	2	3	4
2.	Irritability-frustration-anger	0	1	2	3	4
3.	Anxiety	0	1	2	3	4
4.	Difficulty Concentrating	0	1	2	3	4
5.	Restlessness-Impatience	0	1	2	3	4
6.	Increased appetite	0	1	2	3	4
7.	Disrupted sleep-Insomnia	0	1	2	3	4
8.	Depression	0	1	2	3	4

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1

NODE: ☐☐
CTP-SITE ID: ☐☐-☐☐
PARTICIPANT ID : ☐☐☐☐
STUDYID
STUDY WEEK: (circle one)
USUBJID
EPOCH Screening Baseline VISITNUM
-1 1 2 3 4 5 6 7 8 9 10 11 12 13
14 15 16 17 18 19 20 21 22 23 24 25 26

Assessment Date: ___ ___ / ___ ___ / ___ ___ ___ ___ TUDTC (mm / dd / yyyy)
STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

TUTEST/TUTESTCD

TUORRES ___ 1. How many STUDY smoking cessation counseling sessions were scheduled for the participant? *(0-2)*
If zero sessions scheduled skip to question 4.

TUTEST/TUTESTCD *Circle answer choice for b and c.*
If Other is chosen for section c, then this must be specified in section d.

	(a) Scheduled Session Date TUSTDTC	(b) Attended TUORRES		(c) If Not Attended, Why?				(d) If Other for Not Attended Specify
TUSPID		No	Yes	Counselor cancelled	Participant cancelled	Other	Unk	
2.	___/___/_____	0	1	1	2	3	9	
3.	___/___/_____	0	1	1	2	3	9	

QNAM = TUEOTHER
QLABEL = NOT ATTENDED FOR OTHER REASON
IDVAR = TUSEQ

___ 4. How many NON-STUDY smoking cessation counseling sessions did the participant attend? *(0-5)*
If zero sessions were attended, then skip to question 10.

Circle answer choice for b. If Not Attended, specify reason in c.

	(a) Scheduled Session Date	(b) Attended		(c) If No, specify reason:
TUSPID		No	Yes	
5.	___/___/_____	0	1	
6.	___/___/_____	0	1	
7.	___/___/_____	0	1	
8.	___/___/_____	0	1	
9.	___/___/_____	0	1	

QNAM = TUSREAS
QLABEL = NOT ATTENDED REASON
IDVAR = TUSEQ

___ 10. Has the participant returned to smoking?
0 = No
1 = Yes
8 = Never abstinent *(Treatment As Usual group only)*

___ 11. Has the participant used any non-study self help materials?
(If No, STOP. If Yes, then questions 12 through 14 must be answered)
0 = No
1 = Yes

		(a) Material Used?		(b) Days Used
		No	Yes	
12.	Books	0	1	__ __
13.	Tapes	0	1	__ __
14.	Other *(If Yes, then specify in 15)*	0	1	__ __
15.	Other specified:			

QNAM = TUHOTHER
QLABEL = OTHER SELF HELP MATERIALS
IDVAR = TUSEQ

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: __
NODE: ☐☐	STUDYID	EPOCH Screening Baseline VISITNUM
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one)	-1 1 2 3 4 5 6 7 8 9 10 11 12 13
PARTICIPANT ID : ☐☐☐☐	USUBJID	14 15 16 17 18 19 20 21 22 23 24 25 26
Assessment Date: __ __ / __ __ / __ __ __ __ (mm / dd / yyyy)		STAFF ID: ☐☐☐☐☐
☐ FORM COMPLETION STATUS	1=Form completed as required 2=Participant refused 3=Responsible person did not complete	4=Not enough time at the visit 5=Participant did not attend visit 6=Other (specify: _____)

DACAT=STUDY MEDICATION

This form collects today's distribution of medication to the participant.

DAORRES DATEST

1. Patches Dispensed Today

DADTC

a. Today's Date: __ __ / __ __ / __ __ __ __ *(mm/dd/yyyy)*

__ __ b. Number of patches dispensed *(If "special circumstance" use 77)*

___ c. Dosage of patches dispensed

1 = 21 mg
2 = 14 mg

___ d. Was the dosage dispensed a change from the previous dosage level?

1 = Yes
0 = No

2. Patches Returned Today

___ a. Were patches returned today?

1 = Yes *(If yes, continue)*
0 = No *(If no, skip to q2c & d)*

If patches were expected to be returned at this visit and were not, then specify this in 2.b

b. If patches were returned then specify: _____

__ __ c. Number Returned

__ __ d. Number Lost

DOMAIN: EX

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1
NODE: ☐☐	STUDYID	EPOCH Screening / Baseline — VISITNUM
CTP-SITE ID: ☐☐-☐☐	STUDY WEEK: (circle one) -1 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26	
PARTICIPANT ID : ☐☐☐☐	USUBJID	
Assessment Date: __ __ / __ __ / __ __ __ __ (mm / dd / yyyy)	EXDTC	STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

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4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

This form collects the administration & use information on patches distributed to the participant at the last attended visit.

EXTRT=NICODERM CQ

EXDOSFRM,EXDOSE,EXDOSU=PATCH

	a. EXSTDTC Date of Administration (mm/dd/yyyy)	b. Was Patch Used as Prescribed? (Circle one) 1=Yes 2=Would not stay on 3=Patch removed due to intolerance 4=Patch removed at night 5=Patch removed for other reason 6=Supplement: additional patch, gum or other form of nicotine 7=Other 9=Unknown — EXADJ	c. Comment/Reason dose not Administered EXADJ (If "Was Patch Used as Prescribed" is not Yes, a comment is necessary)
1.	__ __/__ __/__ __ __ __	1 2 3 4 5 6 7 9	
2.	__ __/__ __/__ __ __ __	1 2 3 4 5 6 7 9	
3.	__ __/__ __/__ __ __ __	1 2 3 4 5 6 7 9	
4.	__ __/__ __/__ __ __ __	1 2 3 4 5 6 7 9	
5.	__ __/__ __/__ __ __ __	1 2 3 4 5 6 7 9	
6.	__ __/__ __/__ __ __ __	1 2 3 4 5 6 7 9	
7.	__ __/__ __/__ __ __ __	1 2 3 4 5 6 7 9	
8.	__ __/__ __/__ __ __ __	1 2 3 4 5 6 7 9	
9.	__ __/__ __/__ __ __ __	1 2 3 4 5 6 7 9	
10.	__ __/__ __/__ __ __ __	1 2 3 4 5 6 7 9	

Subject Compliance

___ 11. Was the subject compliant with medication administration?

1 = Yes
0 = No
9 = Unknown

QNAM = EXCOMP
QLABEL = SUBJECT MEDICATION COMPLIANCE
IDVAR = EXSEQ

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1

NODE:	☐☐	STUDYID	EPOCH Screening Baseline VISITNUM
CTP-SITE ID:	☐☐-☐☐	STUDY WEEK: (circle one)	-1 1 2 3 4 5 6 7 8 9 10 11 12 13
PARTICIPANT ID :	☐☐☐☐	USUBJID	14 15 16 17 18 19 20 21 22 23 24 25 26 QSEVAL

Assessment Date: ___ ___ / ___ ___ / ___ ___ ___ ___ (mm / dd / yyyy) QSDTC STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

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2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

Composite Scores
(for site use only):

Medical:	_____	Legal:	_____
Employment:	_____	Family:	_____
Drug:	_____	Psychiatric:	_____
Alcohol:	_____		

KEY:

Patient Rating Scale
0 = Not at all
1 = Slightly
2 = Moderately
3 = Considerably
4 = Extremely

Interviewer Severity Ratings
0-1 = No real problem, treatment not necessary
2-3 = Slight problem, treatment probably not necessary
4-5 = Moderate problem, treatment probably necessary
6-7 = Considerable problem, treatment necessary
8-9 = Extreme problem, treatment absolutely necessary

Hollingshead Categories	
1 =	Higher Executive, Doctoral Level Professional, Owner of Large Business
2 =	Business Manager, Owner (medium sized business), Other Professional (nurse, optician, pharmacist, social worker, teacher)
3 =	Administrative Personnel, Manager, Owner/Proprietor of Small Business (bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent)
4 =	Clerical and Sales, Technician, Owner of Small Business (bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary, car salesperson)
5 =	Skilled Manual—usually having had training (baker, barber, brakeman, chef, electrician, fireman, lineman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, police officer, plumber)
6 =	Semi-skilled (hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator)
7 =	Unskilled (attendant, janitor, construction help, unspecified labor, porter). Include unemployed.
8 =	Homemaker
9 =	Student/No occupation/disabled

Starred items should be rephrased at follow-up as "Since the last ASI interview…"

Throughout the ASI, when noted:

Use X when question not answered.
Use N when question is not applicable

CTP - Site ID	Participant ID	Assessment Date:
☐☐-☐☐	USUBJID ☐☐☐☐	QSDTC __ __ / __ __ / __ __ __ __ (m m / d d / y y y y)

GENERAL INFORMATION =QSSCAT

QSTEST

_____ 9. Contact code:
QSORRES
1=In person
2=Telephone (Intake ASI must be in person)
3=Mail
X=Not Answered

_____ 12. Special:
1=Patient terminated
2=Patient refused
3=Patient unable to respond
N=Not Applicable

_____ 19. Have you been in a controlled environment in the past 30 days?
A place, theoretically, without access to drugs/alcohol.
1=No
2=Jail
3=Alcohol or Drug Treatment
4=Medical Treatment
QSEVLINT=-P30D
5=Psychiatric Treatment
6=Other (specify_____)
X=Not Answered

___ ___ 20. How many days?
QSEVLINT=-P30D QSORRESU=DAY
"NN" if question 19 is "No". Refers to total number of days detained in the past 30 days. *(XX=Not Answered)*

Comments:

THIS DATA NOT ENTERED

CTP - Site ID	USUBJID Participant ID	Assessment Date: __ __ / __ __ / __ __ __ __ (QSDTC)
☐☐-☐☐	☐☐☐☐	m m d d y y y y

MEDICAL STATUS =QSSCAT

QSTEST

__ __ *1. How many times in your life have you been hospitalized for medical problems?

QSORRES

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

_____ 4. Are you taking any prescribed medication on a regular basis for a physical problem?

0=No, 1=Yes

Medication prescribed by a MD for medical conditions; not psychiatric medicines. Include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems. *(X= Not Answered)*

If "Yes," specify: _____

_____ 5. Do you receive a pension for a physical disability? *(X= Not Answered)*

0=No, 1=Yes

Include Workers' compensation, exclude psychiatric disability.

If "Yes," specify: _____

__ __ 6. How many days have you experienced medical problems in the past 30 days?

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

For Questions 7 & 8, please ask the patient to use the Patient Rating scale.

_____ 7. How troubled or bothered have you been by these medical problems in the past 30 days?

QSORRESU=DAY QSEVLINT=-P30D

Restrict response to problem days of Question 6. *(X=Not Answered)*

_____ 8. How important to you now is treatment for these medical problems?

QSEVLINT=-P30D

Refers to the need for new or additional medical treatment by the patient. *(X=Not Answered)*

CONFIDENCE RATINGS

Is the above information significantly distorted by:

_____ 10. Patient's misrepresentation?

0=No, 1=Yes

_____ 11. Patient's inability to understand?

0=No, 1=Yes

COMMENTS:

THIS DATA NOT ENTERED

CTP - Site ID	Participant ID	Assessment Date:
☐☐-☐☐	USUBJID ☐☐☐☐	QSDTC __ __ / __ __ / __ __ __ __ (m m / d d / y y y y)

EMPLOYMENT/SUPPORT STATUS =QSSCAT

QSORRESU=YEAR / QSORRESU=MONTH

__ __ / __ __
a. Yrs. / b. Mos.

*1. Education completed? QSTEST

GED = 12 years. Include formal education only. *(XX/XX=Not Answered)*

QSORRESU=MONTH

__ __
Mos.

*2. Training or technical education completed:

Formal/organized training only. For military training, only include training that can be used in civilian life (i.e., electronics or computers). *(XX=Not Answered)*

QSORRES

_____
0=No, 1=Yes

4. Do you have a valid driver's license? Valid license; not suspended/revoked. *(X=Not Answered)*

_____
0=No, 1=Yes

5. Do you have an automobile available? (If answer to Q4 is "No", then Q5 must be "No")

Does not require ownership, only requires availability on a regular basis. *(X=Not Answered)*

_____

7. Usual (or last) occupation? (specify): _____

(use Hollingshead Categories Reference Sheet) *(X=Not Answered)*

_____
0=No, 1=Yes

9. Does someone contribute the majority of your support?

Is patient receiving any regular support (i.e., cash, food, housing) from family/friend? Include spouse's contribution; exclude support by an institution. *(X=Not Answered)*

QSEVLINT=-P3Y

__ __
QSORRESU=DAY

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

Include "under the table" work, paid sick days, and vacation. *(XX=Not Answered)*

Max=$99999

For questions 12-17: How much money did you receive from the following sources in the past 30 days?

$ __ __ __ __ __ 12. Employment (net income)? (Net or "take home" pay, include any "under the table" money.) *(XXXXX=Not Answered)*

$ __ __ __ __ __ 13. Unemployment Compensation? *(XXXXX=Not Answered)*

$ __ __ __ __ __ 14. Welfare? (Include food stamps, transportation money provided by an agency to go to and from treatment.) *(XXXXX=Not Answered)*

QSEVLINT=-P30D
QSORRESU=DOLLAR

$ __ __ __ __ __ 15. Pensions, benefits or Social Security? (Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.) *(XXXXX=Not Answered)*

$ __ __ __ __ __ 16. Mate, family or friends? (Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g., gambling). Record cash payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.). *(XXXXX=Not Answered)*

$ __ __ __ __ __ 17. Illegal? *(XXXXX=Not Answered)*

__ __
Max = 99

18. How many people depend on you for the majority of their food, shelter, etc.?

Must be regularly depending on patient, do include alimony/child support, do not include the patient or self-supporting spouse, etc. *(X=Not Answered)* QSEVLINT=-P30D

CTP - Site ID	USUBJID Participant ID	Assessment Date: __ __ / __ __ / __ __ __ __ (QSDTC)
☐☐-☐☐	☐☐☐☐	m m d d y y y y

QSORRES ___ ___ QSTEST

19. How many days have you experienced employment problems in the past 30 days?
Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized. *(XX=Not Answered)*

QSEVLINT=-P30D QSORRESU=DAY

For Questions 20 & 21, ask the patient to use the Patient's Rating scale.

The patient's ratings in Questions 20 & 21 refer to Question 19. Stress help in finding or preparing for a job, not giving them a job.

_____ 20. How troubled or bothered have you been by these employment problems in the past 30 days? QSEVLINT=-P30D
If the patient has been incarcerated or detained during the past 30 days, they cannot have employment problems. *(X=Not Answered)*

_____ 21. How important to you now, is counseling for these employment problems? *(X=Not Answered)* QSEVLINT=-P30D

CONFIDENCE RATINGS

Is the above information significantly distorted by:

_____ 23. Patient's misrepresentation?
0=No, 1=Yes

_____ 24. Patient's inability to understand?
0=No, 1=Yes

COMMENTS:

THIS DATA NOT ENTERED

CTP - Site ID	USUBJID Participant ID	Assessment Date: QSDTC
☐☐-☐☐	☐☐☐☐	__ __ / __ __ / __ __ __ __ (m m / d d / y y y y)

DRUG/ALCOHOL USE =QSSCAT

Route of Administration Types:

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

Note the usual or most recent route. For more than one route, choose the most severe. The routes are listed from least severe to most severe. If Past 30 Days and Lifetime Use are zero, route should be coded as "N." *(XX=Not Answered)*

Substance (QSTEST)	QSEVLINT=-P30D a. Past 30 Days (QSORRES)		c. Route of Admin.
01. Alcohol (any use at all)	__ __		
02. Alcohol (to intoxication)	__ __		
03. Heroin	__ __		_____
04. Methadone	__ __		_____
05. Other Opiates/Analgesics	__ __		_____
06. Barbiturates	__ __		_____
07. Other Sedatives/Hypnotics/Tranquilizers	__ __		_____
08. Cocaine	__ __		_____
09. Amphetamines	__ __		_____
10. Cannabis	__ __		_____
11. Hallucinogens	__ __		_____
12. Inhalants	__ __		_____
13. More than 1 substance per day (including alcohol)	__ __		

QSTEST

How many times in your life have you been treated for: Include detoxification, halfway houses, in/outpatient counseling, and AA or NA (if 3+ meetings within one month period). *(XX=Not Answered)*

QSORRES

__ __ *19. Alcohol abuse?

__ __ *20. Drug abuse?

How many of these were detox only?

__ __ 21. Alcohol? If Q19 ="00", then question Q21 is "NN" *(XX=Not Answered)*

__ __ 22. Drugs? If Q20 ="00", then question Q22 is "NN" *(XX=Not Answered)*

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QSORRES QSTEST

Max =$99999

How much money would you say you spent during the past 30 days on:
Only count actual money spent. What is the financial burden caused by drugs/alcohol? *(XXXXX=Not Answered)*

$ ___ ___ ___ ___ ___ 23. Alcohol? QSEVLINT=-P30D QSORRESU=DOLLAR

$ ___ ___ ___ ___ ___ 24. Drugs? QSEVLINT=-P30D QSORRESU=DOLLAR

___ ___ 25. How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days? *(Include AA/NA) (XX=Not Answered)* QSEVLINT=-P30D QSORRESU=DAY

How many days in the past 30 have you experienced:
Include only: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to. *(XX=Not Answered)*

___ ___ 26. Alcohol problems? QSEVLINT=-P30D QSORRESU=DAY

___ ___ 27. Drug problems? QSEVLINT=-P30D QSORRESU=DAY

For questions 28 - 31, please ask the patient to use the Patient's Rating scale.
The Patient is rating the need for additional substance abuse treatment. *(X=Not Answered)*

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

_____ 28. Alcohol problems? QSEVLINT=-P30D

_____ 29. Drug problems? QSEVLINT=-P30D

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

_____ 30. Alcohol problems?

_____ 31. Drug problems?

CONFIDENCE RATINGS

Is the above information significantly distorted by:

_____ 0=No, 1=Yes 34. Patient's misrepresentation?

_____ 0=No, 1=Yes 35. Patient's inability to understand?

COMMENTS:

THIS DATA NOT ENTERED

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LEGAL STATUS =QSSCAT

QSORRES QSTEST

_____ 2. Are you on parole or probation?
0=No, 1=Yes
Note duration and level in comments. *(X=Not Answered)*

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

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

___ ___	* 3. Shoplifting/Vandalism	___ ___	* 10. Assault
___ ___	* 4. Parole/Probation Violations	___ ___	* 11. Arson
___ ___	* 5. Drug Charges	___ ___	* 12. Rape
___ ___	* 6. Forgery	___ ___	* 13. Homicide/Manslaughter
___ ___	* 7. Weapons Offense	___ ___	* 14. Prostitution
___ ___	* 8. Burglary/Larceny/B&E	___ ___	* 15. Contempt of court
___ ___	* 9. Robbery	___ ___	* 16. Other: (specify_____)

___ ___ * 17. How many of these charges resulted in convictions?
If Q3-16="00", then Q17="NN". Do not include misdemeanor offenses from questions 18-20 below. Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas. *(XX=Not Answered)*

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

Do not include misdemeanor offenses.

___ ___ * 18. Disorderly conduct, vagrancy, public intoxication? *(XX=Not Answered)*

___ ___ * 19. Driving while intoxicated (DWI)? *(XX=Not Answered)*

___ ___ * 20. Major driving violations?
Moving violations: speeding, reckless driving, no license, etc. *(XX=Not Answered)*

___ ___ * 21. How many months were you incarcerated in your life? *(XX=Not Answered)*
Mos
QSORRESU=MONTH If incarcerated 2 weeks or more, round this up to 1 month. List total number of months incarcerated.

_____ 24 Are you presently awaiting charges, trial, or sentence? *(X=Not Answered)*
0=No, 1=Yes

___ ___ 25 What for? (Refers to Q24.) Use code 03-16, 18-20. If more than one, choose most severe.
Don't include civil cases, unless a criminal offense is involved. *(XX=Not Answered, NN= Not Applicable)*

03 = Shoplifting	09 = Robbery	15 = Contempt
04 = Probation violation	10 = Assault	16 = Other
05 = Drug	11 = Arson	18 = Disorderly conduct
06 = Forgery	12 = Rape	19 = DWI
07 = Weapons	13 = Homicide	20 = Major driving violation
08 = Burglary	14 = Prostitution	

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QSORRES QSTEST QSEVLINT=-P30D QSORRESU=DAY

___ ___ 26. How many days in the past 30, were you detained or incarcerated?
Include being arrested and released on the same day. *(XX=Not Answered)*

QSEVLINT=-P30D QSORRESU=DAY

___ ___ 27. How many days in the past 30, have you engaged in illegal activities for profit?
Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross- checked with Question 17 under Employment/Family Support Section. *(XX=Not Answered)*

For questions 28 & 29, ask the patient to use the Patient's Rating scale.

_____ 28. How serious do you feel your present legal problems are? Exclude civil problems. *(X=Not Answered)*

_____ 29. How important to you now is counseling or referral for these legal problems?
Patient is rating a need for additional referral to legal counsel for defense against criminal charges. *(X=Not Answered)*

CONFIDENCE RATINGS

Is the above information significantly distorted by:

_____ 0=No, 1=Yes 31. Patient's misrepresentation?

_____ 0=No, 1=Yes 32. Patient's inability to understand?

COMMENTS:

THIS DATA NOT ENTERED

CTP - Site ID	USUBJID Participant ID	Assessment Date: QSDTC
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FAMILY/SOCIAL RELATIONSHIPS =QSSCAT

QSORRES QSTEST

1. Marital Status

   1 = Married 3 = Widowed 5 = Divorced
   2 = Remarried 4 = Separated 6 = Never Married
   Common-law marriage = "1." (Specify in comments) (X=Not Answered)

_____ 0=No, 2=Yes, 1=Indifferent

3. Are you satisfied with this situation? (Refers to Question 1)
   Satisfied = generally liking the situation. *(X=Not Answered)*

_____

4. Usual living arrangements (past 3 years):

QSEVLINT=-P3Y

   1 = With sexual partner & children 4 = With parents 7 = Alone
   2 = With sexual partner alone 5 = With family 8 = Controlled Environment
   3 = With children alone 6 = With friends 9 = No stable arrangement

   Choose arrangements most representative of the past 3 years. If there is an even split in time between these arrangements, choose the most recent arrangement. *(X=Not Answered)*

_____ 0=No, 2=Yes, 1=Indifferent

6. Are you satisfied with these arrangements?
   Refers to response in Question 4. *(X=Not Answered)*

Do you live with anyone who:

_____ 0=No, 1=Yes

7. Has a current alcohol problem? *(X=Not Answered)*

_____ 0=No, 1=Yes

8. Uses non-prescribed drugs? *(X=Not Answered)*

_____ 1=Family, 2=Friends, 3=Alone

9. With whom do you spend most of your free time?
   If a girlfriend/boyfriend is considered as a family by patient, then they must refer to them as family throughout this section, not a friend. Family is not to be referred to as "friend." *(X=Not Answered)*

_____ 0=No, 2=Yes, 1=Indifferent

10. Are you satisfied with spending your free time this way? (Refers to Question 9.)
    A satisfied response must indicate that the person generally likes the situation. *(X=Not Answered)*

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

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

QSEVLINT=-P30D

a. Past 30 Days

0= No, 1= Yes, *(X= Not Answered, N= Not Applicable)*

_____ 18. Mother
_____ 19. Father
_____ 20. Brothers/Sisters
_____ 21. Sexual Partner/Spouse
_____ 22. Children
_____ 23. Other Significant Family
(Specify) _____
_____ 24. Close Friends
_____ 25. Neighbors
_____ 26. Co-workers

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a. Past 30 Days **0= No, 1= Yes *(X=Not Answered)***

QSEVLINT=-P30D QSTEST

Did any of these people (Question 18 - 26) abuse you?

QSORRES

_____ 28. Physically? (Caused you physical harm.)

_____ 29. Sexually? (Forced sexual advances/acts.)

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

___ ___ 30. With your family? *(XX= Not Answered)* QSEVLINT=-P30D QSORRESU=DAY

___ ___ 31. With other people (excluding family)? *(XX= Not Answered)* QSEVLINT=-P30D QSORRESU=DAY

For Questions 32-35, ask the patient to use the Patient Rating scale.

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

_____ 32. Family problems *(X= Not Answered)* QSEVLINT=-P30D

_____ 33. Social problems *(X= Not Answered)* QSEVLINT=-P30D

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

_____ 34. Family problems

Patient is rating his family's need for counseling for family problems, not whether they would be willing to attend. *(X= Not Answered)*

_____ 35. Social problems

Include patient's need to seek treatment for such social problems as loneliness, inability to socialize, and dissatisfaction with friends. Patient rating should refer to dissatisfaction, conflicts, or other serious problems. Exclude problems that would be eliminated if patient had no substance abuse. *(X= Not Answered)*

CONFIDENCE RATING

Is the above information significantly distorted by:

_____ 37. Patient's misrepresentation?
0=No, 1=Yes

_____ 38. Patient's inability to understand?
0=No, 1=Yes

COMMENTS:

THIS DATA NOT ENTERED

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PSYCHIATRIC STATUS=QSSCAT

QSTEST

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

Do not include substance abuse, employment, or family counseling. Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days. Enter diagnosis in comments if known.

QSORRES

___ ___ *1. In a Hospital or inpatient setting? *(XX= Not Answered)*

___ ___ *2. Outpatient/private patient? *(XX= Not Answered)*

_____ 0=No, 1=Yes 3. Do you receive a pension for a psychiatric disability? *(X=Not Answered)*

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

a. Past 30 Days — **0=No, 1=Yes, (X= Not Answered)**

QSEVLINT=-P30D

_____ 4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?

_____ 5. Experienced serious anxiety/tension-uptight, unreasonably worried, inability to feel relaxed?

_____ 6. Experienced hallucinations-saw things or heard voices that were not there?

_____ 7. Experienced trouble understanding, concentrating, or remembering?

For questions 8-10, patient could have been under the influence of alcohol/drugs.

_____ 8. Experienced trouble controlling violent behavior including episodes of rage, or violence? (Patient can be under the influence of alcohol/drugs.)

_____ 9. Experienced serious thoughts of suicide?
Patient seriously considered a plan for taking his/her life.

_____ 10. Attempted suicide? (Include actual suicidal gestures or attempts.)

_____ 11. Been prescribed medication for any psychological or emotional problems?
(Prescribed for the patient by MD. Record "Yes" if a medication was prescribed even if the patient is not taking it.)

___ ___ 12. How many days in the past 30 have you experienced these psychological or emotional problems? (This refers to problems noted in Questions 4-10.) *(XX= Not Answered)*

QSEVLINT=-P30D QSORRESU=DAY

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QSTEST

For Question 13 & 14, ask the patient to use the Patient Rating scale.

QSORRES

_____ 13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days? (Patient should be rating the problem days from Question 12.) *(X= Not Answered)* QSEVLINT=-P30D

_____ 14. How important to you now is treatment for these psychological or emotional problems? *(X= Not Answered)*

CONFIDENCE RATING

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

_____ 22. Patient's misrepresentation?
0=No, 1=Yes

_____ 23. Patient's inability to understand?
0=No, 1=Yes

COMMENTS:

THIS DATA NOT ENTERED

NIDA-CTN-0009	Smoking Cessation Treatment With Transdermal Nicotine Replacement Therapy In Substance Abuse Rehabilitation Programs	Seq. Num.: 1

NODE: ☐☐ STUDYID

CTP-SITE ID: ☐☐-☐☐ STUDY WEEK: (circle one)

PARTICIPANT ID : ☐☐☐☐ USUBJID

EPOCH Screening Baseline VISITNUM

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

14 15 16 17 18 19 20 21 22 23 24 25 **26**

Assessment Date: __ __ / __ __ / __ __ __ __ (mm / dd / yyyy) DSDTC

STAFF ID: ☐☐☐☐☐

☐ FORM COMPLETION STATUS

1=Form completed as required
2=Participant refused
3=Responsible person did not complete
4=Not enough time at the visit
5=Participant did not attend visit
6=Other (specify: _____)

Study Termination is required when study participation is completed, or at the time of termination if a participant terminates the study early.

DSTERM/DSDECOD DSCAT=DISPOSITION EVENT

Section A

1. Date of study completion or early termination: __ __ / __ __ /__ __ __ __ (mm / dd /yyyy) DSSTDTC

   DM.RFENDTC

2. Study week of study completion or early termination: __ __

NO	YES		
0	1	3.	Has the participant completed the study according to the protocol? *If Yes, then end questionnaire.* *If NO, then complete Section B.*

Section B

All Questions 1a through 5 must be answered.
For any question answered YES there must be details provided in question 5.

NO	YES	(circle answer)	
0	1	1a.	Was the Participant discharged from the CTP for administrative reasons? *(i.e., active disruption of CTP procedures, non-compliance with CTP rules, etc.)*
		1b.	IF YES, Date of CTP discharge: __ __ / __ __ /__ __ __ __ (mm/dd/yyyy) DSSTDTC
0	1	2a.	Was the Participant discontinued from the study for administrative reasons? *(i.e., active disruption of counseling, protocol non-compliance, etc.)*
		2b.	IF YES, Date of Study discontinuance:__ __ / __ __ / __ __ __ __ (mm/dd/yyyy) DSSTDTC
0	1	3.	Was the Participant discontinued at his/her request?
0	1	4.	Did the Participant discontinue the protocol for another reason? *(If YES, then specify in question 5)*
		5.	If any question above was answered YES, then provide details: *(continue on back if necessary)*

QNAM = DSTERMWK
QLABEL = TERMINATION STUDY WEEK
IDVAR = DSSEQ

DOMAIN: CO
Variables COVAL-COVALN
RDOMAIN=DS
IDVAR=VISITNUM