DataFax #010 **Plate #001** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE*

CS #1022
"A PHASE 2, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF SELEGILINE TRANSDERMAL SYSTEM (STS) AS AN AID FOR SMOKING CESSATION"

CONSENT FORM CONFIRMATION SHEET

Name of Clinical Site:_____

This subject reviewed the informed consent form approved by this Institution's IRB for CS #1022, "A Phase 2, Double-Blind, Placebo-Controlled Trial of Selegiline Transdermal System (STS) as an aid for Smoking Cessation". This subject has had all procedures and risks explained in detail. All of his/her questions have been answered. He/She has voluntarily signed the consent form before any study procedures took place on (specify date consent was signed by subject):

Subject's Signature Date ☐☐ ☐☐ ☐☐☐☐
month *day* *year*

Investigator's Name (please print)_____

Investigator's Signature_____

Investigator's Signature Date ☐☐ ☐☐ ☐☐☐☐
month *day* *year*

Consent Form version date ☐☐ ☐☐ ☐☐☐☐
month *day* *year*

DataFax #010 **Plate #011** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

month day year

FORM 01 - Entry Criteria & Randomization

Complete this entire form at screening for all subjects who provided informed consent.

Demographic Information

1. Birthdate: . . . . . *month* *day* *year*

2. Gender . . . . . *male* *female*

3. Marital Status:

- ☐ Legally Married
- ☐ Separated
- ☐ Living with Partner/cohabitating
- ☐ Divorced
- ☐ Widowed
- ☐ Never Married
- ☐ Unknown

4. Ethnicity: . . . . . ☐ *Hispanic or Latino* ☐ *Not Hispanic or Latino*

5. Race: (mark (x) all that apply) (see the operations manual on how to code race)

- ☐ American Indian, or Alaska Native
- ☐ Native Hawaiian, or other Pacific Islander
- ☐ Asian
- ☐ White
- ☐ Black, or African-American

6. Years of Formal Education: (GED = 12 years) . . . . . ☐☐

7. Usual Employment Pattern in the last 30 days?

- ☐ Full-Time, 35+ hrs/week
- ☐ Student
- ☐ Homemaker
- ☐ Part-Time, regular hrs
- ☐ Military Service
- ☐ Unemployed
- ☐ Part-Time, irregular hrs/day work
- ☐ Retired/Disabled
- ☐ In controlled environment
- ☐ Unknown

DataFax #010 **Plate #012** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE*

Inclusion Criteria

(For Inclusion Criteria questions 8-15, mark (x) for the appropriate answer. All answers must be YES for inclusion in the study, unless otherwise indicated by an asterisk.)*

	No	Yes	
8. Did the subject provide written Informed Consent?	☐	☐	

	No	Yes	Not Screened
9. Is the subject's age 18 years or greater?	☐	☐	☐
10. Does the subject have a DSM-IV diagnosis of nicotine dependence?	☐	☐	☐
11. Is the subject currently (past 30 days) smoking ≥ 15 cigarettes per day and has the subject smoked cigarettes for the past 5 years?	☐	☐	☐
12. Is the subject motivated to quit smoking? *(Score ≥6 on the motivation to quit visual analog scale Form 10)*	☐	☐	☐
13. Does the subject have an expired CO level ≥ 9 ppm during screening?	☐	☐	☐
*14. If female, does the subject have a negative urine pregnancy test and agrees to use an acceptable method of birth control (as defined within the protocol)? *For males, mark 'Not Screened'*	☐	☐	☐
15. Is the subject available for participation in the study for 28 weeks?	☐	☐	☐

DataFax #010 **Plate #013** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE*

Exclusion Criteria

(For Exclusion Criteria questions 16-30, mark (x) for the appropriate answer. All answers must be NO for inclusion in the study, unless otherwise indicated by an asterisk.)*

	No	Yes	Not Screened
16. Does subject have any current neurological or psychiatric disorders diagnosed by DSM-IV criteria as assessed with the SCID that require ongoing treatment and/or will make compliance difficult?	☐	☐	☐
17. Does subject have a current serious medical illness including, but not limited to, uncontrolled hypertension, significant heart disease (including myocardial infarction or stroke within one year of enrollment), angina, cardiovascular abnormality, clinically significant irregular heart beat (arrhythmia), pheochromocytoma, vasoplastic diseases (e.g., Buerger's disease, Prinzmetal's angina), diabetes requiring insulin, hepatic or renal disorders, a serious endocrine disorder, or any other unstable medical disorder that may compromise subject's safety or study conduct?	☐	☐	☐
18. Does subject have a history of substance use disorders by DSM-IV criteria within the past year as determined by SCID with the exception of alcohol, caffeine, marijuana, and nicotine abuse (subjects with physiological dependence on alcohol that requires medical detoxification will be excluded)?	☐	☐	☐
19. Is subject anticipating elective surgery within 10 weeks of signing the informed consent that will preclude his/her active study participation?	☐	☐	☐
20. Is the subject, in the opinion of the investigator, someone who is not expected to complete the study protocol?	☐	☐	☐
21. Does the subject have a known or suspected hypersensitivity to selegiline, or any monoamine oxidase inhibitor?	☐	☐	☐
22. Does the subject have a history of allergy to latex or known allergic or active dermatologic illness (e.g., psoriasis) that might interfere with drug absorption or that may be exacerbated by patch application?	☐	☐	☐
23. Does the subject have any allergy that requires carrying prophylactic epinephrine?	☐	☐	☐
24. Is the subject taking a medication that could interact adversely with selegiline? (as defined in the protocol)	☐	☐	☐

DataFax #010 **Plate #014** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE*

	No	Yes	Not Screened
25. Has the subject participated in any experimental study within 4 weeks, or has the subject ever taken oral selegiline or used the STS?	☐	☐	☐
26. Does subject have a positive drug screen for cocaine, opiates, tetrahydrocannabinol (THC), and methamphetamine, except that the subject may test positive for THC once, but a subsequent negative test result must be obtained during the screening period?	☐	☐	☐
27. Is the subject currently using any other treatment (medication or behavioral) for smoking cessation?	☐	☐	☐
28. Does the subject use any tobacco products other than cigarettes?	☐	☐	☐
*29. Is the subject a pregnant or lactating female? (for males mark 'Not Screened')	☐	☐	☐
30. Does the subject have any clinically significant abnormal lab values (per judgement of the investigator)?	☐	☐	☐

	no	*yes*	*yes, but declined randomization*
31. Is the subject eligible for randomization?	☐	☐	☐

32. What was the subject's score on the Hamilton Depression Scale (HAM-D)? . . . . . ☐☐

33. When does the subject indicate smoking first cigarette after awakening? ☐ *≤ 30 mins.* ☐ *> 30 mins.*

34. What is the average number of cigarettes smoked per day in the 30 days prior to signing of the informed consent? ☐☐☐

35. What is the subject's target quit date? . . . . . ☐☐ *month* ☐☐ *day* ☐☐☐☐ *year*

(The target quit date should occur 1 week after date of randomization.)

DataFax #010 **Plate #015** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE*

If the subject is eligible and willing to be randomized, call the CSPCC to randomize the subject.
The subject must be present in clinic at time of randomization.
The CSPCC will provide the following information:

36. Date of randomization: . . . . . *month* *day* *year*

37. Treatment kit number: . . . . . .

Form Completed By:_____ Date:_____ ☐

Investigator's Signature:_____ Date:_____ ☐

DataFax #010 Plate #021 Visit #000

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

month day year

FORM 02 - Medical History

Study staff, please complete this form at screening.

Medical Conditions	History		Explanation
	No	Yes	*An explanation must be provided if History is marked Yes.*
1. Allergies, drug	☐	☐	
2. Allergies, other	☐	☐	
3. Sensitivity to selegiline or other MAOI	☐	☐	
4. HEENT Disorder	☐	☐	
5. Cardiovascular Disorder	☐	☐	
6. Renal Disorder	☐	☐	
7. Hepatic Disorder	☐	☐	
8. Pulmonary Disorder	☐	☐	
9. Gastrointestinal Disorder	☐	☐	
10. Musculoskeletal Disorder	☐	☐	
11. Neurologic Disorder	☐	☐	
a. Neuroleptic Malignant Syndr.	☐	☐	
b. Other Neurologic Syndr.	☐	☐	

DataFax #010 Plate #022 Visit #000

SITE NO. *SUBJECT ID.* *ALPHA CODE*

Medical Conditions	History		Explanation
	No	**Yes**	*An explanation must be provided if History is marked Yes.*
12. Psychiatric Disorder	☐	☐	
13. Seizure Disorder	☐	☐	
14. Dermatologic Disorder	☐	☐	
15. Metabolic Disorder	☐	☐	
16. Hematologic Disorder	☐	☐	
17. Endocrine Disorder	☐	☐	
18. Genitourinary Disorder	☐	☐	
19. Reproductive System Disorder	☐	☐	
20. Infectious Disease Disorder	☐	☐	
21. Other, specify _____	☐	☐	
22. Other, specify _____	☐	☐	

DataFax #010 Plate #023 Visit #000

SITE NO. *SUBJECT ID.* *ALPHA CODE*

no *yes*

23. Has the subject had any major surgeries? . . . . . ☐ ☐
If 'YES', list MAJOR SURGERIES below.

Type of Surgery:

a. _____ ☐☐ *month* ☐☐☐☐ *year*

b. _____ ☐☐ *month* ☐☐☐☐ *year*

c. _____ ☐☐ *month* ☐☐☐☐ *year*

d. _____ ☐☐ *month* ☐☐☐☐ *year*

e. _____ ☐☐ *month* ☐☐☐☐ *year*

Form Completed By: _____ Date: _____ ☐

Investigator's Signature: _____ Date: _____ ☐

DataFax #010 Plate #031

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

month day year

FORM 03 - Physical Exam

Complete at screening and update Question 17 on study day 1, before the first study patch is applied.
Complete at week 10, or termination visit if earlier.

1. Height (complete at Screening Only) . . . . . ☐☐.☐ inches

	Normal	Abnormal	Not Done	Details must be provided if anything other than Normal is marked:
2. HEENT (incl. thyroid/neck)	☐	☐	☐	
3. Cardiovascular	☐	☐	☐	
4. Lungs	☐	☐	☐	
5. Abdomen (incl. liver, spleen)	☐	☐	☐	
6. Extremities	☐	☐	☐	
7. Skin	☐	☐	☐	
8. Neuropsychiatric:				
8a. Mental Status	☐	☐	☐	
8b. Sensory/Motor	☐	☐	☐	
9. Lymph Nodes	☐	☐	☐	
10. Musculoskeletal	☐	☐	☐	
11. General Appearance	☐	☐	☐	

DataFax #010 Plate #032

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

Complete questions 12 - 16 if other body systems were assessed. For any body systems marked abnormal please provide comments.

	Normal	Abnormal	Not Done	
12. Other, specify _____	☐	☐	☐	
13. Other, specify _____	☐	☐	☐	
14. Other, specify _____	☐	☐	☐	
15. Other, specify _____	☐	☐	☐	
16. Other, specify _____	☐	☐	☐	

Please go to page 3 to complete Question #17.

DataFax #010 Plate #033

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Complete question 17 on study day 1, prior to 1st study patch application.

no *yes*

17. Does the subject have any acute or ongoing medical problems other than his/her smoking addiction? ☐ ☐

If 'YES', describe below.

a. Nature of Problem, Illness, or clinically significant abnormal Lab Value: _____

Date of Onset (*month* *day* *year*) Date of Resolution (*month* *day* *year*) Severity Code Outcome Code

☐ *Mark (x) if continuing*

b. Nature of Problem, Illness, or clinically significant abnormal Lab Value: _____

Date of Onset (*month* *day* *year*) Date of Resolution (*month* *day* *year*) Severity Code Outcome Code

☐ *Mark (x) if continuing*

c. Nature of Problem, Illness, or clinically significant abnormal Lab Value: _____

Date of Onset (*month* *day* *year*) Date of Resolution (*month* *day* *year*) Severity Code Outcome Code

☐ *Mark (x) if continuing*

d. Nature of Problem, Illness, or clinically significant abnormal Lab Value: _____

Date of Onset (*month* *day* *year*) Date of Resolution (*month* *day* *year*) Severity Code Outcome Code

☐ *Mark (x) if continuing*

If you do not need to use e-h on page 4 please continue on to page 4 and sign and date the form before you fax it in to DataFax!

DataFax #010 Plate #034

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

e. Nature of Problem, Illness, or clinically significant abnormal Lab Value: _____

Date of Onset (*month* *day* *year*) Date of Resolution (*month* *day* *year*) Severity Code Outcome Code

☐ *Mark (x) if continuing*

f. Nature of Problem, Illness, or clinically significant abnormal Lab Value: _____

Date of Onset (*month* *day* *year*) Date of Resolution (*month* *day* *year*) Severity Code Outcome Code

☐ *Mark (x) if continuing*

g. Nature of Problem, Illness, or clinically significant abnormal Lab Value: _____

Date of Onset (*month* *day* *year*) Date of Resolution (*month* *day* *year*) Severity Code Outcome Code

☐ *Mark (x) if continuing*

h. Nature of Problem, Illness, or clinically significant abnormal Lab Value: _____

Date of Onset (*month* *day* *year*) Date of Resolution (*month* *day* *year*) Severity Code Outcome Code

☐ *Mark (x) if continuing*

Form Completed By: _____ Date:_____ ☐

Investigator's Signature:_____ Date:_____ ☐

DataFax #010 Plate #041 Visit #000

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

month day year

FORM 04 - SCID

To be completed at screening only.

	no	*yes*
1. Did the subject meet DSM-IV criteria for nicotine dependence?	☐	☐

2. Indicate below (items a-l) any other DSM-IV diagnoses that were met during the SCID interview.
Please mark here if no other Diagnoses were met: . . . . . ☐

For items a - l, indicate the three, four or five-digit DSM-IV diagnostic code for all Axis 1 diagnoses. After the '/", use the sixth digit to indicate the following specifiers:

0 = current, severity not specified
1 = current, mild
2 = current, moderate
3 = current, severe
* 5 = in partial remission
6 = in full remission

*No Number '4'.

NOTE: When the specifier information is already included in the fifth digit of the code, repeat this information as the sixth digit.

a.) ☐☐☐.☐☐/☐	e.) ☐☐☐.☐☐/☐	i.) ☐☐☐.☐☐/☐
b.) ☐☐☐.☐☐/☐	f.) ☐☐☐.☐☐/☐	j.) ☐☐☐.☐☐/☐
c.) ☐☐☐.☐☐/☐	g.) ☐☐☐.☐☐/☐	k.) ☐☐☐.☐☐/☐
d.) ☐☐☐.☐☐/☐	h.) ☐☐☐.☐☐/☐	l.) ☐☐☐.☐☐/☐

SCID Administered By: _____ Date: _____ ☐

Investigator's Signature: _____ Date: _____ ☐

DataFax #010 Plate #051

PAGE *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 05 - Prior Medication Form

Complete this form on the day the subject signs the informed consent and update on study day 1, before first study patch is applied. List all medications taken by the subject in the past 60 days.

1. Did the Subject report taking any medications during the period 60 days prior to signing the Informed Consent through Day 1, prior to patch application? . . . . . *no* ☐ *yes* ☐

a.

Generic Name of Med _____ **Purpose/Indication** _____ **Medication Start Date** *month* *day* *year*

Medication Stop Date

Dose ☐☐☐☐.☐☐ **Route** ☐ **Units** ☐☐ **Frequency** ☐ ☐ ***Mark (x) if continuing***

b.

Generic Name of Med _____ **Purpose/Indication** _____ **Medication Start Date** *month* *day* *year*

Medication Stop Date

Dose ☐☐☐☐.☐☐ **Route** ☐ **Units** ☐☐ **Frequency** ☐ ☐ ***Mark (x) if continuing***

c.

Generic Name of Med _____ **Purpose/Indication** _____ **Medication Start Date** *month* *day* *year*

Medication Stop Date

Dose ☐☐☐☐.☐☐ **Route** ☐ **Units** ☐☐ **Frequency** ☐ ☐ ***Mark (x) if continuing***

no *yes*

- Will an additional page be used to record prior medications? . . . . . ☐ ☐
- **If Yes**, record the next page number . . . . . ☐☐

Use the following codes to complete the form:

Route

1 = Oral
2 = Nasal
3 = Intravenous
4 = Inhalation
5 = Topical/transdermal
6 = Intramuscular
7 = Sublingual
8 = Subcutaneous
9 = Other

Units

01 = Capsule/Tablet
02 = Drop
03 = Milligram
04 = Milliliter
05 = Puff
06 = Spray/squirt
07 = Tablespoon
08 = Teaspoon
09 = Unknown
10 = Other

Frequency

1 = Once a day
2 = Twice a day
3 = Three times a day
4 = Four times a day
5 = PRN

Form Completed By: _____ Date: _____ ☐

DataFax #010 Plate #061

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*		
				month	day	year

FORM 06 - Electrocardiogram Results (ECG)

Complete this form at screening and at week 10, or termination visit if earlier.

	Normal	*Abnormal*
1. ECG overall results were	☐	☐

2. If ECG is abnormal, MARK ALL that apply below:

☐ Increased QRS voltage	☐ Sinus tachycardia
☐ Qtc prolongation	☐ Sinus bradycardia
☐ Left ventricular hypertrophy	☐ Supraventricular premature beat
☐ Right ventricular hypertrophy	☐ Ventricular premature beat
☐ Acute infarction	☐ Supraventricular tachycardia
☐ Subacute infarction	☐ Ventricular tachycardia
☐ Old infarction	☐ 1st degree A-V block
☐ Myocardial ischemia	☐ 2nd degree A-V block
☐ Symmetrical t-wave inversions	☐ 3rd degree A-V block
☐ Poor R-wave progression	☐ Other, specify_____
☐ Other nonspecific ST/T	☐ Other, specify_____

3. Ventricular rate (bpm) . . . . . ☐☐☐

4. PR (ms) . . . . . ☐☐☐

5. QRS (ms). . . . . ☐☐☐

6. Qtc (ms). . . . . ☐☐☐

ECG read by _____ Date Read: ☐☐ ☐☐ ☐☐☐☐

month *day* *year*

Form Completed By: _____ Date: _____ ☐

Investigator's Signature: _____ Date: _____ ☐

DataFax #010 Plate #071

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*
				month / day / year

FORM 07 - Laboratory Report Form

Complete this form at screening and at week 10, or termination visit if earlier. Labs may be repeated as necessary.

Please indicate if the lab values reported on this form are for: ☐ *Scheduled Labs* ☐ *Repeat Labs*

	Value	**Evaluation** 1=Normal 2=Abnormal, not clinically significant 3=Abnormal, clinically significant 9=Not done	**Comments** Must be provided if a '3' or a '9' is recorded under Evaluation.
BLOOD CHEMISTRY			
1. Sodium (mEq/L)	☐☐☐	☐	
2. Potassium (mEq/L)	☐.☐	☐	
3. Chloride (mEq/L)	☐☐☐	☐	
4. CO2 (mEq/L)	☐☐	☐	
5. Glucose (mg/dL)	☐☐☐	☐	
6. Creatinine (mg/dL)	☐.☐	☐	
7. Alkaline phosphatase [ALP] (U/L)	☐☐☐	☐	

DataFax #010 Plate #072

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

	Value	**Evaluation** 1=Normal 2=Abnormal, not clinically significant 3=Abnormal, clinically significant 9=Not done	**Comments** Must be provided if a '3' or a '9' is recorded under Evaluation.
8. Calcium (mg/dL)	☐☐.☐	☐	
9. SGOT/AST (U/L)	☐☐☐☐	☐	
10. SGPT/ALT (U/L)	☐☐☐☐	☐	
11. GGT (U/L)	☐☐☐☐	☐	
12. Total bilirubin (mg/dL)	☐☐.☐	☐	
13. Urea Nitrogen (BUN) (mg/dL)	☐☐	☐	
CBC			
14. Hemoglobin (g/dL)	☐☐.☐	☐	
15. Hematocrit (%)	☐☐.☐	☐	
16. RBC (M/mm3)	☐☐.☐☐	☐	

DataFax #010 Plate #073

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

	Value	**Evaluation** 1=Normal 2=Abnormal, not clinically significant 3=Abnormal, clinically significant 9=Not done	**Comments** Must be provided if a '3' or a '9' is recorded under Evaluation.
17. Platelet count (K/mm3)	☐☐☐	☐	
18. WBC (K/mm3)	☐☐.☐☐	☐	
19. Neutrophils (%)	☐☐.☐	☐	
20. Lymphocytes (%)	☐☐.☐	☐	
21. Monocytes (%)	☐☐.☐	☐	
22. Eosinophils (%)	☐☐.☐	☐	
23. Basophils (%)	☐☐.☐	☐	

Form Completed By: _____ Date: _____ ☐

Investigator's Signature: _____ Date: _____ ☐

DataFax #010 **Plate #081**

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

month day year

FORM 08 - Vital Signs & Weight Assessment

Complete this form at every study visit from screening through week 10, or termination visit if earlier.
Complete this form at follow-up visits, weeks 14 and 26.

Note: orthostatic vital signs are to be obtained at screening and study weeks 1 through 4.

Refer to the Operations Manual for instruction on performing vital signs and weight assessment.

Time of Collection: (use 24-hour clock) . . . . . :

1. Weight (to nearest pound) . . . . .

2. Temperature (F) . . . . . .

3. Respiratory Rate (breaths/min) . . . . .

4. Blood Pressure (sitting for 3 mins) . . . . . /

5. Pulse Rate (sitting for 3 mins) (beats/min) . . . . .

Items Q6 and Q7 are only required at screening through study week 4.

6. Blood Pressure (standing for 1 min) . . . . . /

7. Pulse Rate (standing for 1 min) (beats/min) . . . . .

Only answer Q8 at screening, week 10, and week 26.

8. Waist circumference (round to the nearest quarter inch) . . . . . .

Form Completed By: _____ Date: _____

Physician's Signature: _____ Date: _____

DataFax #010 Plate #091

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*		
				month	day	year

FORM 09 - Birth Control/Pregnancy Assessment (Women Only)

Complete this assessment at screening and within 48 hours prior to first study patch application.
Complete this assessment at weeks 4, 8, and 10, or termination visit if earlier.

1. What method of birth control is participant currently using? (Check all that apply)

- ☐ Oral contraceptive
- ☐ Contraceptive skin patch (Ortho Evra®)
- ☐ Vaginal contraceptive ring (NuvaRing®)
- ☐ Barrier (diaphragm, condom, cervical cap, sponge or Lea's Shield) with spermicide
- ☐ Intrauterine Progesterone Contraceptive system (IUD)
- ☐ Levonorgestrel implant (Norplant®)
- ☐ Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera®)
- ☐ Hysterectomy (documentation must be provided)
- ☐ Tubal ligation (documentation must be provided)
- ☐ Bi-lateral Oophorectomy (documentation must be provided)
- ☐ Post-menopausal (one year post-menopausal)
- ☐ Other, specify _____

	no	*yes*
2. Was a pregnancy test performed?	☐	☐

If "YES", answer Q3. If "NO," form is complete.

	positive	*negative*
3. Result of pregnancy test:	☐	☐

If "Positive" after randomization, complete the AE Log, Form 20.

Form Completed By: _____ Date:_____

Investigator's Signature:_____ Date:_____

DataFax #010 **Plate #101** **Visit #000**

SITE NO. ☐☐☐ *SUBJECT ID.* ☐☐☐☐ *ALPHA CODE* ☐☐☐☐ *DATE OF ASSESSMENT* ☐☐ month ☐☐ day ☐☐☐☐ year

FORM 10 - Weight Control Scale/Motivation to Quit Scale

This form is to be completed by the subject at screening.

Weight Control Scale:
Please mark (x) the box which most closely matches how you feel about the following statements.
You may mark only one box per statement.

	Not at all	*A little*	*Quite a bit*	*Very much so*
1. I smoke to keep from gaining weight:	☐	☐	☐	☐
2. Smoking helps me control my appetite:	☐	☐	☐	☐
3. I don't get so hungry when I smoke:	☐	☐	☐	☐

Motivation to Quit Scale:

4. Please mark (x) only one box below to describe how motivated you are to quit smoking with 0 being "Not at all Motivated" and 10 being "Highly Motivated:"

0 Not at all Motivated	1	2	3	4	5	6	7	8	9	10 Highly Motivated
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Thank you. This form is complete.

Form Reviewed By: _____ Date: _____ ☐

DataFax #010 Plate #111

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

month day year

FORM 11 - Godin Leisure-Time Exercise Questionnaire

This form is to be completed by the subject at screening and at weeks 10 or early termination and 26.

Considering the past **7-day period** (a week), how many times on average did you do the following kinds of exercise for **more than 15 minutes** during your **free time**?

1. Strenuous Exercise (Heart Beats Rapidly)
   (such as: running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling) . . . ☐☐

2. Moderate Exercise (Not Exhausting)
   (such as: fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing). . . . . ☐☐

3. Mild Exercise (Minimal Effort)
   (such as: yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking) . . . . . ☐☐

Thank you. This form is complete.

Form Reviewed By:_____Date: _____ ☐

DataFax #010 Plate #121 Visit #000

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

month day year

FORM 12 - Smoking History Questionnaire

This form is to be completed on the day informed consent is signed at screening.

Record the Subject's answers to the following questions:

1. How old were you when you first smoked a cigarette? (years) . . . . . ☐☐

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

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

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

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

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

7. What methods have you used to attempt to quit smoking? (mark all that apply)

☐ stopped without assistance
☐ counseling
☐ nicotine replacement therapy (gum, patch, spray)
☐ hypnosis/hypnotherapy
☐ acupuncture
☐ prescription medication

no *yes*

8. Are you currently using any tobacco products aside from cigarettes? . . . . . ☐ ☐
If YES, please mark all tobacco products used below.

☐ Cigars
☐ Pipe
☐ Bidis (tobacco wrapped in a temburni leaf)
☐ Smokeless tobacco (pan, chewing tobacco, snuff)

NOTE: Use of any tobacco products other than cigarettes is an Exclusion criteria for study participation.

Form Completed By:_____ Date:_____ ☐

DataFax #010 Plate #131 Visit #000

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

month day year

FORM 13 - Fagerstrom Test for Nicotine Dependence (FTND)

To be completed by the Subject at screening.

Please read each question below. For each question, mark (X) the answer choice which best describes your response.

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

☐ Within 5 Minutes ☐ Within 31 - 60 Minutes

☐ Within 6 - 30 Minutes ☐ 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.?

☐ Yes ☐ No

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

☐ The first one in the morning ☐ All others

4. How many cigarettes per day do you smoke?

☐ 10 or Less ☐ 21 - 30

☐ 11 - 20 ☐ 31 or More

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

☐ Yes ☐ No

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

☐ Yes ☐ No

Thank You. This form is complete.

Form Reviewed By: _____ Date: _____ ☐

DataFax #010 Plate #141

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*		
				month	day	year

FORM 14 - Wisconsin Smoking Withdrawal Scale (WSWS)

This form is to be completed by the Subject at screening and study weeks 1 - 10, or termination visit if earlier.

For each question, please mark an 'X' in the box which describes how you have felt within the past week.

	Strongly Disagree	Disagree	Feel Neutral	Agree	Strongly Agree
1. Food is not particularly appealing to me.	☐	☐	☐	☐	☐
2. I am getting restful sleep.	☐	☐	☐	☐	☐
3. I have been tense or anxious.	☐	☐	☐	☐	☐
4. My level of concentration is excellent.	☐	☐	☐	☐	☐
5. I awaken from sleep frequently during the night.	☐	☐	☐	☐	☐
6. I have felt important.	☐	☐	☐	☐	☐
7. I have felt upbeat and optimistic.	☐	☐	☐	☐	☐
8. I have found myself worrying about my problems.	☐	☐	☐	☐	☐
9. I have had frequent urges to smoke.	☐	☐	☐	☐	☐
10. I have felt calm lately.	☐	☐	☐	☐	☐
11. I have been bothered by the desire to smoke a cigarette.	☐	☐	☐	☐	☐
12. I have felt sad or depressed.	☐	☐	☐	☐	☐
13. I have been irritable, or easily angered.	☐	☐	☐	☐	☐
14. I want to nibble on snacks or sweets.	☐	☐	☐	☐	☐

DataFax #010 Plate #142

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

	Strongly Disagree	Disagree	Feel Neutral	Agree	Strongly Agree
15. I have been bothered by negative moods such as anger, frustration and irritability.	☐	☐	☐	☐	☐
16. I have been eating a lot.	☐	☐	☐	☐	☐
17. I am satisfied with my sleep.	☐	☐	☐	☐	☐
18. I have felt frustrated.	☐	☐	☐	☐	☐
19. I have felt hopeless or discouraged.	☐	☐	☐	☐	☐
20. I have thought about smoking a lot.	☐	☐	☐	☐	☐
21. I have felt angry.	☐	☐	☐	☐	☐
22. I feel that I am getting enough sleep.	☐	☐	☐	☐	☐
23. It's hard to pay attention to things.	☐	☐	☐	☐	☐
24. I have felt happy and content.	☐	☐	☐	☐	☐
25. My sleep has been troubled.	☐	☐	☐	☐	☐
26. I have trouble getting cigarettes off my mind.	☐	☐	☐	☐	☐
27. It has been difficult to think clearly.	☐	☐	☐	☐	☐
28. I think about food a lot.	☐	☐	☐	☐	☐

Thank You. This form is complete.

Form Reviewed By: _____ Date: _____ ☐

DataFax #010 Plate #151

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*		
				month	day	year

FORM 15 - Hamilton Depression Rating Scale (HAM-D)

This form is to be completed at screening and at weeks 4, 8, and 10 or termination visit if earlier.

Instructions: For each item, write the number in the space corresponding with the "CUE" which best characterizes the subject.

1. Depressed Mood (sadness, hopeless, helpless, worthless): . . . . . ☐

(0) Absent

(1) These feeling states indicated on questioning

(2) These feeling states spontaneously reported verbally

(3) Communicates feeling states non verbally - i.e., through facial expression, posture, voice, & tendency to weep

(4) Subject reports VIRTUALLY ONLY these feeling states in his spontaneous verbal & nonverbal communication

2. Feelings of Guilt: . . . . . ☐

(0) Absent

(1) Self-reproach, feels he has let people down

(2) Ideas of guilt or rumination over past errors or sinful deeds

(3) Present illness is a punishment. Delusions of guilt.

(4) Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. Suicide: . . . . . ☐

(0) Absent

(1) Feels life is not worth living

(2) Wishes he were dead or any thoughts of possible death to self

(3) Suicide ideas or gesture

(4) Attempts at suicide (any serious attempt rates 4)

DataFax #010 Plate #152

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

4. Insomnia Early:. . . . . ☐

(0) No difficulty falling asleep

(1) Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour

(2) Complains of nightly difficulty falling asleep

5. Insomnia Middle: . . . . . ☐

(0) No difficulty

(1) Subject complains of being restless and disturbed during the night

(2) Waking during the night - any getting out of bed rates 2 (except for purpose of voiding)

6. Insomnia Late: . . . . . ☐

(0) No difficulty

(1) Waking in early hours of the morning but goes back to sleep

(2) Unable to fall asleep again if gets out of bed

7. Work and Activities: . . . . . ☐

(0) No difficulty

(1) Thoughts and feelings of incapacity, fatigue or weakness related to activities, work or hobbies

(2) Loss of interest in activity, hobbies or work - either directly reported by subject, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)

(3) Decrease in actual time spent in activities or decrease in productivity.

(4) Stopped working because of present illness.

8. Retardation: (slowness of thought and speech; impaired ability to concentrate; decreased motor activity) . . . . . ☐

(0) Normal speech and thought

(1) Slight retardation at interview

(2) Obvious retardation at interview

(3) Interview difficult

(4) Complete stupor

DataFax #010 Plate #153

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

9. Agitation: . . . . . ☐

(0) None

(1) Fidgetiness

(2) “Playing with” hands, hair, etc.

(3) Moving about, cannot sit still

(4) Hand-wringing, nail-biting, hair pulling, biting of lips

10. Anxiety Psychic: . . . . . ☐

(0) No difficulty

(1) Subjective tension and irritability

(2) Worrying about minor matters

(3) Apprehensive attitude apparent in face or speech

(4) Fears expressed without questioning

11. Anxiety Somatic: . . . . . ☐

(0) Absent

(1) Mild

(2) Moderate

(3) Severe

(4) Incapacitating

Physiological concomitants of anxiety, such as:
Gastrointestinal - dry mouth, wind, indigestion, diarrhea, cramps, belching
Cardiovascular - palpitations, headaches
Respiratory - hyperventilation, sighing
Urinary frequency, sweating

12. Somatic Symptoms Gastrointestinal: . . . . . ☐

(0) None

(1) Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen

(2) Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

DataFax #010 Plate #154

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

13. Somatic Symptoms General: . . . . . ☐

(0) None

(1) Heaviness in limbs, back and head. Backaches, headache, muscle ache. Loss of energy and fatigability

(2) Any clear-cut symptom rates 2

14. Genital Symptoms: . . . . . ☐

(0) Absent *Symptoms such as: Loss of libido, Menstrual disturbances*

(1) Mild

(2) Severe

15. Hypochondrias: . . . . . ☐

(0) Not present

(1) Self-absorption (bodily)

(2) Preoccupation with health

(3) Frequent complaints, requests for help, etc.

(4) Hypochondriacal delusions

16. Loss of weight: . . . . . ☐

(0) No weight loss

(1) Probable weight loss associated with present illness

(2) Definite (according to subject) weight loss

17. Insight: . . . . . ☐

(0) Acknowledges being depressed and ill

(1) Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.

(2) Denies being ill at all

DataFax #010 Plate #155

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

18. Diurnal Variation: . . . . . ☐
(If no variation, mark "0". If variation exists note whether symptoms are worse in the morning or evening.)

(0) No variation

(1) Mild ☐ *Worse in a.m.* ☐ *Worse in p.m.*

(2) Severe

19. Depersonalization and Derealization:. . . . . ☐
Such as: Feelings of unreality, Nihilistic ideas

(0) Absent

(1) Mild

(2) Moderate

(3) Severe

(4) Incapacitating

20. Paranoid Symptoms: . . . . . ☐

(0) None

(1) Suspicious

(2) Ideas of reference

(3) Delusions of reference and persecution

(4) Incapacitating

21. Obsessional and Compulsive Symptoms: . . . . . ☐

(0) Absent

(1) Mild

(2) Severe

22. Helplessness:. . . . . ☐

(0) Not present

(1) Subjective feelings which are elicited only by inquiry

(2) Subject volunteers his helpless feelings

(3) Requires urging, guidance, and reassurance to accomplish chores or personal hygiene

(4) Requires physical assistance for dress, grooming, eating, bedside tasks or personal hygiene

DataFax #010 Plate #156

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

23. Hopelessness: . . . . . ☐

(0) Not present

(1) Intermittently doubts that “things will improve” but can be reassured

(2) Consistently feels “hopeless” but accepts reassurances

(3) Expresses feelings of discouragement, despair, pessimism about future, which cannot be dispelled

(4) Spontaneously and inappropriately perseveres, “I’ll never get well” or its equivalent

24. Worthlessness: . . . . . ☐
Ranges from mild loss of esteem, feelings of inferiority, self-depreciation (loss of self-esteem) to delusional notions of worthlessness.

(0) Not present

(1) Indicates feelings of worthlessness (loss of self-esteem) only on questioning

(2) Spontaneously indicates feelings of worthlessness (loss of self-esteem)

(3) Different from above by degree: subject volunteers that he is “no good,” “inferior,” etc.

(4) Delusional notions of worthless -e.g., “I am a heap of garbage” or its equivalent

Enter Sum of Responses for Items 1 - 24: . . . . . ☐☐

Form Completed By: _____Date: _____ ☐

DataFax #010 Plate #161

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*		
				month	day	year

FORM 16 - Positive & Negative Affect Scale (PANAS)

This form is to be completed by the Subject at screening and study weeks 4, 8, and 10, or termination visit if earlier.

This scale consists of a number of words that describe different feelings and emotions. Read each item and then mark (X) the appropriate answer. Indicate to what extent you feel this way right now, that is, at the present moment.

Negative Affect Items:

	Not at All	A Little	Moderately	Quite a Bit	Extremely
1. Afraid	☐	☐	☐	☐	☐
2. Ashamed	☐	☐	☐	☐	☐
3. Distressed	☐	☐	☐	☐	☐
4. Guilty	☐	☐	☐	☐	☐
5. Hostile	☐	☐	☐	☐	☐
6. Irritable	☐	☐	☐	☐	☐
7. Jittery	☐	☐	☐	☐	☐
8. Nervous	☐	☐	☐	☐	☐
9. Scared	☐	☐	☐	☐	☐
10. Upset	☐	☐	☐	☐	☐

Please continue to Next Page

DataFax #010 Plate #162

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Positive Affect Items:	**Not at All**	**A Little**	**Moderately**	**Quite a Bit**	**Extremely**
11. Active	☐	☐	☐	☐	☐
12. Alert	☐	☐	☐	☐	☐
13. Attentive	☐	☐	☐	☐	☐
14. Determined	☐	☐	☐	☐	☐
15. Enthusiastic	☐	☐	☐	☐	☐
16. Excited	☐	☐	☐	☐	☐
17. Inspired	☐	☐	☐	☐	☐
18. Interested	☐	☐	☐	☐	☐
19. Proud	☐	☐	☐	☐	☐
20. Strong	☐	☐	☐	☐	☐

Thank You. This form is complete.

Form Reviewed By: _____ Date: _____ ☐

DataFax #010 **Plate #171**

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*		
				month	day	year

FORM 17 - Expired CO

This form is to be completed at screening, weeks 1 - 10, or termination visit if earlier, and at follow-up visits, weeks 14 and 26.

1. Time of Collection: (use 24-hour clock). . . . . :

2. Exhaled air CO measurement: (ppm) . . . . .

Form Completed By:_____ Date:_____ ☐

Investigator's Signature:_____ Date:_____ ☐

DataFax #010 Plate #181

PAGE *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 18 - Concomitant Medications Form

☐ Mark if **NO** concomitant meds were reported during the active treatment period.

a.

Generic Name of Med _____ **Purpose/Indication** _____

month *day* *year*

Medication Start Date ☐☐ ☐☐ ☐☐☐☐

Medication Stop Date ☐☐ ☐☐ ☐☐☐☐

Related Adverse Event Numbers *(from Form 20 Adverse Event Log)* ☐☐, ☐☐, ☐☐, ☐☐

Dose ☐☐☐☐.☐☐ **Route** ☐ **Units** ☐☐ **Frequency** ☐ ☐ ***Mark (x) if continuing***

---

b.

Generic Name of Med _____ **Purpose/Indication** _____

month *day* *year*

Medication Start Date ☐☐ ☐☐ ☐☐☐☐

Medication Stop Date ☐☐ ☐☐ ☐☐☐☐

Related Adverse Event Numbers *(from Form 20 Adverse Event Log)* ☐☐, ☐☐, ☐☐, ☐☐

Dose ☐☐☐☐.☐☐ **Route** ☐ **Units** ☐☐ **Frequency** ☐ ☐ ***Mark (x) if continuing***

---

c.

Generic Name of Med _____ **Purpose/Indication** _____

month *day* *year*

Medication Start Date ☐☐ ☐☐ ☐☐☐☐

Medication Stop Date ☐☐ ☐☐ ☐☐☐☐

Related Adverse Event Numbers *(from Form 20 Adverse Event Log)* ☐☐, ☐☐, ☐☐, ☐☐

Dose ☐☐☐☐.☐☐ **Route** ☐ **Units** ☐☐ **Frequency** ☐ ☐ ***Mark (x) if continuing***

---

no *yes*

• Will an additional page be used to record concomitant medications? . . . . . ☐ ☐

• **If Yes**, record the next page number. . . . . ☐☐

Use the following codes to complete the form:

Route

1 = Oral
2 = Nasal
3 = Intravenous
4 = Inhalation
5 = Topical/transdermal
6 = Intramuscular
7 = Sublingual
8 = Subcutaneous
9 = Other

Units

01 = Capsule/Tablet
02 = Drop
03 = Milligram
04 = Milliliter
05 = Puff
06 = Spray/squirt
07 = Tablespoon
08 = Teaspoon
09 = Unknown
10 = Other

Frequency

1 = Once a day
2 = Twice a day
3 = Three times a day
4 = Four times a day
5 = PRN

Form Completed By:_____ Date:_____ ☐

DataFax #010 Plate #191

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 19 - Behavioral Compliance

To be completed by study staff for weeks 1 through 9.

1. During the study week indicated in the header did the subject attend the weekly treatment session with the study staff? . . . . . *no* ☐ *yes* ☐
   (If NO, skip to Q. 5. If YES, continue.)

2. Where did the session take place? . . . . . *clinic* ☐ *phone* ☐

3. Date of Session . . . . . ☐☐ ☐☐ ☐☐☐☐
   month *day* *year*

4. Length of Session in Minutes . . . . . ☐☐

5. During this study week indicated in the header, did the subject report taking part in any non-study treatment for smoking cessation? . . . . . *no* ☐ *yes* ☐

If YES, please mark all types of treatment the subject took part in.

- ☐ a. Non-study related counseling session(s) including Quit Line
- ☐ b. Hypnosis/hypnotherapy
- ☐ c. Acupuncture/acupressure
- ☐ d. Other: _____

Form Completed By:_____ Date:_____ ☐

DataFax #010 Plate #201

AE # | *PAGE* | *SITE NO.* | *SUBJECT ID.* | *ALPHA CODE*

FORM 20 - Adverse Event Log

Complete a Form 20 for every individual AE reported after the first study patch is applied. Reassess each AE at subsequent study visits to capture changes in relation, severity, action taken, or outcome.

Give each AE a unique AE #. Keep one log for each AE and complete subsequent pages as needed. Submit this form to CSPCC once the page is complete, or once the AE resolves. If the AE is continuing, carry the AE # to a new page and continue to update at each study visit.

•Mark this box if **NO** adverse events were reported during the entire study ☐

Nature of Illness, Event, or Abnormal Lab Value	**Date of Onset** *month day year*	**Date AE Assessed/Reassessed** *month day year*	**Relation to Study Agent** I	**Highest Level of Severity** II	**Reported as SAE?** III No Yes	**Action Taken** IV	**Outcome** V

Date AE Resolved *month day year*

Mark (X) if Continuing No Yes

Will additional page be used to record this AE? No Yes →

Page #

Form Completed By: _____ Date:_____ ☐

Investigator's Signature:_____ Date:_____ ☐

DataFax #010 Plate #211

AE #	SITE NO.	SUBJECT ID.	ALPHA CODE	DATE OF ASSESSMENT		
				month	day	year
(From Form 20)						

FORM 21 - Serious Adverse Event Form

- This form is used as the source of record for the SAE. Keep a copy of this completed form in the subject's study binder.

Participant Data

*Mandatory Field

1. Sex ☐ *Male* ☐ *Female*
2. Ethnicity *(select one)* ☐ *Hispanic or Latino* ☐ *Not Hispanic or Latino* ☐ *Unknown/Not Given*
3. Race *(select as many as deemed appropriate)*
   ☐ *American Indian or Alaskan Native* ☐ *Asian* ☐ *Black or African-American* ☐ *Native Hawaiian, or Pacific Islander* ☐ *White*
4. Intervention/Treatment group assignment: ☐ *Active Medication* ☐ *Placebo* ☐ *Blinded*
5. First study consent date: *(partial allowed - mm/dd/yy || mm/yy)* — *month* *day* *year*
6. First dose of study agent date *(partial allowed - mm/dd/yy || mm/yy)* — *month* *day* *year*

General Information

7. *Birth date — *month* *day* *year*
8. Age ☐☐ *Years*
9. Weight ☐☐☐.☐ ☐ *Pounds* ☐ *Kilograms*
10. Height ☐☐☐.☐ ☐ *Inches* ☐ *Centimeters*
11. *Event onset date — *month* *day* *year*
12. *Report date — *month* *day* *year*
13. *Event name _____
14. *Description of adverse event *(symptoms, course, duration, treatment, and sequelae)* _____
15. Relevant test data *(relevant tests/laboratory data, including dates)* _____

DataFax #010 Plate #212

AE # | *SITE NO.* | *SUBJECT ID.* | *ALPHA CODE*

(From Form 20)

16. Relevant medical psychiatric history
(AIDS, high blood pressure, hepatic/renal dysfunction, pregnancy, drug, alcohol, and smoking use, allergies, etc.)

17. Study phase *(select one)*
- ☐ *Screening/Baseline*
- ☐ *Treatment*
- ☐ *Follow-up*

month *day* *year*

18. Last dose of study agent date
(partial allowed - mm/dd/yy || mm/yy)

19. Event end date
(partial allowed - mm/dd/yy || mm/yy)

Contact Person
(Please list the person at the clinical site to whom questions regarding the SAE should be addressed)

20. Name of person _____

21. Phone _____

22. Email address _____

Categorization
(Select as many as deemed appropriate)

23. Categorization
- ☐ *Death*
- ☐ *Life threatening*
- ☐ *Hospitalization (initial or prolonged)*
- ☐ *Disability*
- ☐ *Congenital (if checked, select one congenital from below)*
  - ☐ *Anomaly*
  - ☐ *Miscarriage*
  - ☐ *Aborted*
  - ☐ *Stillbirth*
  - ☐ *Infant death within first year of life*
- ☐ *Required intervention to prevent impairment/damage*
- ☐ *Other (if other, specify)* _____

DataFax #010 Plate #213

AE # | *SITE NO.* | *SUBJECT ID.* | *ALPHA CODE*

(From Form 20)

Assessment of SAE

24. Severity *(select one)*
- ☐ *Mild*
- ☐ *Moderate*
- ☐ *Severe*

25. Expectedness *(select one)*
- ☐ *Expected*
- ☐ *Unexpected*

26. Study agent related *(select one)*
- ☐ *Definitely*
- ☐ *Probably*
- ☐ *Possibly*
- ☐ *Definitely not*
- ☐ *Unknown*

27. Outcome *(select one)*
- ☐ *Recovered/Resolved*
- ☐ *Recovering/Resolving*
- ☐ *Not recovered/Not resolved*
- ☐ *Recovered/Resolved w/sequelae*
- ☐ *Fatal*
- ☐ *Lost to follow-up*

28. Death date *(partial allowed - mm/dd/yy || mm/yy)* *month* | *day* | *year*

29. Autopsy performed *(select one)*
- ☐ *Yes*
- ☐ *No*
- ☐ *Unknown*

30. Cause of death _____

_____

_____

Psychiatric History

31. Is there a history of psychotic episodes?
- ☐ *Yes*
- ☐ *No*

32. Is the participant taking psychotropic medications?
- ☐ *Yes**
- ☐ *No*

33. Is the participant taking any other type of medications?
- ☐ *Yes**
- ☐ *No*

** List all concomitant medications on Form 18. If concomitant meds are suspected to have contributed to the SAE, complete concomitant meds section on page 8.*

DataFax #010 Plate #214

AE #	SITE NO.	SUBJECT ID.	ALPHA CODE

(From Form 20)

34. Is there a history of suicidal ideation?
- ☐ *Yes*
- ☐ *No*

35. Is there a history of suicidal behavior?
- ☐ *Yes*
- ☐ *No*

36. Is there a history of homicidal ideation?
- ☐ *Yes*
- ☐ *No*

37. Is there a history of homicidal behavior?
- ☐ *Yes*
- ☐ *No*

38. Is there a history of violent behavior?
- ☐ *Yes*
- ☐ *No*

Substance Use

39. Is there recent increased drug use?
- ☐ *Yes*
- ☐ *No*
- ☐ *Unknown*

40. Is there recent increased alcohol use
- ☐ *Yes*
- ☐ *No*
- ☐ *Unknown*

41. Describe drug/alcohol use during two weeks prior to event:

_____

_____

_____

42. Amount/Days of drug/alcohol use during two weeks prior to event: _____

Action Resulting from SAE

43. Study agent *(select one)*
- ☐ *No Action*
- ☐ *Discontinued permanently*
- ☐ *Discontinued temporarily*
- ☐ *Reduced dose*
- ☐ *Increased dose*
- ☐ *Delayed dose*
- ☐ *Continued dose*
- ☐ *Unknown*

DataFax #010 Plate #215

AE #	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

(From Form 20)

44. Study treatment participation *(select one)*
- ☐ *Continue in study*
- ☐ *Discontinue from study*
- ☐ *Transferred to follow-up*

45. IRB notification date *(Date must be completed prior to authorization and validation)*

month	*day*	*year*

46. Informed Consent *(select one)*
- ☐ *No change*
- ☐ *Changed Informed Consent*

47. Study protocol *(select one)*
- ☐ *No change*
- ☐ *Change in study protocol*
- ☐ *Pending*

Additional Comments

DataFax #010 Plate #216

AE # | *SITE NO.* | *SUBJECT ID.* | *ALPHA CODE*

(From Form 20)

*Mandatory Field

Study Agent

* Name _____ Lot Number _____

Expiration date *(partial allowed - mm/dd/yy || mm/yy)* *month* *day* *year*

Route _____ Frequency _____ Blind ☐ *Blinded* ☐ *Unblinded* _____

Dosage _____ Form _____

Start date *(partial allowed mm/dd/yy || mm/yy)* *month* *day* *year*

Stopdate *(partial allowed mm/dd/yy || mm/yy)* *month* *day* *year*

Restart date *(partial allowed mm/dd/yy || mm/yy)* *month* *day* *year*

Continuing ☐ *Yes* ☐ *No*

Comments: _____

_____

Study agents intake: _____

_____

DataFax #010 Plate #217

AE # | *SITE NO.* | *SUBJECT ID.* | *ALPHA CODE*

(From Form 20)

Study staff, enter Concomitant Medications on this page only if they are suspected to have contributed to the SAE.
All concomitant medications taken during the study are to be listed on Form 18, Concomitant Meds.

Concomitant Medications *Mandatory Field

1. * Name _____ Indication _____ Lot Number _____

Expiration date *month day year* | Start date *month day year* | Stop date *month day year* | Continuing ☐ *Yes* ☐ *No*

(partial allowed for Expiration, Start and Stop dates- mm/dd/yy || mm/yy)

Route _____ Frequency _____ Strength _____ Dosage _____ Form _____

2. * Name _____ Indication _____ Lot Number _____

Expiration date *month day year* | Start date *month day year* | Stop date *month day year* | Continuing ☐ *Yes* ☐ *No*

(partial allowed for Expiration, Start and Stop dates- mm/dd/yy || mm/yy)

Route _____ Frequency _____ Strength _____ Dosage _____ Form _____

3. * Name _____ Indication _____ Lot Number _____

Expiration date *month day year* | Start date *month day year* | Stop date *month day year* | Continuing ☐ *Yes* ☐ *No*

(partial allowed for Expiration, Start and Stop dates- mm/dd/yy || mm/yy)

Route _____ Frequency _____ Strength _____ Dosage _____ Form _____

4. * Name _____ Indication _____ Lot Number _____

Expiration date *month day year* | Start date *month day year* | Stop date *month day year* | Continuing ☐ *Yes* ☐ *No*

(partial allowed for Expiration, Start and Stop dates- mm/dd/yy || mm/yy)

Route _____ Frequency _____ Strength _____ Dosage _____ Form _____

Form Completed By: _____ Date: _____ ☐

Investigator's Signature: _____ Date: _____ ☐

DataFax #010 Plate #221

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*	*DATE FORM COMPLETED*		
				month	day	year

FORM 22 - Study Completion/Termination

Complete this form for <u>all</u> randomized subjects upon completion of, or termination from, the treatment phase (weeks 1-9) of the study.

1. Using the list below, choose the answer that best describes the subject's status at the end of the study. (mark only <u>ONE</u> box below)

- ☐ Subject completed the trial (attended at least 1 visit in weeks 10 or 11)
- ☐ Termination due to medical reason unrelated to study medication, specify _____
- ☐ Termination due to medical reason related to study medication, specify _____
- ☐ Subject failed to return to clinic.
- ☐ Termination at subject's request. Specify reason for termination:

  _____
- ☐ Subject moved from area
- ☐ Subject became incarcerated
- ☐ Subject was terminated by clinic physician because of intercurrent illness or medical complications precluding safe administration of study medication.
- ☐ Subject was terminated due to serious or unexpected adverse events. List AE numbers from Form 20 that correspond.

  # ☐☐ # ☐☐ # ☐☐ # ☐☐ # ☐☐
- ☐ Subject was administratively discharged. Specify incident: _____
- ☐ Birth control non-compliance
- ☐ Pregnancy - Females only **(Complete AE Form 20 and SAE Form 21)**
- ☐ Death - **Complete SAE Form 21**

  Date of Death: . . . . . ☐☐ ☐☐ ☐☐☐☐
  month *day* *year*

  Cause of Death (if known): _____

  _____

	no	*yes*
2. Was subject referred to another treatment program?	☐	☐

Form Completed By: _____ Date: _____ ☐

DataFax #010 Plate #231

WEEK | *SITE NO.* | *SUBJECT ID.* | *ALPHA CODE* | *DATE OF ASSESSMENT* (month / day / year)

FORM 23 - Follow-Up

Complete this form <u>For All Randomized Subjects</u> at follow-up, weeks 14 and 26.
For subject's that terminate earlier than week 10, complete this form once approximately 30 days after termination.

1. Has contact been made with the subject? . . . . . no ☐ yes ☐
If YES, complete questions 1a through 1e. If NO, go to question 2.

a. If YES, date of contact: . . . . . ☐☐ ☐☐ ☐☐☐☐ (*month* / *day* / *year*)

b. Does the subject report smoking <u>any</u> cigarettes since the last contact? . . . . . no ☐ yes ☐

c. If **YES**, indicate the average number of cigarettes smoked per day: . . . . . ☐☐

d. Does the subject report engaging in treatment for smoking cessation since the last contact? . . . . no ☐ yes ☐

If YES, specify all treatment used: _____

e. Does the subject report that he/she would use the study medication again if it were generally available for smoking cessation? . . . . . no ☐ yes ☐

2. If contact has not been made with the subject, specify the reason:

_____

3. If unable to reach subject, has contact been made with someone who can verify his/her status? . . . . no ☐ yes ☐

a. If YES, date of contact . . . . . ☐☐ ☐☐ ☐☐☐☐ (*month* / *day* / *year*)

b. If NO, explain _____

4. Has the subject died? . . . . . no ☐ yes ☐ unknown ☐

a. Date of Death . . . . . ☐☐ ☐☐ ☐☐☐☐ (*month* / *day* / *year*)

b. Cause of Death _____

c. Information verified by site staff (e.g., coroner's office, death certificate) . . . . . no ☐ yes ☐

Form Completed By: _____ Date: _____ ☐

DataFax #010 Plate #241

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 24 - Compliance

Study staff, complete one entry on this form for each day of the study week for weeks 1 - 10.
If no patches were dispensed or returned, enter 00. If no cigarettes were smoked, enter 00.

Day	Date	Attended clinic?	# Patches Dispensed	Was patch worn?	# of unused patches returned
1.	*month* *day* *year*	*no* ☐ *yes* ☐		*no* ☐ *yes* ☐	
	# of cigarettes smoked:	Has the subject used any other non-cigarette tobacco products? ☐ *no* ☐ *yes*			
	Comments:				
2.	*month* *day* *year*	*no* ☐ *yes* ☐		*no* ☐ *yes* ☐	
	# of cigarettes smoked:	Has the subject used any other non-cigarette tobacco products? ☐ *no* ☐ *yes*			
	Comments:				
3.	*month* *day* *year*	*no* ☐ *yes* ☐		*no* ☐ *yes* ☐	
	# of cigarettes smoked:	Has the subject used any other non-cigarette tobacco products? ☐ *no* ☐ *yes*			
	Comments:				
4.	*month* *day* *year*	*no* ☐ *yes* ☐		*no* ☐ *yes* ☐	
	# of cigarettes smoked:	Has the subject used any other non-cigarette tobacco products? ☐ *no* ☐ *yes*			
	Comments:				

DataFax #010 Plate #242

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Day	Date	Attended clinic?	# Patches Dispensed	Was patch worn?	# of unused patches returned
5.	*month* *day* *year*	*no* ☐ *yes* ☐		*no* ☐ *yes* ☐	
	# of cigarettes smoked:	Has the subject used any other non-cigarette tobacco products? ☐ *no* ☐ *yes*			
Comments:					
6.	*month* *day* *year*	*no* ☐ *yes* ☐		*no* ☐ *yes* ☐	
	# of cigarettes smoked:	Has the subject used any other non-cigarette tobacco products? ☐ *no* ☐ *yes*			
Comments:					
7.	*month* *day* *year*	*no* ☐ *yes* ☐		*no* ☐ *yes* ☐	
	# of cigarettes smoked:	Has the subject used any other non-cigarette tobacco products? ☐ *no* ☐ *yes*			
Comments:					

Form Completed By: _____ Date:_____ ☐

Investigator's Signature:_____ Date:_____ ☐

DataFax #010 Plate #251 Visit #000

SITE NO.	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*		
			month	day	year

FORM 25 - Urine Drug Screen

Study staff, perform a urine drug screen at screening to evaluate inclusion/exclusion criteria.

NOTE: Urine drug screen may be repeated once if a subject screens positive for THC. Complete this form at screening for the qualifying urine drug screen ONLY.

1. Urine Temperature within expected range? ☐ *No* ☐ *Yes*

SCREEN FOR:

A. COCAINE ☐ *Neg* ☐ *Pos*

B. METHAMPHETAMINE ☐ *Neg* ☐ *Pos*

C. OPIATES ☐ *Neg* ☐ *Pos*

D. THC ☐ *Neg* ☐ *Pos*

Form Completed By: _____ Date: _____ ☐

DataFax #010 Plate #261

PAGE	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

FORM 26 - Protocol Non-Compliance

*This form is to be completed by a study monitor to record every event of protocol non-compliance throughout the study. Use the Non-Compliance codes at the foot of this form to describe the event. For multiple events of non-compliance that occur on the same date, assign a sequential event number to each event. Single events for a date should be assigned an event number of 01.

	Date of Non-compliance *month*	*day*	*year*	Event #	Non-compliance Code	Reason for Non-compliance
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Non-compliance codes:
1 = Informed consent signed after patient started screening procedures (record date screening procedures were initiated as date of non-compliance)
2 = Inclusion/Exclusion criteria not met (record date patient was randomized as date of non-compliance)
3 = Pregnancy test not performed at screening (record date patient was randomized as date of non-compliance)
4 = Screening information incomplete (record date patient was randomized as date of non-compliance)
5 = Required study data not obtained or obtained late during treatment phase (record date data was due from starter sheet as date of non-compliance)
6 = Source data documentation not available (record date data collected as date of non-compliance)
7 = Serious adverse event not reported appropriately (record date of serious adverse event as date of non-compliance)
8 = Other, if other please provide description and reason under "Reason for Non-compliance".

Form Completed By: _____ Date: _____ ☐

Investigator's Signature: _____ Date: _____ ☐