

Nicotine Replacement Therapy Sampling & Selection

Study Protocol

NCT03276780

May 19, 2021

Karen Cropsey, PsyD, Principal Investigator

University of Alabama at Birmingham

Birmingham, AL 35294

# **Nicotine Replacement Therapy Sampling and Selection**

(Nicotine Replacement Therapy Sampling and Selection to Increase Medication Adherence)

(IRB-151019004)

Dr. Karen Cropsey

---

## **Introduction**

This Manual of Procedures (MOP) has been created to help build a framework upon which all research staff can base their approach to dealing with enrolling participants in the study and adhering to study protocol. The goal of this manual is to create more consistency across study researchers and students.

## **Brief Purpose of Study**

This study is designed to examine whether In Vivo nicotine replacement therapy (NRT) experience intervention will be effective in quitting smoking as compared to behavioral standard of care smoking cessation treatment. For this study, In Vivo experience is: the use of one of four different short-acting NRT products in conjunction with nicotine patches during session. Specialized counseling focused around the experience of NRT, including how the use of NRT may help with quitting smoking, side effects, and smoking cessation expectancies will also be utilized.

If eligible to participate, subjects will be randomized into one of the four Intervention (In-Vivo) groups or the control group. They will be asked to fill out forms regarding smoking behavior, demographics, medical information, and a contact sheet. Some questionnaires will be repeated at every visit and others will be repeated less frequently. Participants are asked to complete 13 weeks of intervention, comprised of five weeks of smoking cessation therapy (Intervention or Control; Weeks 1-5) and three treatment sessions designed to measure medication adherence (Weeks 6, 9 and 13). Following intervention completion, participants will be asked to return for a follow up visit at one month.

Participants in the Intervention groups will be asked to go as long as they can without smoking the day of the therapy sessions. They will put a nicotine patch on during each of the weekly sessions. During the first four weekly sessions, participants in the Intervention groups will also use a different form of short-acting NRT each week (nicotine gum, lozenge, inhaler, nasal spray) and in the fifth week, will select which short-acting medication they would prefer to use for the duration of the study. Participants will discuss the experience of wearing the patch and/or using the short-acting NRT while they are in session. The Control group will not use NRT medication during the sessions but will be given standard counseling regarding quitting smoking.

At each visit a carbon monoxide (CO) test will be administered (like an alcohol breathalyzer), which will show how much CO is in a participant's lungs as a result of smoking. A cotinine test will always be done at Baseline, and then at subsequent visits if the CO test indicates a participant is not smoking. Throughout the study, women of child bearing potential will be asked to give a urine sample to test for pregnancy a total of 4 times, and for all participants a urine drug screen will be completed at Baseline. See the chart below for more details regarding frequency of tests and questionnaires.

## Table of Contents

Introduction	1
Brief Purpose of Study	1
Table of Contents	3
Measurement Occurrence Chart	5
Accessing the Shared Drive	6
Recruitment and Eligibility	6
Subject Recruitment	6
Subject Enrollment	6
Inclusion Criteria	6
Exclusion Criteria	6
Protocol for Enrollment	7
Forms/Links	7
Participant Folder Preparation	7
Carbon Monoxide Monitor	8
Carbon Monoxide Monitor Use Steps	8
Carbon Monoxide Monitor and Intervention Sessions	8
Carbon Monoxide Gas Ordering	8
Calibration Log	8
Calibration	8
Carbon Monoxide Gas Disposal	9
Urine Collection Protocol	9
Collection	9
Surface Pros, REDCap, Dropbox, Digital Recorders	10
Surface Pros	10
Login for Surface Pros and REDCap	10
Wi-Fi Login	10
Troubleshooting Wi-Fi Login	10
UAB Psychiatry IT	10
REDCap	11
UAB REDCap Contact	11
REDCap Video Tutorials	11
Entering New Participant Data	11
Random Assignment	11
Adding to Existing Participant Data	12
Editing Data	12
Survey Queue	12
Audio Option in Questionnaires	13
Exporting to Excel/SPSS	13
Scheduling a New Participant	14

Changes to Schedule	14
No-Show/Cancel	14
Reschedule	14
Dropbox	14
Prescriptions	15
Study Physician/Co-Investigator Contact Information	15
Pharmacy/Pharmacist Contact Information	15
Nicotine Patch	15
Nicotine Gum	15
Nicotine Lozenge	15
Nicotine Inhaler	16
Nicotine Nasal Spray	16
Medication Ordering	16
Medication Inventory	16
Medication Storage	17
Medication Dispensing	17
Intervention Group A	17
Intervention Group B	18
Intervention Group C	19
Intervention Group D	20
Control Group	21
Medication Instructions	21
Appointment Reminder Calls	22
Appointment Reminder Text Messages	22
Rescheduling Parameters	23
Compensation	23
Compensation Amount per Study Visit	23
Documenting Distributed Compensation	23
GreenPhire ClinCard	24
Login Information	24
How to Look Up a Subject	24
How to Register a Subject	24
How to Register a Subject in an Additional or Extension Study	25
How to Assign a ClinCard to a Subject	25
How to Make a Site Visit Payment	25
How to Request Assistance	26
Adverse Events (AEs) & Serious Adverse Events (SAEs)	26
Suicidality	28
Baseline Appointments	29
Materials	29
Procedures	29
Intervention Fidelity	30
Therapy Protocol	31
Week 1 – 5	31
Intervention Group A	31

Intervention Group B	40
Intervention Group C	48
Intervention Group D	57
Control Group	66
Week 6	71
Week 9	72
Week 13	73
Month 1 Follow-up	74
Ecological Momentary Assessment (EMA)	74
Data Entry	75
Data Collection Parameters	76
Amendments/Protocol Changes	78

## Measurement Occurrence Chart

Data Collection Instrument	Baseline (1)	Wk1 (2)	Wk2 (3)	Wk3 (4)	Wk4 (5)	Wk5 (6)	Wk6 (7)	Wk9 (8)	Wk13 (9)	M1FU (10)
Screening Questionnaire (survey)										
Session Status (survey)										
Med Given (survey)		✓	✓	✓	✓	✓	✓	✓	✓	✓
CO Level	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Cotinine Test	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pregnancy Test	✓				✓		✓	✓	✓	
Urine Drug Screen	✓									
Mini International Neuropsychiatric Interview Mini	✓									
Demographic Form (survey)	↓									
NRT Adherence (survey)		↓	↓	↓	↓	↓	↓	↓	↓	↓
Minnesota Nicotine Withdrawal Scale Pre (survey)	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Questionnaire Of Smoking Urges Short Form Pre (survey)	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Smoking History Form (survey)	↓									
Weekly Smoking Behavior	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Thoughts About Abstinence (survey)	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Fagerstrom Test For Nicotine Addiction (survey)	↓					↓	↓	↓	↓	↓
Perceived Stress Scale (survey)	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Wisconsin Inventory of Smoking Dependence Motives (survey)	↓					↓	↓	↓	↓	↓
Treatment Expectations (survey)	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Smoking Abstinence Questionnaire (survey)	↓					↓	↓	↓	↓	↓
Abstinence Related Motivational Engagement ARME (survey)	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Attitudes About Nicotine Replacement Therapy (survey)	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Treatment Satisfaction Survey (survey)						↓		↓	↓	↓
Credibility Expectancy Questionnaire CEQ (survey)						↓		↓	↓	↓
Symptom Side Effects (survey)	↓	↓	↓	↓	↓	↓	↓	↓	↓	
Barratt Impulsivity Scale	✓									
Pittsburgh Sleep Quality Index	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Minnesota Nicotine Withdrawal Scale Post (survey)	↓	↓	↓	↓	↓	↓				
Questionnaire Of Smoking Urges Short Form Post (survey)	↓	↓	↓	↓	↓	↓				
Alliance Questionnaire						✓				
Alliance Questionnaire Therapist						✓				
Group Assignment (survey)										
Audio Recording Length		✓	✓	✓	✓	✓				

## Accessing the Shared Drive

1. Click on the home button at the bottom left hand corner of the computer screen.
2. Go to “Computer.”
3. Click on “PBN.” Enter your Blazer ID and password if necessary.
4. Click on “Cropsey-Lab.”
5. Click on the “NRT Sampling” folder (this is the folder for our study).

## Recruitment and Eligibility

### Subject Recruitment

Participants will be recruited from the community. Flyers describing the study will be placed in low income areas around the city. Potential participants should be instructed to call the study team for eligibility screening (205) 975-7809.

### Subject Enrollment

#### Inclusion Criteria

- At least 18 years old
- Qualifying as low income (making <150% above the poverty line, or <\$22,260 as a single, or <\$45,570 for a family of four)
- Smoked at least 10 cigarettes per day (CPD) for the last year
- Live in an unrestricted environment (e.g., living in a halfway house, or independently)
- Expire carbon monoxide (CO) >8 ppm at Baseline
- Positive cotinine test at Baseline

#### Exclusion Criteria

- Pregnant or nursing
- Currently receiving treatment to quit smoking (enrolled in smoking cessation treatment program, using NRT products, or prescribed bupropion or varenicline)
- Known sensitivity to nicotine replacement or allergy to adhesive used in nicotine patches
- Trouble breathing, a pulmonary condition, or sinus problems
- Untreated severe angina or heart attack within last month
- TMJ (temporomandibular joint) problems (unable to use nicotine gum)
- Cognitive impairment or unstable psychiatric condition that interferes with the informed consent process
- Daily or exclusive use of other tobacco products (electronic cigarettes, little cigars, etc.)
- Non-English Speaking

#### Protocol for Enrollment

1. Check the Ineligible section of the Screening Form folder and/or Screening Database to see if the person inquiring has already been screened
2. Complete a Screening Form for each potential participant
3. If participant is ineligible, do not tell them they are ineligible until the screening form is complete
4. Enter the Screening Form into the Screening Database
5. File the Screening Form in the Screening Form folder according to eligibility. The folder is kept in the filing cabinet C in room L107B.

## Forms/Links

Screening Form → P:\Cropsey-Lab\NRT Sampling\Measures\Screening Form NRT R34  
Screening Database → Z:\Cropsey-Lab\NRT Sampling\Datasets\Screening

## Carbon Monoxide Monitor

### Carbon Monoxide Monitor Use Steps

1. Insert t-valve into the taper on the top of the machine case
2. Turn on machine
3. Put on gloves and attach a new white mini mouthpiece to the t-valve
4. Make sure machine is reading at zero
  - If it does not zero out, move black slider above the Vitalograph logo to left or right until it reads zero
5. Tell participant to take a deep breath, hold for 10 seconds, and breathe out slowly through the mouthpiece over a period of 20 seconds or more
6. Record the highest number from the machine on the NRT adherence sheet and enter into REDCap

\*\*You may also want to remind the participant of their CO level when you begin the therapy session with them. \*\*

### Carbon Monoxide Monitor and Intervention Sessions

- Participants are to provide a CO sample at each visit.
- **If they blow  $\leq 8$  on a Baseline visit, they are not eligible to participate**
- **If they blow  $\leq 3$  on subsequent visits, a cotinine test must be done and recorded in REDCap**

### Carbon Monoxide Gas Ordering

- CO gas is to be ordered through the Vitalograph website
- Email Leslie George to order: [lesliegeorge@uabmc.edu](mailto:lesliegeorge@uabmc.edu)
- Link to website: <https://vitalograph.com/shop>

### Calibration Log

- T-valves must be replaced after every 50 uses (approximately every two months)

### Calibration

1. Turn on CO Breathalyzer Machine
2. Attach t-valve into the taper on the top of the machine case

3. Take CO calibration gas and insert end of gas tube into t-valve
4. Slowly open the gas cap (either twist open or push up) and watch the CO machine reader go up in number until it slows down. When the reader stays on the same number for approximately 5 seconds, you know it is now calibrated.
5. Close the gas tank by twisting the cap or pulling it down
6. Disconnect the gas tank
7. Leave the machine on until it brings the number back down to zero (approximately 30 seconds) then turn the machine off
8. Calibration is complete

## Carbon Monoxide Gas Disposal

- Throw in trash (safe gas) and make sure cap is opened all the way
- Each gas container has approximately enough pressure to calibrate a machine 5-6 times
- Need to replace when it runs low on pressure, or runs out of pressure (at 0 psi). You can read the pressure gauge to find out just how much pressure is in each canister.

Instructions: Return unused product to the supplier. If product must be disposed of on-site, incineration using a suitable flare is typically used. Disposal of carbon monoxide must be done in an environmentally acceptable manner in compliance with all applicable national and local codes. (Also known as: Throw in trash)

\*CO Machine Training Manual is located at: <https://vitalograph.co.uk/downloads/display/8>

## Urine Collection Protocol

- **WEAR GLOVES AT ALL TIMES WHEN HANDLING URINE SAMPLES.**
- Drug testing should be completed at Baseline appointment for all participants
- Cotinine testing is to be conducted Baseline appointment for all participants
- Cotinine testing is done at subsequent visits if the participant blows 3 or below on their CO test
  - Instructions for Cotinine tests located at: <http://www.xlar.com/I/NICOTINE-TEST.pdf>
- Pregnancy testing is completed at Baseline, Week 5 and Week 9
  - Instructions for Pregnancy tests are located at: <https://static.fishersci.com/cmsassets/downloads/segment/Healthcare/pdf/HCGdipPI23900527.pdf>
- We will conduct the pregnancy and cotinine testing for participants

## Collection

1. To prepare you will need:
  1. Urine cup
  2. Urine lid
  3. Cotinine test (for Baseline or when participant blows less than 3 on CO test)

4. Pregnancy test (for women at Baseline, Week 5 and Week 9)
5. Gloves
2. Urine cups and lids can be found in the filing cabinet in room L107E.
3. Escort participant to the bathroom
4. Test female urine for pregnancy
5. Test urine for cotinine at Baseline and if participant blows  $\leq 3$  on CO monitor at subsequent visits
6. Record drug and pregnancy test results in REDCap

## Surface Pros, REDCap, Dropbox, Digital Recorders

### Surface Pros

Surface Pros can be found in the locked desk drawers located in rooms L107A & B. At the beginning of each day, study staff will get both tablets out and turn them on to ensure they are fully charged and updated in preparation for the day's appointments.

***Login for Surface Pros and REDCap:*** Use your Blazer ID and password

***Wi-Fi Login:*** Be sure to use UABSecure network, which is secure (do NOT use UABStartHere or UABHS Public). You will only need to enter your credentials once. You will need to do this under your own login for each Surface Pro.

### ***Troubleshooting Wi-Fi Login:***

- Go to “Start” (flag at bottom left hand corner) and select Settings
- Select Network
- Disconnect from Wi-Fi and re-connect
- If that still does not work, reboot/shut-down surface pro and try again

### ***UAB Psychiatry IT***

UAB Department of Medicine  
1808 7th Avenue South. BDB-455  
Birmingham, AL 35294-0012

Physical Location: Boshell Diabetes Building (BDB-455)  
Website: <http://www.uab.edu/DomIT>

### **Regular Business Hours**

Monday - Friday: 8:00 AM to 5:00 PM.  
[Support](#) website can be accessed 24 hours / 7 days a week.

## Help Desk Information

Phone: (205) 975-HELP (975-4357)  
E-mail: [domhelp@uab.edu](mailto:domhelp@uab.edu)  
Website: <https://support.dom.uab.edu>

## REDCap

### UAB REDCap Contact:

Shalini Saini  
BlazerID: ssaini  
Phone: (205) 975-4357  
Email: ssaini@uabmc.edu

**REDCap Video Tutorials:** Videos are located in REDCap under the Help & Information tab on the lower left side of the screen. More are also available on the Welcome Page under **Training Videos**. Specific tutorials will usually be located in the instructions of the application you are currently working in.

### Entering New Participant Data:

1. Go the website <https://redcap.dom.uab.edu/redcap/index.php> and log into REDCap with your UAB BlazerID and password.
2. Click on **My Projects** in the upper left hand corner of the page.
3. From the **My Projects** page, select the Project Title **“NRT Sampling and Selection to Increase Medication Adherence”**
4. Click **Add/Edit Records** on the left side of the screen under the **Data Collection** tab and select **Arm 2: Pre-Randomization** from the drop down menu.
5. Click **Add New Record** to be taken to the **Record Home Page** of the new participant.
6. From this page select the Data Collection Instrument **CO Level** (Make sure to select the correct one, which is dependent upon which visit they have come in for) to begin the data collection process with the participant.

### Random Assignment:

Complete the Data Entry Process as instructed under **Entering New Participant**. One of the forms under the REDCap documents for the Baseline Visit (BL) is titled **Group Assignment**. Once in this form, click the randomize button on this document to randomly assign the participant.

### Adding to Existing Participant Data:

1. Go to the website <https://redcap.dom.uab.edu/redcap/index.php> and log into REDCap with your UAB BlazerID and password
2. Click on **My Projects** in the upper left hand corner of the page
3. From the **My Projects** page, select the Project Title **“NRT Sampling and Selection to Increase Medication Adherence”**
4. Click **Add/Edit Records** on the left side of the screen under the **Data Collection** tab
5. Select the existing participant’s ID # from the drop-down list that you would like to add the new data to
6. From the **Data Collection** page choose the desired data form under the correct study visit event to enter the data

### **Editing Data:**

1. Go the website <https://redcap.dom.uab.edu/redcap/index.php> and log into REDCap with your UAB BlazerID and password
2. Click on **My Projects** in the upper left hand corner of the page
3. From the **My Projects** page, select the Project Title **“NRT Sampling and Selection to Increase Medication Adherence”**
4. Click **Add/Edit Records** on the left side of the screen under the **Data Collection** tab
5. Select the existing participant’s ID # from the drop-down list that you would like to add the new data to

### **Survey Queue:**

The survey queue is a way for participants to fill out questionnaires in REDCap in a more user-friendly display. When in survey mode, the screen simply shows the questionnaire with a submit button at the bottom. Once begun, the questionnaires will automatically load in the appropriate order corresponding to whichever session or visit the participant is attending. If a subject accidentally forgets to answer something, the survey prevents them from moving on, which gives staff the opportunity to assist if necessary. It is very important to note that surveys must be completed in the order they are shown.

To access the survey queue:

- Follow the steps as above, titled “Entering New Participant Data” or “Adding to Existing Participant Data”, depending on whether you are working with a new or existing subject
- From the **Record Home Page**, select the **CO Level** Data Collection Instrument, corresponding to the appropriate appointment, e.g. Baseline, Week 1, etc.
- Toward the upper right corner of the form, there is a gray drop down box titled **“Survey Options.”** Click this box and select **“Open Survey.”** A new tab will open displaying the form now in survey display. If the tab does not open, try clicking **“Open Survey”** again or double-clicking.
- Staff should fill out **CO Level**, select **“Submit”**, and the next form will auto load. The survey queue is set up to stop before loading the questionnaires for participants. The screen will indicate you have finished with that set of surveys, and will provide a link at the bottom to start the next set to be filled out by the participant.

- When appropriate, select that link and have the participant proceed through the queue. The queue will automatically stop again before loading any other questionnaires intended to be filled out after the counseling session or completed by staff, for example.

\*\*You can access the survey queue from any of the measures set up as surveys by again selecting “**Open Survey**” from the gray “**Survey Queue**” drop down box toward the upper right corner of the page.

\*\*Surveys display on the **Record Home Page** as complete with a green circle and white check mark.

#### To edit data once surveys are complete:

- From the **Record Home Page** for a given subject, select the measure you want to edit
- In the red box toward the top of the form, select the gray button “**Edit Response**”
- Once desired changes have been made, select “**Save and Exit Form**” at the bottom

#### Audio Option in Questionnaires:

Within each questionnaire, click the dropdown box labeled “**Survey Options**”, then select “**Open Survey**.” This will open up the questionnaire in a new tab. On this new page, have the participant click on the speaker icon next to the question. The computer will read the question aloud. Once completed, click the submit button on the bottom of the page. Repeat the prior steps for the remainder of the necessary questionnaires.

#### Exporting to Excel/SPSS:

1. Go the website <https://redcap.dom.uab.edu/redcap/index.php> and log into REDCap with your UAB BlazerID and password
2. Click on **My Projects** in the upper left hand corner of the page
3. From the **My Projects** select the Project Title “**NRT Sampling and Selection to Increase Medication Adherence**”
4. Under the **Applications Tab** in the middle left hand column of the screen click on **Data Exports, Reports, and Stats**
5. To export all of the data from REDCap to SPSS click **Export Data** under the **View/Export Options** column for the row A.) All Data. Check the circle for the software you will be exporting the data to and then click **Export Data**
6. Download the 3 files to one folder, run the mapping file, then hit **Run All** (under run tab in the SPSS data module) after opening the SPSS folder. A new Untitled database will then be created. Name and save the database on the share drive.

#### Scheduling a New Participant:

1. Go the Google Calendar website <https://www.google.com/calendar> and log into the Cropsey Lab Google Calendar with the Cropsey Lab username and password
2. Check the **NRT Sampling Calendar** for availability.

3. Add the participant to the **NRT Sampling Calendar** by clicking on the designated day and time.
4. Fill out the **Title of Event** with either the participants' initials for a Baseline appointment or the participants' study ID, intervention type, session week, and who the session will be with.
5. Select the correct time and duration of the appointment.
6. Select save and make sure the appointment appears on the **NRT Sampling Calendar**.

### **Changes to Schedule:**

#### **No-Show/Cancel**

1. Go to the Cropsey Lab Google Calendar and select appointment
2. Under **Title of Event**, type in **No Show** or **Canceled**
3. Attempt to reschedule participant
4. Once a reschedule has been confirmed, follow the instructions below

#### **Reschedule**

1. Go to the Cropsey Lab Google Calendar and select appointment
2. Under **Title of Event**, type in **“Rescheduled”** once the appointment is rescheduled.
3. Change the appointment time and duration.
4. Select save and make sure the appointment appears on the **NRT Sampling Calendar**.
5. If you are adjusting by a whole week or more, select “Yes, adjust all dates” and be sure to adjust any that fall on weekends or days you are not available
6. If you are changing an appointment by a day or two and subsequent appointments will not be affected, select “No, just this one”
7. Double check your calendar against other appointments, and make sure you have no future conflicts

#### **Box.com**

Go to [www.uab.edu/adminsys](http://www.uab.edu/adminsys) and log into the Box.com on the Surface Pro under your blazerid and password. Then proceed with the following steps:

#### **Log-In Information:**

BlazerID:

Password:

### **Prescriptions**

#### **Study Physician/Co-Investigator**

Dr. Richard Shelton

Email: [rcshelton@uabmc.edu](mailto:rcshelton@uabmc.edu)

Phone: (205) 975-9295

#### **Co-Investigator**

Dr. Peter Hendricks  
Email: phendricks@uab.edu  
Phone: (205) 202-1387

### **Pharmacy:**

The Kirklin Clinic Pharmacy, 2000 6<sup>th</sup> Avenue South, Birmingham, AL 35233

### **Pharmacist:**

Dr. Clay Patterson or Wynna Hebson  
Phone: (205) 801-8731  
Fax: (205) 801-8902

### **Nicotine Patch**

- Nicotine patches (21, 14, or 7 mg): One box contains 14 patches.
- 21 mg : For participants who self-report smoking *over 10 CPD*
- 14 mg: For participants who self- report smoking *10 or less CPD*
- 7 mg: Lowest-dose patch and dispensed at Week 9

### **Nicotine Gum**

- Nicotine gum (2 or 4 mg): One box contains 110 pieces
- 4 mg: For participants who self-report smoking first cigarette within 30 minutes after awakening (reported on Fagerström Test for Nicotine Dependence at Baseline)
- 2 mg: For participants who self-report smoking first cigarette more than 30 minutes after awakening (reported on Fagerström Test for Nicotine Dependence at Baseline)

### **Nicotine Lozenge**

- Nicotine lozenges (2 or 4 mg, mint flavor): One box contains 3 Quit Tubes, with 24 lozenges per tube, for a total of 72 lozenges per box.
- 4 mg: For participants who self-report smoking first cigarette within 30 minutes after awakening (reported on Fagerström Test for Nicotine Dependence at Baseline)
- 2 mg: For participants who self-report smoking first cigarette more than 30 minutes after awakening (reported on Fagerström Test for Nicotine Dependence at Baseline)
- Participants are encouraged to use 8-10 lozenges per day, and at most 20 per day

### **Nicotine Inhaler**

- One box contains the device and 168 cartridges
- 4mg (20 minutes of active puffing): For participants who self-report smoking first cigarette within 30 minutes after awakening (reported on Fagerström Test for Nicotine Dependence at Baseline)

- 2mg (10 minutes of active puffing): For participants who self-report smoking first cigarette more than 30 minutes after awakening (reported on Fagerström Test for Nicotine Dependence at Baseline)

### Nicotine Nasal Spray

- One box contains four 10ml bottles
- 2mg: 2 sprays (1mg) in each nostril

### Medication Ordering

The patches, gum, lozenges, inhalers, and nasal spray are ordered from The Kirklin Clinic (TKC) in bulk prescriptions.

1. Order 75 boxes of 21mg patches at a time, or as needed
2. Order 90 boxes of 14mg patches at a time, or as needed
3. Order 90 boxes of 7mg patches at a time, or as needed
4. Order 15 boxes of 4mg nicotine gum at a time, or as needed
5. Order 15 boxes of 2mg nicotine gum at a time, or as needed
6. Order 15 boxes of 4mg mint lozenges at a time, or as needed
7. Order 15 boxes of 2mg mint lozenges at a time, or as needed
8. Order 15 boxes of inhalers at a time, or as needed
9. Order 15 boxes of nasal spray at a time, or as needed
10. The respective blank RX form(s) and “Pharmacy Memo” should be completed and scanned to Dr. Shelton’s assistant for his signature
11. The scanner can be found in the break room
12. Send the documents to Dr. Shelton’s assistant Melissa Blair: melissablair@uabmc.edu, with the subject line: **Cropsey Smoking Cessation RX- Signature Requested**
13. Dr. Shelton’s assistant will then send the signed RX back and then should be faxed along with the memo to TKC.
14. Allow 24 hours for the pharmacy to prepare the bulk prescription
15. Call pharmacy to confirm prescription is ready prior to picking up

### Medication Inventory

We will keep a running inventory for medication. This Excel sheet will be located on the share drive. It should be filled out by study staff when medications are acquired and distributed to participants.

**File → P:\Cropsey-Lab\ NRT Sampling\Medication\Medication Inventory**

### Medication Storage

All medications should be kept in the medication cabinet in room L107E. Check the medication weekly to be sure that the medication is accounted for.

## Medication Dispensing

All study participants will be receiving medication for this study. The type of medication they receive will depend upon the group to which they are assigned.

### Intervention Group A

Week 1:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
11 blister packs of gum (dose based on if subject reports at Baseline smoking first cigarette within 30 minutes of waking)

Week 2:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
1 box inhaler and cartridges

Week 3:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
1 nasal spray bottle

Week 4:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
2 quit tubes of baseline-indicated lozenge dose, and 1 quit tube of the other dose (for approx. 8-10/day, with both doses to try, e.g., if subject reports at Baseline smoking first cigarette within 30 minutes of awakening, he or she will receive 2 tubes of the 4 mg dose and 1 tube of the 2 mg dose).

Week 5:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
Participant's selection of short-acting NRT (week long supply)

Week 6:

21 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
Participant's selection of short-acting NRT (3 week supply)

Week 9:

28 patches  
Participant's selection of short-acting NRT (4 week supply)

\*21 mg participants will begin to taper dose. They will receive 2 weeks' worth of 14 mg patches and 2 weeks' worth of 7 mg patches.

\*\*14 mg participants will receive 4 weeks of 7mg patches.

\*\*Participants using gum or lozenges will taper amount used. They will use half of their original amount for the first two weeks and  $\frac{1}{4}$  of their original amount for the next two weeks.

### Intervention Group B

Week 1:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
2 quit tubes of baseline-indicated lozenge dose, and 1 quit tube of the other dose (for approx. 8-10/day, with both doses to try, e.g., if subject reports at Baseline smoking first cigarette within 30 minutes of awakening, he or she will receive 2 tubes of the 4 mg dose and 1 tube of the 2 mg dose).

Week 2:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
1 nasal spray bottle

Week 3:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
1 box of inhaler and cartridges

Week 4:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
11 blister packs of gum (dose based on if subject reports at Baseline smoking first cigarette within 30 minutes of waking)

Week 5:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
Participant's selection of short-acting NRT (week long supply)

Week 6:

21 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
Participant's selection of short-acting NRT (3 week supply)

Week 9:

28 patches  
Participant's selection of short-acting NRT (4 week supply)

\*21 mg participants will begin to taper dose. They will receive 2 weeks' worth of 14 mg patches and 2 weeks' worth of 7 mg patches.

\*\*14 mg participants will receive 4 weeks of 7mg patches.

\*\*Participants using gum or lozenges will taper amount used. They will use half of their original amount for the first two weeks and  $\frac{1}{4}$  of their original amount for the next two weeks.

### Intervention Group C

Week 1:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
1 nasal spray bottle

Week 2:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
11 blister packs of gum (dose based on if subject reports at Baseline smoking first cigarette within 30 minutes of waking)

Week 3:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
2 quit tubes of baseline-indicated lozenge dose, and 1 quit tube of the other dose (for approx. 8-10/day, with both doses to try, e.g., if subject reports at Baseline smoking first cigarette within 30 minutes of awakening, he or she will receive 2 tubes of the 4 mg dose and 1 tube of the 2 mg dose).

Week 4:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
1 box of inhaler and cartridges

Week 5:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
Participant's selection of short-acting NRT (week long supply)

Week 6:

21 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
Participant's selection of short-acting NRT (3 week supply)

Week 9:

28 patches  
Participant's selection of short-acting NRT (4 week supply)

\*21 mg participants will begin to taper dose. They will receive 2 weeks' worth of 14 mg patches and 2 weeks' worth of 7 mg patches.

\*\*14 mg participants will receive 4 weeks of 7mg patches.

\*\*Participants using gum or lozenges will taper amount used. They will use half of their original amount for the first two weeks and  $\frac{1}{4}$  of their original amount for the next two weeks.

#### Intervention Group D

Week 1:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)

1 box of inhaler and cartridges

Week 2:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
2 quit tubes of baseline-indicated lozenge dose, and 1 quit tube of the other dose (for approx. 8-10/day, with both doses to try, e.g., if subject reports at Baseline smoking first cigarette within 30 minutes of awakening, he or she will receive 2 tubes of the 4 mg dose and 1 tube of the 2 mg dose).

Week 3:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
11 blister packs of gum (dose based on if subject reports at Baseline smoking first cigarette within 30 minutes of waking)

Week 4:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
1 nasal spray bottle

Week 5:

7 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
Participant's selection of short-acting NRT (week long supply)

Week 6:

21 patches (dose based on # of cigarettes smoked per day as reported by subject at Baseline)  
Participant's selection of short-acting NRT (3 week supply)

Week 9:

28 patches

Participant's selection of short-acting NRT (4 week supply)

\*21 mg participants will begin to taper dose. They will receive 2 weeks' worth of 14 mg patches and 2 weeks' worth of 7 mg patches.

\*\*14 mg participants will receive 4 weeks of 7mg patches.

\*\*Participants using gum or lozenges will taper amount used. They will use half of their original amount for the first two weeks and  $\frac{1}{4}$  of their original amount for the next two weeks.

### Control Group

Week 1-4: No medication dispensed

Week 5: 7 patches and selected short-acting NRT

Week 6: 21 patches and selected short-acting NRT (3 week supply)

Week 9: 28 patches and selected short-acting NRT (4 week supply)

**If participants using the 21 mg patch report negative side effects, their dose should be adjusted down to the 14 mg patch for patient safety and medication adherence.**

**If participants using the 4mg gum report negative side effects, their dose should be adjusted down to the 2mg gum for patient safety and medication adherence.**

**If participants using the 4 mg lozenge report negative side effects, their dose should be adjusted down to the 2 mg lozenge for patient safety and medication adherence.**

**If participants using the 4mg dosing instructions for the inhaler report negative side effects, their dose should be adjusted down to the 2mg dosing instructions for patient safety and medication adherence.**

**Participants must sign the Medication Sign-Out Log when receiving medications. Research staff must initial the form and must also log the medication in the Medication Inventory Database.**

### **Medication Instructions**

Medication instruction sheets are located in folders in the filing cabinet in room L107B. These are to be given to participants at Week 5, Week 6, and Week 9,. General instructions on how to use the medications are also located within participants' workbooks.

### **Files can be found at:**

Pharmacy Memo →  
Forms

P:\Cropsey-Lab\NRT Sampling\Medication/RX

Nicotine Patch Blank Rx Form →  
Forms

P:\Cropsey-Lab\NRT Sampling\Medication\R

Nicotine Gum 4mg Rx Form → Forms	P:\Cropsey-Lab\NRT Sampling\Medication\R
Nicotine Gum 2mg Rx Form → Forms	P:\Cropsey-Lab\NRT Sampling\Medication\R
Nicotine Lozenge Blank Rx Form → Forms	P:\Cropsey-Lab\NRT Sampling\Medication\R
Nicotine Inhaler Blank Rx Form → Forms	P:\Cropsey-Lab\NRT Sampling\Medication\R
Nicotine Nasal Spray Blank Rx Form → Forms	P:\Cropsey-Lab\NRT Sampling\Medication\R
Medication Sign-Out Log →	P:\Cropsey-Lab\NRT Sampling\Medication
Medication Instructions Folder →	P:\Cropsey-Lab\NRT
Sampling\Medication/Medication Instructions	

## Appointment Reminder Calls

Please call participants 1-2 days before each scheduled appointment to confirm their appointment date and time. It is also helpful to remind participants to bring back their workbooks and calendars to their appointments, and remind them of any specific instructions previously discussed (for example, reminding an Intervention participant to please not smoke for as long as she/he can the night before the session 1 appointment, and to not smoke the morning of). If a participant wants to change the time or needs to reschedule an appointment, please work with them to do so. Our participants often have hectic lives and are dependent on public transportation or others to get to and from appointments. There may be times when someone has to reschedule a week or more later than their original appointment time. Try to get them to reschedule within a few weeks. If they cannot return for 3 weeks or more, call Dr. Cropsey for guidance. Be sure to follow the instructions on how to reschedule on the calendar in REDCap (MOP pg. 14).

## Appointment Reminder Text Messages

If the participant has agreed to receive text messages, appointment reminders can be completed by sending reminder text messages. All appointment reminder text messages are to be done on the study cell phone. It is very important that the reminder texts are only sent to the participant and follow the appointment reminder scripts located on the share drive. Be sure that when you send an appointment reminder text message, you are sending it to the participant and not the contacts. If you are not sure if the participant is okay with receiving text messages, please refer to the signed consent form located in office L107B or in the Participant Tracking database.

**File** → P:\Cropsey-Lab\ NRT Sampling\Text Messaging\Text Messaging Scripts

**File** → P:\Cropsey-Lab\ NRT Sampling\Datasets\Participant Tracking

## Rescheduling Parameters

We recruit from a population that has very little stability. We should work with them as best we can when it comes to rescheduling them for missed appointments. However, this is done within reason. Here are some parameters to keep in mind when rescheduling participants:

- Baseline appointments will not be rescheduled more than 5 times. After 5 times of the participant no showing or cancelling, we will no longer actively call them to reschedule. However, they are not barred from taking part in the study at a later date when they can actually commit to it.
- If a participant comes in for their Baseline appointment, but does not show up for any of their weekly sessions, they should be called and rescheduled within three months. If they refuse to come in or are unreachable after a month, mark them as a Loss to Follow-up within our databases.
- Participants who become incarcerated such that they miss their intervention appointments will be able to continue their participation in the study and should resume where they left off with appointments.
- Participants that have completed at least the session 1 appointment should be called every other day to try and get them back into the study, until they have been reached. They must be rescheduled or verbally indicate they are no longer interested in participating in the study for us to stop calling them.

## Compensation

### Compensation Amount per Study Visit

- \$10.00 for Baseline appointment
- \$20.00 for Session appointments (Weeks 1-6)
- \$40.00 for Weeks 9 and 13, and for Follow Up at Month 1
- If participants complete 90% of the EMAs they will be compensated with a one-time payment of \$100 at Week 13. If participants complete 80% of the EMAs, they will be compensated with a one-time payment of \$75 during their Week 13 appointment. If participants complete 50% of the EMAs, they will be compensated with a one-time payment of \$50 during their Week 13 appointment.

## GreenPhire ClinCard

### Login Information

1. Login to [www.clincard.com](http://www.clincard.com).
2. Enter your login and password as provided to you. Keep in mind that your login and password are case sensitive so make sure to use capital letters as necessary.
3. If you have difficulty logging into [www.clincard.com](http://www.clincard.com), please click on the “Forgot username and password?” link, enter your email address, and click “Reset my password.” This will instantly send you an email with a link allowing you to reset your password.

Note: You can also call site support team at 215-609-4378.

## How to Look Up a Subject

1. Login to [www.clincard.com](http://www.clincard.com)
2. Click on “Look Up Subject”
3. Search for the subject you want to pay by entering one of the following pieces of information and click on “Search”
  - a. First name and/or last name
  - b. Subject ID
  - c. Subject’s initials
4. Click on the underlined name of the Subject
5. You will be brought to the “Subject Information” screen where you can perform any of the actions required for the subject, e.g., add another study or issue payment.
6. If the subject already exists in the system and has been enrolled in the ALL STUDY - UAB, then skip to the section on “How to Register a Subject in an Additional or Extension Study.”
7. If the subject cannot be found, then you must follow the next steps and register that subject in the ALL STUDY - UAB, first then our respective study (311701600-2018049-151019004).

## How to Register a Subject

1. Login to [www.clincard.com](http://www.clincard.com)
2. Click on “Register Subject”
3. From the “Select Study” drop-down menu, choose “ALL STUDY – UAB”
4. From the “Site” drop-down menu, select UAB All Study (Central).
5. Enter the required information into the brief form. At minimum, you must include the subject’s first name, last name, initials, SSN, address, and DOB.  
**Note:** If you would like the Subject to receive payment confirmations or appointment reminders, be sure the “Email (Enable)” and/or “Text Messaging (Enable)” checkboxes are selected
6. Click on the “Register” button
7. You will be brought to the “Subject Information” screen where you can enroll the subject in our study, assign a card number, make a payment, schedule an appointment reminder, replace a ClinCard or edit a subject’s information
8. If you have difficulty making a payment for the first time please call the ClinCard site support team at 215- 609-4378

## How to Register a Subject in an Additional or Extension Study

1. Locate the existing “Subject Information” page through the “Look Up Subject” menu tab.
2. Click on the last name of the subject to open the subject’s information tab
3. Click on the **Edit Subject** option in the list to the right.
4. Click on the **Add Study** link located under the list of the subject’s current study(ies) and select our study from the drop-down menu.
5. Enter the new **Subject ID** and select the additional study subject **Status**.
6. Scroll to the bottom of the page, and click “Save”.

This will allow the subject to receive reimbursements for any additional studies on a previously assigned ClinCard.

## How to Assign a ClinCard to a Subject

Once you have selected an existing subject or registered a new subject, you will be brought to the “Subject Information” screen. On the right hand side of the screen, you will see options that represent all of the actions you can perform on the Subject.

**Note:** If the subject already has a ClinCard assigned, you should not assign another card. (You can tell the subject already has a ClinCard if the first option in the list of options to the right-hand side of the screen is “Replace ClinCard.”)

1. Click on “Assign ClinCard” and a pop-up screen will appear.
2. In the “New Card” field, enter the 8 digit token number visible through the window of one of the ClinCard card packages you received

**Note:** There is no need to open the envelope prior to providing to the Subject

3. Click on the “Assign” button
4. Once the card has successfully been assigned, you will receive a confirmation message at the top of the “Subject Information” screen
5. Now an option to “Replace ClinCard” appears. In the event that a subject loses their card, you can replace that card for them by clicking on “Replace ClinCard,” and follow the steps above, using the 8 digit token number from a new ClinCard card package

**Note:** This will deactivate the lost card and automatically transfer any available/pending balance to the newly assigned ClinCard

## How to Make a Site Visit Payment

Once you have selected a subject or registered a new subject, you will be brought to the “Subject Information” screen. On the right hand side of the screen, you will see options that represent all of the actions you can perform on the Subject.

**Note:** If the subject has a ClinCard assigned, follow the next steps. If the subject has no ClinCard assigned, see the previous “How to Assign a ClinCard to a Subject” instruction section.

1. Verify that the “Study Name” field displays the name of our study. If the subject is enrolled in more than one study, you may have to select our study from the “Study Name” drop-down menu.
2. Click on “Make Site Visit Payment” and a pop-up screen will appear.
3. Select from the dropdown box which milestone the patient is being paid, e.g., Visit 1, Visit 2, etc.
4. Click on the “Pay” button
5. Once the payment has successfully been requested the “Pending Payment” area of the “Subject Information” screen will reflect the payment. It will also be reflected in your “Recent Activity”

6. Once a payment request has been approved and processed, the amount will be removed from the “Pending Payment” area and reflected in the “Available Balance” area.
7. If the subject has opted to receive email and/or text messages, the Subject will receive a payment confirmation communication when the payment is made.

## How to Request Assistance

If you have questions about using the [www.clincard.com](http://www.clincard.com) Admin Portal, you may reach the ClinCard site support team by:

1. Submitting an email request through the “Support” link within the [www.clincard.com](http://www.clincard.com) website
2. Directly emailing at [support@greenphire.com](mailto:support@greenphire.com)
3. Calling site support team directly at 215-609-4378 between the hours of 8:00AM and 10:00PM Eastern Time (Monday through Friday) in order to speak with a ClinCard team member

Full ClinCard Instructions are located on the share drive:

**File → P:\Cropsey-Lab\NRT Sampling\Compensation\ClinCard Reference Guide**

## Adverse Events (AEs) & Serious Adverse Events (SAEs)

### Document all AEs and SAEs in REDCap

**During participant visits, while in REDCap, document in the AE/SAE arms all side effects/AEs/SAEs reported by participant.**

**Record the AE/SAE ID number in the participant tracking database.**

**Report all SAEs or moderate/severe AEs to Dr. Cropsey immediately for further guidance.**

### Reporting Mechanisms of AEs/SAEs to the IRB, FDA, and NIDA

All adverse events that occur in the course of the study will be documented in the research record. Further, all adverse events will be compiled and reported in summary form on an annual basis to the IRB, DSMB, and NIDA, and at the conclusion of the study. Unanticipated (non-serious) adverse events will be reported to the IRB, DSMB and NIDA within 30 days via submission of the UAB IRB Adverse Event Report. Serious adverse events will be reported to the IRB, DSMB and NIDA Program Officer within 24 hours by phone, email or fax; a completed UAB IRB Adverse Event Report will be submitted within 72 hours of initial IRB and NIDA notification. All deaths will be reported to the IRB and NIDA within 48 hours. The following are possible Adverse Events associated with participation in this study:

Use of combination or single NRT is associated with side effects such as:

1. Nausea or vomiting
2. Dizziness
3. Heart racing
4. Anxiety
5. Insomnia
6. Headache
7. Itching at the site of patch application

Nicotine withdrawal symptoms if the person stops or reduces their smoking include:

8. Dysphoric or depressed mood
9. Difficulty concentrating
10. Insomnia
11. Craving
12. Distress/irritability
13. Anxiety
14. Restlessness
15. Increased appetite or weight gain
16. Decreased heart rate

***Serious Adverse Events:*** Expedited review will occur for all events meeting the FDA definition of Serious Adverse Events (SAEs) that are: a) fatal or life threatening, b) produce or prolong inpatient hospitalization, c) results in persistent or significant disability, d) congenital anomaly, e) results in an important medical event that may jeopardize the patient or require intervention to prevent a serious outcome, f) cancer, g) overdose, or h) results in the development of drug dependency or abuse. For purposes of this study, all SAEs will be required to be reported to the DSMB, regardless of any judgment of their relatedness to the study drug. All relevant information will be reported to the DSMB for each SAE including information about the event and its outcome, dosing history of all study drugs, concomitant medications, the subject's medical history and current conditions, and all relevant laboratory data. Notification by e-mail, and FAX transmittal of all related study forms shall be made to the DSMB within 24 hours of the occurrence of any SAE, followed by a full report within 10 working days. Information will be reviewed and a determination made of whether there was any possible relevance to the study drug.

***Non-Serious Adverse Events:*** Annually, the DSMB will be provided with un-blinded summaries of the numbers and rates of adverse events by treatment. These reports will include types of events, severity, and treatment phase.

## **Suicidality**

While unlikely, it is possible that a participant will indicate to you that they want to harm themselves. Suicidality can present in two forms, active and passive.

- Someone who has **active suicidal ideation** is frequently termed suicidal, and they will not only want to cause serious harm, injury, or death to themselves, but they also have a plan to do so.
- **Passive suicidal ideation** refers to someone who wishes to die but does not have a plan, this is frequently referred to simply as suicidal ideation and it is quite common.

**If your participant presents with active suicidal ideation at any time during session, refer to the following:**

1. Ask them what their plan is (e.g., I am going to shoot myself in the head).
2. Determine whether they have the means to carry out their plan (Means: “I have a gun at home,” “My dad has a gun”; No means: “I do not have a gun and I don’t know anyone with a gun”)
3. Explain to participant that in order to keep them safe from themselves, you are required to break confidentiality.
4. Ask if they have a close family member or friend you can call. Call this person and explain to them that their loved one is suicidal and needs assistance. Arrange for that person (or someone else) to pick them up and take them to the emergency room (this is to save them ambulance bills). Ask the loved one to confiscate the means to commit suicide (pills, gun, etc.).
5. If participant does not have someone to escort them to the emergency room, or if they are unwilling to cooperate, call security to walk with them to the Emergency Room.
6. Inform the study team what has occurred, including Dr. Cropsey.
7. An adverse event form will need to be completed and submitted to the IRB.
8. Be sure to take note of what transpired (who you spoke to, what happened etc.).

If you have any questions during the process, are unsure of what to say/do, call Michelle Sisson, Keith Chichester, or Dr. Cropsey for assistance.

## Baseline Appointments

**We are looking to get an accurate reading of CO levels. Therefore, be sure to schedule these appointments during late morning or early afternoon.**

**Administration time: Approximately 150 minutes**

**Do not schedule any appointments until 2.5 hours after the start of your baseline appointment.**

## Materials

- CO Machine and new white mini mouthpiece
- Urine cup

- Urine lid and gloves
- Pregnancy test (if participant is female)
- Cotinine test
- Surface Pro
- Two Consent forms
- Contact sheet
- Screening form
- Greenphire ClinCard

## Procedures

1. Go through the Consent Form with the participant, addressing any questions or concerns they may have.
2. Have the participant sign and date where it states “Signature of Participant” on page 6 of the Consent Form. Make sure that they also sign on page 7 (Authorization for Use/Disclosure of Personal Health Information (PHI) for Research), on which they need to print their name at the top of the page and sign/date at the bottom of the page where it says “Signature of Participant.”
3. Be sure that you also sign the consent form on page 6 as the “Person Obtaining Consent.”
4. The participant will receive one signed copy of the consent, and we will keep one signed copy for our records.
5. Administer the CO test. Refer to the CO directions under the “Carbon Monoxide Monitor” section on page 8 of this manual.
6. Place a lid on urine cup and take the participant to the restroom for the urine screen.
7. After the participant uses the restroom, have them hand you the cup so that you can administer the pregnancy test (for women only) and the cotinine test. After these tests, you should discard the urine sample and all tests and head back to the office.
8. Have the participant complete the contact sheet.
9. Set up the participant in the Pre-Randomization arm.
10. Once the Pre-Randomization is completed, complete the last form remaining in REDCap, “Group Assignment,” to randomize the participant into one of the groups.
11. Once the participant is randomized into a group, have the participant fill out the Baseline questionnaires for that group on the tablet or on the computer in an office. Do not allow them to fill out in waiting room or any other office where we are not present.
12. Monitor the participant’s progress in REDCap.
13. Schedule the first intervention session for the following week, at least 5 days from Baseline. Also, it is important for participants in the Intervention groups to be scheduled for their weekly appointment in the morning. Once you have it scheduled, make sure the appointment is placed on your UABMC calendar and google calendar (MOP, pg. 14).
14. Instructions for participants for Session 1 are as below, according to which group they have been assigned:
  - If the participant is in an **Intervention** group then say, “**When you come in for your appointment on \_\_\_\_\_ at \_\_\_\_\_ please refrain from smoking the night before your appointment, and the morning of.**”
  - If the participant is in the **Control** group, there are no special instructions for the next appointment.

15. Complete the \$10.00 ClinCard payment.
16. Give the participant an appointment card. That completes the Baseline appointment!

## Intervention Fidelity

Approximately 20% of sessions will be reviewed for fidelity purposes. Specifically, weekly sessions will be reviewed by any study member, other than the therapist. The randomization scheme is already determined and is located on the share drive along with the fidelity worksheets. If a reviewer is randomly assigned their own session, the reviewer will trade with the reviewer who comes after them, taking their next assigned session to review. A score of 80% or greater is required to pass. Once completed, the reviewer will score the interviewer and record the score and their initials in the randomization spreadsheet. Completed fidelity worksheets will be stored in the Fidelity folder located in room L107B file cabinet C. **Feedback should be provided to the therapist about important points that are missed.**

### Forms:

Fidelity Control Worksheet → P:\Cropsey-Lab\NRT Sampling\Manuals\Control  
Fidelity Intervention Worksheet → P:\Cropsey-Lab\NRT Sampling\Manuals\Sampling Intervention\Treatment A, B, C, or D

## Therapy Protocol

### Week 1 – Week 5

**Participants should work with the same staff member for the 5 weekly counseling sessions.**

#### Intervention Group A

##### Week 1

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on Page 8 of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **Patch dosage is based on number of cigarettes smoked determined at Baseline appointment. Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
4. Gather either the 4mg gum or 2mg gum and give it to the participant. **Gum mg is based on how soon the participant smokes a cigarette after waking determined at Baseline**

**appointment). Wait to give the gum to the participant until the session is being recorded.**

5. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the Credibility Expectancies Questionnaire, the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
6. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
7. Tell the client that you are about to start the recording for the session. Explain that “this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively.”
8. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant’s name while being recorded.**
9. Give the participant the assigned client Intervention workbook and tell them to follow along as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks.**
10. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant’s response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
11. Un-pause the audio recording and continue the intervention by going over the participant’s before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
12. Go over the Tobacco Use and NRT Use calendars.
13. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
14. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
15. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). **Once you have it scheduled, make sure the appointment is placed on your UABMC calendar, desk calendar, and recorded in the REDCap Calendar application.**
16. Instruct the participant to **bring the calendars and workbook back so they can be reviewed next session.**
17. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
18. Give the participant one package of gum. The pack of gum will last through to the next appointment. **Be sure to emphasize they are not to use the gum on the morning of the next appointment.**
19. Have the participant sign for the medication in the medication sign-out log.

20. Mark in the Medication Inventory Excel sheet how many of the patches and gum packages you have given out so that we maintain a running total of prescriptions we have on hand.
21. Remind the participant of the instructions on how to use the patches and gum and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
22. Compensate the participant on their Greenphire ClinCard.
23. Give the participant an appointment card. **Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or gum on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and gum packages back to the next appointment.**
24. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 2**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and gum packages and dispose of them after reviewing the calendars. Any unused patches/gum packages can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **Patch dosage is based on number of cigarettes smoked determined at Baseline appointment. Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Gather the inhaler box and give it to the participant to use. **Wait to give the inhaler to the participant until the session is being recorded.**
7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
9. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
10. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**

11. Tell the participant to follow along in their client Intervention workbook as you go through your Therapist Intervention manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks.**
12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
13. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.
15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
18. Instruct the participant to **bring the calendars and workbook back so they can be reviewed next session.**
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
20. Give the participant the box with the inhaler and cartridges. The inhaler cartridges will last through to the next appointment. **Be sure to emphasize they are not to use the inhaler on the morning of the next appointment.**
21. **Have the participant sign for the medication in the medication sign-out log.**
22. Mark in the Medication Inventory Excel sheet how many of the patches and inhaler boxes you have given out so that we maintain a running total of prescriptions we have on hand.
23. Remind the participant of the instructions on how to use the patches and inhaler and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. **Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a inhaler on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and inhaler cartridges back to the next appointment.**
26. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 3**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and inhaler cartridges and dispose of them after reviewing the calendars. Any unused patches/inhaler cartridges can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Gather the nasal spray bottle and give it to the participant to use. **Wait to give the nasal spray to the participant until the session is being recorded.**
7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
9. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
10. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**
11. Tell the participant to follow along in their client Intervention workbook as you go through your Therapist Intervention Manual
12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
13. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.

15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
18. Instruct the participant to **bring the calendars and workbook back so they can be reviewed next session.**
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
20. Give the participant one bottle of nasal spray. The nasal spray bottle will last through to the next appointment. **Be sure to emphasize they are not to use the nasal spray on the morning of the next appointment.**
21. Have the participant sign for the medication in the medication sign-out log.
22. Mark in the Medication Inventory Excel sheet how many of the patches and nasal spray bottles you have given out so that we maintain a running total of prescriptions we have on hand.
23. Remind the participant of the instructions on how to use the patches and nasal spray and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. **Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or nasal spray on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and nasal spray bottles back to the next appointment.**
26. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 4**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use Calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and nasal spray bottles and dispose of them after reviewing the calendars. Any unused patches/nasal spray bottles can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm.**

**Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**

6. Gather the 4mg or 2mg nicotine lozenge and give it to the participant to use. **(Lozenge dosage is based on how soon participant smokes their first cigarette after waking, as reported at Baseline appointment). Wait to give the lozenge to the participant until the session is being recorded.**
7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
9. Tell the client that you are about to start the recording for the session. Explain that “this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively.”
10. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant’s name while being recorded.**
11. Tell the participant to follow along in their client Intervention workbook as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks.**
12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant’s response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
13. Un-pause the audio recording and continue the intervention by going over the participant’s before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.
15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
18. Instruct the participant to **bring the calendars and workbook back so they can be reviewed next session.**
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
20. Give the participant one box of lozenges (3 quit tubes = 72 lozenges). The 72 lozenges should last through to the next appointment if the participant uses 10 daily as advised. **Be**

**sure to emphasize they are not to use the lozenges on the morning of the next appointment.**

21. Have the participant sign for the medication in the medication sign-out log.
22. Mark in the Medication Inventory binder how many of the patches and quit tubes you have given out so that we maintain a running total of prescriptions we have on hand.
23. Remind the participant of the instructions on how to use the patches and lozenges and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. **Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or lozenges on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and lozenge quit tubes back to the next appointment.**
26. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 5**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and lozenge quit tubes and dispose of them after reviewing the calendars. Any unused patches/lozenges can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the Alliance Questionnaire, SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
7. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
8. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."

9. Turn on the recording and state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.
10. Tell the participant to follow along in their client Intervention workbook as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and they are urged to write down information in their workbooks.
11. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The Alliance Questionnaire**
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.
12. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
13. Review each week and the participant's experience with the short-acting forms of NRT from the participant's manual. Answer any questions the participant has regarding the medications. Present the medication selection sheet, review it with the participant, and explain that they will be selecting their preferred short-acting NRT to use in conjunction with the patch for the rest of the medication period of the study. Once the participant has made a selection, enter it into REDCap and ask them to write it in their manual.
14. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
15. Schedule the next appointment for the next week (preferably the same day of the week and the same morning time). This appointment should be scheduled with another study staff member other than the therapist who saw the participant for the five weekly sessions. Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.
16. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
17. Give the participant enough of the short-acting NRT they chose to last through to the next appointment.
18. Have the participant sign for the medication in the medication sign-out log.
19. Mark in the Medication Inventory Excel sheet how many of the patches and gum packages/lozenge quit tubes/inhaler cartridges/nasal spray bottles you have given out so that we maintain a running total of prescriptions we have on hand.
20. Remind the participant of the instructions on how to use the patches and gum/lozenges/inhaler/nasal spray and let them know they can reference their workbook if they forget.
21. Give the participant a study phone and charger and instruct them to complete the EMA's daily.
22. Compensate the participant on their Greenphire ClinCard.

23. Give the participant an appointment card. Also, remind them to bring all used and unused patches, patch packets, and short-acting NRT back to the next appointment.
24. Upload the session recording toBox.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## Intervention Group B

### Week 1

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on Page 8 of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. (Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.
4. Gather the 4mg or 2mg nicotine lozenge and give it to the participant to use. (Lozenge dosage is based on how soon participant smokes their first cigarette after waking, as reported at Baseline appointment). Wait to give the lozenge to the participant until the session is being recorded.
5. Have the participant fill out all of the questionnaires related to the session in REDCap, except the Credibility Expectancies Questionnaire, SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.
6. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
7. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
8. Turn on the recording and state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.
9. Give the participant the assigned client Intervention workbook and tell them to follow along as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and they are urged to write down information in their workbooks.
10. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**

- **Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**

11. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
12. Go over the Tobacco Use and NRT Use calendars.
13. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
14. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
15. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
16. Instruct the participant to **bring the calendars and workbook back so they can be reviewed next session.**
17. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
18. Give the participant one box of lozenges (3 quit tubes = 72 lozenges). The 72 lozenges should last through to the next appointment if the participant uses 10 daily as advised. **Be sure to emphasize they are not to use the lozenges on the morning of the next appointment.**
19. Have the participant sign for the medication in the medication sign-out log.
20. Mark in the Medication Inventory binder how many of the patches and quit tubes you have given out so that we maintain a running total of prescriptions we have on hand.
21. Remind the participant of the instructions on how to use the patches and lozenges and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
22. Compensate the participant on their Greenphire ClinCard.
23. Give the participant an appointment card. **Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or lozenges on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and lozenge quit tubes back to the next appointment.**
24. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 2**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.

3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and lozenge quit tubes and dispose of them after reviewing out the calendars. Any unused patches/lozenges can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Gather the nasal spray bottle and give it to the participant to use. **Wait to give the nasal spray to the participant until the session is being recorded.**
7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
9. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
10. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**
11. Tell the participant to follow along in their client Intervention workbook as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks.**
12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
13. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.
15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.

17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.
18. Instruct the participant to bring the calendars and workbook back so they can be reviewed next session.
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
20. Give the participant 1 bottle of nasal spray. The nasal spray bottle will last through to the next appointment. Be sure to emphasize they are not to use the nasal spray on the morning of the next appointment.
21. Have the participant sign for the medication in the medication sign-out log.
22. Mark in the Medication Inventory Excel sheet how many of the patches and nasal spray bottles you have given out so that we maintain a running total of prescriptions we have on hand.
23. Remind the participant of the instructions on how to use the patches and nasal spray and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or nasal spray on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and nasal spray bottles back to the next appointment.
26. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

### Week 3

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on Page 8 of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and nasal spray bottles and dispose of them after reviewing the calendars. Any unused patches/nasal spray bottles can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. (Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.
6. Gather the inhaler box and give it to the participant to use. Wait to give the inhaler to the participant until the session is being recorded.

7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
9. Tell the client that you are about to start the recording for the session. Explain that “this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively.”
10. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant’s name while being recorded.**
11. Tell the participant to follow along in their client Intervention workbook as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks.**
12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant’s response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
13. Un-pause the audio recording and continue the intervention by going over the participant’s before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.
15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
18. Instruct the participant to **bring the calendars and workbook back so they can be reviewed next session.**
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
20. Give the participant 1 box of inhaler/cartridges. The inhaler cartridges will last through to the next appointment. **Be sure to emphasize they are not to use the inhaler on the morning of the next appointment.**
21. Have the participant sign for the medication in the medication sign-out log.
22. Mark in the Medication Inventory Excel sheet how many of the patches and inhaler boxes you have given out so that we maintain a running total of prescriptions we have on hand.

23. Remind the participant of the instructions on how to use the patches and inhaler and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. **Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or inhaler on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and inhaler cartridges back to the next appointment.**
26. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 4**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and inhaler cartridges and dispose of them after reviewing the calendars. Any unused patches/inhaler cartridges can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Gather either the 4mg gum or 2mg gum and give it to the participant. **(Gum mg is based on how soon the participant smokes a cigarette after waking determined at Baseline appointment). Wait to give the gum to the participant until the session is being recorded.**
7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
9. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
10. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**

11. Tell the participant to follow along in their client Intervention workbook as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks.**
12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
13. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.
15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
18. Instruct the participant to **bring the calendars and workbook back so they can be reviewed next session.**
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
20. Give the participant 1 package of gum. The package of gum will last through to the next appointment. **Be sure to emphasize they are not to use the gum on the morning of the next appointment.**
21. Have the participant sign for the medication in the medication sign-out log.
22. Mark in the Medication Inventory Excel sheet how many of the patches and gum packages you have given out so that we maintain a running total of prescriptions we have on hand.
23. Remind the participant of the instructions on how to use the patches and gum and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. **Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or gum on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and gum packages back to the next appointment.**
26. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 5**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and gum packages and dispose of them after reviewing the calendars. Any unused patches/gum packages can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **Patch dosage is based on number of cigarettes smoked determined at Baseline appointment. Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the Alliance Questionnaire, SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
7. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
8. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
9. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**
10. Tell the participant to follow along in their Client Intervention workbook as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks.**
11. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The Alliance Questionnaire**
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
12. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
13. Review each week and the participant's experience with the short-acting forms of NRT from the participant's manual. Answer any questions the participant has regarding the

medications. Present the medication selection sheet, review it with the participant, and explain that they will be selecting their preferred short-acting NRT to use in conjunction with the patch for the rest of the medication period of the study. Once the participant has made a selection, enter it into REDCap and ask them to write it in their manual.

14. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
15. Schedule the next appointment for the next week (preferably the same day of the week and the same morning time). This appointment should be scheduled with another study staff member other than the therapist who saw the participant for the five weekly sessions. **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
16. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
17. Give the participant enough of the short-acting NRT they chose to last through to the next appointment.
18. Have the participant sign for the medication in the medication sign-out log.
19. Mark in the Medication Inventory Excel sheet how many of the patches and gum packages/lozenge quit tubes/inhaler cartridges/nasal spray bottles you have given out so that we maintain a running total of prescriptions we have on hand.
20. Remind the participant of the instructions on how to use the patches and gum/lozenges/inhaler/nasal spray and let them know they can reference their workbook if they forget.
21. Give the participant a study phone and charger and instruct them to complete the EMA's daily.
22. Compensate the participant on their Greenphire ClinCard.
23. Give the participant an appointment card. **Also, remind them to bring all used and unused patches, patch packets, and short-acting NRT back to the next appointment.**
24. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## Intervention Group C

### Week 1

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**

4. Gather the nasal spray bottle and give it to the participant to use. **Wait to give the nasal spray to the participant until the session is being recorded.**
5. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the Credibility Expectancies Questionnaire, SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
6. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
7. Tell the client that you are about to start the recording for the session. Explain that “this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively.”
8. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant’s name while being recorded.**
9. Give the participant the assigned client Intervention workbook and tell them to follow along as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks.**
10. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant’s response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
11. Un-pause the audio recording and continue the intervention by going over the participant’s before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
12. Go over the Tobacco Use and NRT Use calendars.
13. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
14. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
15. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
16. Instruct the participant to **bring the calendars and workbook back so they can be reviewed next session.**
17. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
18. Give the participant 1 bottle of nasal spray. The nasal spray bottle will last through to the next appointment. **Be sure to emphasize they are not to use the nasal spray on the morning of the next appointment.**
19. Have the participant sign for the medication in the medication sign-out log.

20. Mark in the Medication Inventory Excel sheet how many of the patches and nasal spray bottles you have given out so that we maintain a running total of prescriptions we have on hand.
21. Remind the participant of the instructions on how to use the patches and nasal spray and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
22. Compensate the participant on their Greenphire ClinCard.
23. Give the participant an appointment card. **Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or nasal spray on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and nasal spray bottles back to the next appointment.**
24. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 2**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous weeks into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and nasal spray bottles and dispose of them after reviewing the calendars. Any unused patches/nasal spray bottles can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Gather either the 4mg gum or 2mg gum and give it to the participant. **(Gum mg is based on how soon the participant smokes a cigarette after waking determined at Baseline appointment). Wait to give the gum to the participant until the session is being recorded.**
7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.

9. Tell the client that you are about to start the recording for the session. Explain that “this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively.”
10. Turn on the recording and state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant’s name while being recorded.
11. Tell the participant to follow along in their Client Intervention workbook as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and they are urged to write down information in their workbooks.
12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - Based on the participant’s response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.
13. Un-pause the audio recording and continue the intervention by going over the participant’s before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.
15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.
18. Instruct the participant to bring the calendars and workbook back so they can be reviewed next session.
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
20. Give the participant 1 package of gum. The package of gum will last through to the next appointment. Be sure to emphasize they are not to use the gum on the morning of the next appointment.
21. Have the participant sign for the medication in the medication sign-out log.
22. Mark in the Medication Inventory Excel sheet how many of the patches and gum packages you have given out so that we maintain a running total of prescriptions we have on hand.
23. Remind the participant of the instructions on how to use the patches and gum and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or

**gum on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and gum packages back to the next appointment.**

26. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

### **Week 3**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the date for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and gum packages and dispose of them after reviewing the calendars. Any unused patches/gum packages can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Gather the 4mg or 2mg nicotine lozenge and give it to the participant to use. **(Lozenge dosage is based on how soon participant smokes their first cigarette after waking, as reported at Baseline appointment). Wait to give the lozenge to the participant until the session is being recorded.**
7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
9. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
10. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**
11. Tell the participant to follow along in their client Intervention workbook as you got through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbook.**
12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**

- Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.

13. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.
15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.
18. Instruct the participant to bring the calendars and workbook back so they can be reviewed next session.
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
20. Give the participant one box of lozenges (3 quit tubes = 72 lozenges). The 72 lozenges should last through to the next appointment if the participant uses 10 daily as advised. Be sure to emphasize they are not to use the lozenges on the morning of the next appointment.
21. Have the participant sign for the medication in the medication sign-out log.
22. Mark in the Medication Inventory binder how many of the patches and quit tubes you have given out so that we maintain a running total of prescriptions we have on hand.
23. Remind the participant of the instructions on how to use the patches and lozenges and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or lozenges on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and lozenge quit tubes back to the next appointment.
26. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## Week 4

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on Page 8 of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.

3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and lozenge quit tubes and dispose of them after reviewing the calendars. Any unused patches/lozenges can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Gather the inhaler box and give it to the participant to use. **Wait to give the inhaler to the participant until the session is being recorded.**
7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
9. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
10. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**
11. Tell the participant to follow along in their client Intervention workbook as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbook.**
12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
13. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.
15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.

17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
18. Instruct the participant to **bring the calendars and workbook back so they can be reviewed next session.**
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
20. Give the participant 1 box of inhaler/cartridges. The inhaler cartridges will last through to the next appointment. **Be sure to emphasize they are not to use the inhaler on the morning of the next appointment.**
21. Have the participant sign for the medication in the medication sign-out log.
22. Mark in the Medication Inventory Excel sheet how many of the patches and inhalers you have given out so that we maintain a running total of prescriptions we have on hand.
23. Remind the participant of the instructions on how to use the patches and inhaler and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. **Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or inhaler on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and inhaler cartridges back to the next appointment.**
26. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 5**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and inhaler cartridges and dispose of them after reviewing the calendars. Any unused patches/inhaler cartridges can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the Alliance Questionnaire, SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**

7. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
8. Tell the client that you are about to start the recording for the session. Explain that “this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively.”
9. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant’s name while being recorded.**
10. Tell the participant to follow along in their client Intervention workbook as you go through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks.**
11. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The Alliance Questionnaire**
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant’s response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
12. Un-pause the audio recording and continue the intervention by going over the participant’s before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
13. Review each week and the participant’s experience with the short-acting forms of NRT from the participant’s manual. Answer any questions the participant has regarding the medications. Present the medication selection sheet, review it with the participant, and explain that they will be selecting their preferred short-acting NRT to use in conjunction with the patch for the rest of the medication period of the study. Once the participant has made a selection, enter it into REDCap and ask them to write it in their manual.
14. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
15. Schedule the next appointment for the next week (preferably the same day of the week and the same morning time). This appointment should be scheduled with another study staff member other than the therapist who saw the participant for the five weekly sessions. **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
16. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
17. Give the participant enough of the short-acting NRT they chose to last through to the next appointment.
18. Have the participant sign for the medication in the medication sign-out log.
19. Mark in the Medication Inventory Excel sheet how many of the patches and gum packages/lozenge quit tubes/inhaler cartridges/nasal spray bottles you have given out so that we maintain a running total of prescriptions we have on hand.

20. Remind the participant of the instructions on how to use the patches and gum/lozenges/inhaler/nasal spray and let them know they can reference their workbook if they forget.
21. Give the participant a study phone and charger and instruct them to complete the EMA's daily.
22. Compensate the participant on their Greenphire ClinCard.
23. Give the participant an appointment card. **Also, remind them to bring all used and unused patches, patch packets, and short-acting NRT back to the next appointment.**
24. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## Intervention Group D

### Week 1

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
4. Gather the inhaler and give it to the participant to use. **Wait to give the inhaler to the participant until the session is being recorded.**
5. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the Credibility Expectancies Questionnaire, SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
6. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
7. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
8. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**
9. Tell the participant to follow along in their client Intervention workbook as you got through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbook.**
10. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**

- **The second Questionnaire of Smoking Urges**
  - Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.

11. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
12. Go over the Tobacco Use and NRT Use calendars.
13. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
14. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
15. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.
16. Instruct the participant to bring the calendars and workbook back so they can be reviewed next session.
17. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
18. Give the participant 1 box of inhaler/cartridges. The inhaler cartridges will last through to the next appointment. Be sure to emphasize they are not to use the inhaler on the morning of the next appointment.
19. Have the participant sign for the medication in the medication sign-out log.
20. Mark in the Medication Inventory Excel sheet how many of the patches and inhalers you have given out so that we maintain a running total of prescriptions we have on hand.
21. Remind the participant of the instructions on how to use the patches and inhaler and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
22. Compensate the participant on their Greenphire ClinCard.
23. Give the participant an appointment card. Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or nasal spray on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and inhaler cartridges back to the next appointment.
24. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## Week 2

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on Page 8 of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.

4. Collect the used nicotine patches and inhaler cartridges and dispose of them after reviewing the calendars. Any unused patches/inhaler cartridges can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Gather the 4mg or 2mg nicotine lozenge and give it to the participant to use. **(Lozenge dosage is based on how soon participant smokes their first cigarette after waking, as reported at Baseline appointment). Wait to give the lozenge to the participant until the session is being recorded.**
7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
9. Tell the client that you are about to start the recording for the session. Explain that “this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively.”
10. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**
11. Tell the participant to follow along in their client Intervention workbook as you got through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbook.**
12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
13. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.
15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**

18. Instruct the participant to **bring the calendars and workbook back so they can be reviewed next session.**
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
20. Give the participant one box of lozenges (3 quit tubes = 72 lozenges). The 72 lozenges should last through to the next appointment if the participant uses 10 daily as advised. **Be sure to emphasize they are not to use the lozenges on the morning of the next appointment.**
21. Have the participant sign for the medication in the medication sign-out log.
22. Mark in the Medication Inventory binder how many of the patches and quit tubes you have given out so that we maintain a running total of prescriptions we have on hand.
23. Remind the participant of the instructions on how to use the patches and lozenges and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. **Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or lozenges on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and lozenge quit tubes back to the next appointment.**
26. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

### **Week 3**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and lozenge quit tubes and dispose of them after reviewing calendars. Any unused patches/lozenges can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Gather either the 4mg gum or 2mg gum and give it to the participant. **(Gum mg is based on how soon the participant smokes a cigarette after waking determined at Baseline appointment). Wait to give the gum to the participant until the session is being recorded.**

7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
9. Tell the client that you are about to start the recording for the session. Explain that “this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively.”
10. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant’s name while being recorded.**
11. Tell the participant to follow along in their client Intervention workbook as you got through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbook.**
12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant’s response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
13. Un-pause the audio recording and continue the intervention by going over the participant’s before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.
15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
18. Instruct the participant to **bring the calendars and workbook back so they can be reviewed next session.**
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
20. Give the participant 1 package of gum. The package of gum will last through to the next appointment. **Be sure to emphasize they are not to use the gum on the morning of the next appointment.**
21. Have the participant sign for the medication in the medication sign-out log.
22. Mark in the Medication Inventory Excel sheet how many of the patches and gum packages you have given out so that we maintain a running total of prescriptions we have on hand.

23. Remind the participant of the instructions on how to use the patches and gum and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. **Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or gum on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and gum packages back to the next appointment.**
26. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 4**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and gum packages and dispose of them after reviewing the calendars. Any unused patches/gum packages can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Gather the nasal spray bottle and give it to the participant to use. **Wait to give the nasal spray to the participant until the session is being recorded.**
7. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
8. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
9. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
10. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**
11. Tell the participant to follow along in their client Intervention workbook as you got through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbook.**

12. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.
13. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
14. Go over the Tobacco Use and NRT Use calendars.
15. Provide them with the copies of the calendars (in their folder) to keep in their pocket/wallet for use when they do not have their manual with them.
16. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
17. Schedule the next appointment for the following week (preferably the same day of the week and the same morning time). Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.
18. Instruct the participant to bring the calendars and workbook back so they can be reviewed next session.
19. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment. Be sure to emphasize they are not to wear the patch the morning of the next appointment.
20. Give the participant 1 bottle of nasal spray. The nasal spray bottle will last through to the next appointment. Be sure to emphasize they are not to use the nasal spray on the morning of the next appointment.
21. Have the participant sign for the medication in the medication sign-out log.
22. Mark in the Medication Inventory Excel sheet how many of the patches and nasal spray bottles you have given out so that we maintain a running total of prescriptions we have on hand.
23. Remind the participant of the instructions on how to use the patches and nasal spray and let them know they can reference their workbook if they forget. Give the participant the instructions sheet.
24. Compensate the participant on their Greenphire ClinCard.
25. Give the participant an appointment card. Be sure to remind the participant to try and refrain from smoking the night before the appointment and not to use a patch or nasal spray on the morning of the appointment. Also, remind them to bring all used and unused patches, patch packets, and nasal spray bottles back to the next appointment.

## Week 5

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on Page 8 of this manual. Record the CO level in REDCap.

- If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.

3. Collect the participant's Tobacco Use and NRT Use calendars and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Collect the used nicotine patches and nasal spray bottles and dispose of them after reviewing the calendars. Any unused patches/nasal spray bottles can be given back to the participant.
5. Gather either the 21 mg patch or the 14 mg patch and give it to the participant. **(Patch dosage is based on number of cigarettes smoked determined at Baseline appointment). Be sure to write down the time that the patch is placed on their arm. Ideally, the participant should have the patch on for 30 minutes before the intervention begins.**
6. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the Alliance Questionnaire, SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
7. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
8. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
9. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**
10. Tell the participant to follow along in their client Intervention workbook as you got through your Therapist Intervention Manual. Let them know that the counseling could take up to 30 minutes and **they are urged to write down information in their workbook.**
11. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The Alliance Questionnaire**
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
12. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
13. Review each week and the participant's experience with the short-acting forms of NRT from the participant's manual. Answer any questions the participant has regarding the medications. Present the medication selection sheet, review it with the participant, and explain that they will be selecting their preferred short-acting NRT to use in conjunction with the patch for the rest of the medication period of the study. Once the participant has made a selection, enter it into REDCap and ask them to write it in their manual.

14. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
15. Schedule the next appointment for the next week (preferably the same day of the week and the same morning time). This appointment should be scheduled with another study staff member other than the therapist who saw the participant for the five weekly sessions. **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
16. Give the participant 6 patches. The 6 patches and the patch they are currently wearing (total of 7) will last through to the next appointment.
17. Give the participant enough of the short-acting NRT they chose to last through to the next appointment.
18. Have the participant sign for the medication in the medication sign-out log.
19. Mark in the Medication Inventory Excel sheet how many of the patches and gum packages/lozenge quit tubes/inhaler cartridges/nasal spray bottles you have given out so that we maintain a running total of prescriptions we have on hand.
20. Remind the participant of the instructions on how to use the patches and gum/lozenges/inhaler/nasal spray and let them know they can reference their workbook if they forget.
21. Give the participant a study phone and charger and instruct them to complete the EMA's daily.
22. Compensate the participant on their Greenphire ClinCard.
23. Give the participant an appointment card. **Also, remind them to bring all used and unused patches, patch packets, and short-acting NRT back to the next appointment.**
24. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## Control Group

### Week 1

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO.
  - If the CO is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Have the participant fill out all of the questionnaires related to the Session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal scale, and the SECOND Questionnaire of Smoking Urges.**
4. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
5. Tell the client that you are about to start the recording for their session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."

6. Turn on the recording and state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.
7. Give the participant the assigned client Control workbook and tell them to follow along as you go through your therapist control manual. Remind them that the counseling could take up to 30 minutes and they are urged to write down information in their workbooks.
8. **Make sure that you have gone over the Tobacco Use calendar before you finish the recording.** Provide them with copies of the calendar to keep in their pocket/wallet for use when they do not have their manual. Ask that they bring back the calendar and workbook to each visit.
9. After the therapy ask the participant if they have any questions. If they do not, tell them you are ending the recording.
10. Have the participant complete the remaining session measures (Credibility Expectancies Questionnaire, second Minnesota Nicotine Withdrawal Scale, and second Questionnaire of Smoking Urges).
11. Schedule the next appointment for the following week (preferably the same day of the week and same time). Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.
12. Compensate the participant on their Greenphire ClinCard.
13. Give the participant an appointment card.
14. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## Week 2

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on Page 8 of this manual. Record the CO.
  - If the CO is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use calendar and enter the data for the previous week into the appropriate SPSS database, then return the calendar to the participant.
4. Have the participant fill out all of the questionnaires related to the Session in REDCap, except the SECOND Minnesota Nicotine Withdrawal scale, and the SECOND Questionnaire of Smoking Urges.
5. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
6. Tell the client that you are about to start the recording for their session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."

7. Turn on the recording and state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.
8. Tell the participant to follow along in their client control workbook as you go through your therapist control manual. Remind them that the counseling could take up to 30 minutes and they are urged to write down information in their workbooks.
9. **Make sure that you have gone over the Tobacco Use calendar before you finish the recording.** Provide them with copies of the calendar to keep in their pocket/wallet for use when they do not have their manual. Ask that they bring back the calendar and workbook to each visit.
10. After the therapy ask the participant if they have any questions. If they do not, tell them you are ending the recording.
11. Have the participant complete the remaining session measures (Credibility Expectancies Questionnaire, second Minnesota Nicotine Withdrawal Scale, and second Questionnaire of Smoking Urges).
12. Schedule the next appointment for the following week (preferably the same day of the week and same time). Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.
13. Compensate the participant on their Greenphire ClinCard.
14. Give the participant an appointment card.
15. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

### Week 3

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on Page 8 of this manual. Record the CO.
  - If the CO is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use calendar and enter the data for the previous week into the appropriate SPSS database, then return the calendar to the participant.
4. Have the participant fill out all of the questionnaires related to the Session in REDCap, except the SECOND Minnesota Nicotine Withdrawal scale, and the SECOND Questionnaire of Smoking Urges.
5. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
6. Tell the client that you are about to start the recording for their session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
7. Turn on the recording and state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.

8. Tell the participant to follow along in their client control workbook as you go through your therapist control manual. Remind them that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks.**
9. **Make sure that you have gone over the Tobacco Use calendar before you finish the recording.** Provide them with copies of the calendar to keep in their pocket/wallet for use when they do not have their manual. Ask that they bring back the calendar and workbook to each visit.
10. After the therapy ask the participant if they have any questions. If they do not, tell them you are ending the recording.
11. Have the participant complete the remaining session measures (Credibility Expectancies Questionnaire, second Minnesota Nicotine Withdrawal Scale, and second Questionnaire of Smoking Urges).
12. Schedule the next appointment for the following week (preferably the same day of the week and same time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
13. Compensate the participant on their Greenphire ClinCard.
14. Give the participant an appointment card.
15. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 4**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO.
  - If the CO is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use calendar and enter the data for the previous week into the appropriate SPSS database, then return the calendar to the participant.
4. Have the participant fill out all of the questionnaires related to the Session in REDCap, **except the SECOND Minnesota Nicotine Withdrawal scale, and the SECOND Questionnaire of Smoking Urges.**
5. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
6. Tell the client that you are about to start the recording for their session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
7. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**
8. Tell the participant to follow along in their client control workbook as you go through your therapist control manual. Remind them that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks**

9. **Make sure that you have gone over the Tobacco Use calendar before you finish the recording.** Provide them with copies of the calendar to keep in their pocket/wallet for use when they do not have their manual. Ask that they bring back the calendar and workbook to each visit.
10. After the therapy ask the participant if they have any questions. If they do not, tell them you are ending the recording.
11. Have the participant complete the remaining session measures (Credibility Expectancies Questionnaire, second Minnesota Nicotine Withdrawal Scale, and second Questionnaire of Smoking Urges).
12. Schedule the next appointment for the following week (preferably the same day of the week and same time). **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
13. Compensate the participant on their Greenphire ClinCard.
14. Give the participant an appointment card.
15. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 5**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Collect the participant's Tobacco Use calendar and enter the data for the previous week into the appropriate SPSS database, then return the calendars to the participant.
4. Have the participant fill out all of the questionnaires related to the session in REDCap, **except the Alliance Questionnaire, SECOND Minnesota Nicotine Withdrawal Scale and the SECOND Questionnaire of Smoking Urges.**
5. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
6. Tell the client that you are about to start the recording for the session. Explain that "this is a manualized intervention; therefore it will not feel like traditional therapy. We will be working from a manual and will adhere to the manual content, exclusively."
7. Turn on the recording and **state your name, the date, and the time that you are starting the therapy. Do your best not to say the participant's name while being recorded.**
8. Tell the participant to follow along in their client control workbook as you go through your therapist control manual. Remind them that the counseling could take up to 30 minutes and **they are urged to write down information in their workbooks**
9. **Make sure that you have gone over the Tobacco Use and NRT Use calendars before you finish the recording.** Provide them with copies of the calendars to keep in their

pocket/wallet for use when they do not have their manual. Ask that they bring back the calendar and workbook to each visit.

10. When appropriate, pause the audio recording and have the participant fill out the following:
  - **The Alliance Questionnaire**
  - **The second Minnesota Nicotine Withdrawal Scale**
  - **The second Questionnaire of Smoking Urges**
    - **Based on the participant's response to the Minnesota Nicotine Withdrawal Scale and the Questionnaire of Smoking Urges, graph the before and after scores in their workbook.**
11. Un-pause the audio recording and continue the intervention by going over the participant's before and after scores for the Minnesota Nicotine Withdrawal Scale and Questionnaire of Smoking Urges.
12. Review each of the short-acting forms of NRT with the participant. Answer any questions the participant has regarding the medications. Present the medication selection sheet, review it with the participant, and explain that they will be selecting their preferred short-acting NRT to use in conjunction with the patch for the rest of the medication period of the study. Once the participant has made a selection, enter it into REDCap and ask them to write it in their manual.
13. After the therapy, ask the participant if they have any questions. If they do not, tell them you are ending the recording.
14. Schedule the next appointment for the next week (preferably the same day of the week and the same morning time). This appointment should be scheduled with another study staff member other than the therapist who saw the participant for the five weekly sessions. **Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
15. Give the participant 7 patches. The patches will last through to the next appointment.
16. Give the participant enough of the short-acting NRT they chose to last through to the next appointment.
17. Have the participant sign for the medication in the medication sign-out log.
18. Mark in the Medication Inventory Excel sheet how many of the patches and gum packages/lozenge quit tubes/inhaler cartridges/nasal spray bottles you have given out so that we maintain a running total of prescriptions we have on hand.
19. Remind the participant of the instructions on how to use the patches and gum/lozenges/inhaler/nasal spray and let them know they can reference their workbook if they forget.
20. Make sure to give the participant the slip card.
21. Give the participant a study phone and charger and instruct them to complete the EMA's daily.
22. Compensate the participant on their Greenphire ClinCard.
23. Give the participant an appointment card. **Also, remind them to bring all used and unused patches, patch packets, and short-acting NRT back to the next appointment.**
24. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## Weeks 6, 9 & 13

### Week 6

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Have the participant fill out all of the questionnaires related to the session in REDCap.
4. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
5. Ask the participant if they experienced any issues in the past week with the short-acting NRT they selected. If they report experiencing issues, follow the discussion guidelines in the therapist manual.
6. If the participant reports issues, determine whether the dosage of the short-acting NRT they selected should be lowered.
7. Remind the participant of the instructions on how to use the patches and gum/lozenges/inhaler/nasal spray and let them know they can reference their workbook if they forget.
8. Ask the participant if they have any questions.
9. Schedule the next appointment in three weeks (preferably the same day of the week and the same morning time). This appointment should be scheduled with another study staff member other than the therapist who saw the participant for the five weekly sessions.

**Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**

10. Give the participant 21 patches. The patches will last through to the next appointment.
11. Give the participant enough of the short-acting NRT they chose to last through to the next appointment.
12. Have the participant sign for the medication in the medication sign-out log.
13. Mark in the Medication Inventory Excel sheet how many of the patches and gum packages/lozenge quit tubes/inhaler cartridges/nasal spray bottles you have given out so that we maintain a running total of prescriptions we have on hand.
14. Compensate the participant on their Greenphire ClinCard.
15. Give the participant an appointment card. **Also, remind them to bring all used and unused patches, patch packets, and short-acting NRT back to the next appointment.**

### Week 9

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. Have the participant fill out all of the questionnaires related to the session in REDCap.

4. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
5. Ask the participant if they experienced any issues in the past three weeks with the short-acting NRT they selected. If they report experiencing issues, follow the discussion guidelines in the therapist manual.
6. If the participant reports issues, determine whether the dosage of the short-acting NRT they selected should be lowered.
7. Remind the participant of the instructions on how to use the patches and gum/lozenges/inhaler/nasal spray and let them know they can reference their workbook if they forget.
8. Discuss the purpose of tapering medication dosage and review tapering instructions.
9. Ask the participant if they have any questions.
10. Schedule the next appointment in a month (preferably the same day of the week and the same morning time). This appointment should be scheduled with another study staff member other than the therapist who saw the participant for the five weekly sessions.

**Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**

11. Give the participant 28 patches (14 14mg patches and 14 7mg patches). The patches will last through to the next appointment. See therapist manual for tapering guidelines.
12. Give the participant enough of the short-acting NRT they chose to last through to the next appointment. See therapist manual for tapering guidelines.
13. Have the participant sign for the medication in the medication sign-out log.
14. Mark in the Medication Inventory Excel sheet how many of the patches and gum packages/lozenge quit tubes/inhaler cartridges/nasal spray bottles you have given out so that we maintain a running total of prescriptions we have on hand.
15. Compensate the participant on their Greenphire ClinCard.
16. Give the participant an appointment card. **Also, remind them to bring all used and unused patches, patch packets, and short-acting NRT back to the next appointment.**
17. Upload the session recording to Box.com (MOP, pg. 14) and complete the Audio Recording Length form in REDCap.

## **Week 13**

1. Check to see if any information on participant's contact sheet needs to be updated.
2. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
3. **Collect the study phone and charger given to the participant.**
4. Have the participant fill out all of the questionnaires related to the session in REDCap.
5. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.

6. Schedule the next appointment in a month (preferably the same day of the week and the same morning time). This appointment should be scheduled with another study staff member other than the therapist who saw the participant for the five weekly sessions.  
**Once you have it scheduled, make sure the appointment is placed in the Cropsey Lab Google Calendar.**
7. Compensate the participant on their Greenphire ClinCard.

## Month 1 Follow-up

8. Check to see if any information on participant's contact sheet needs to be updated.
9. Administer the CO test. Refer to the CO directions under the "CO Monitor" section on **Page 8** of this manual. Record the CO level in REDCap.
  - If the CO level is 3 or below, you need to administer a urine cotinine test to confirm that the participant is using nicotine products.
10. Have the participant fill out all of the questionnaires related to the session in REDCap.
11. While the participant is filling out the questionnaires on REDCap, have REDCap open on the desktop and double check for participant entry errors as they progress through the questionnaires.
12. Compensate the participant on their Greenphire ClinCard.
13. Thank the participant for being a part of the study.

## Ecological Momentary Assessment (EMA)

Ecological Momentary Assessment (EMA) is a platform we will be using to conduct daily assessments of smoking behavior, medication adherence, mood, sleep, and social support. This technology is provided by the University of Oklahoma Health Services Center, and they will be assisting with set up. Participants will be given a smart phone during their Week 5 appointment and will return the smart phone to study staff during their Week 13 appointment. Each day, within 30 minutes of waking, participants will receive a text on this smart phone with a link to the following survey questions:

1. How many cigarettes did you smoke yesterday?
2. Did you use any other tobacco products yesterday?
3. I am motivated to AVOID smoking.
4. Did you receive the nicotine patch at your last visit?
5. Did you use your nicotine patch yesterday?
6. What are the main reasons you did not use the patch?
7. How many hours did you wear your patch?
8. What other medication did you receive?
9. Did you use your (other medication) yesterday?
10. What are the main reasons you did not use the (other medication)?
11. How much of (other medication) did you use yesterday?
12. How confident are you that you will be able to fully quit smoking?
13. Did you drink alcohol yesterday?
14. How many standard drinks did you have yesterday?
15. Did you use marijuana yesterday?

16. Do you believe you experienced discrimination yesterday?
17. What do you believe was the main reason(s) for the discrimination?
18. Sometimes people do not fall asleep right away when they go to bed at night. What time did you actually fall asleep last night?
19. What time did you wake up this morning?
20. How would you rate the quality of your sleep last night?
21. How much support from friends/family members did you receive yesterday to help you with quitting smoking?
22. Did you feel like you needed the support yesterday to help you with quitting?
23. I have an urge to smoke.
24. I feel stressed.
25. I feel irritable.
26. I feel happy.
27. I feel frustrated /angry.
28. I feel sad.
29. I feel worried.
30. I feel miserable.
31. I feel restless.
32. I feel calm.
33. I feel bored.
34. I feel depressed.
35. I feel anxious.
36. Cigarettes are available to me.

Response options will be no/yes, Likert-type, or continuous scale depending on the question.

Participants who complete 90% of the EMAs and return the smart phone will be compensated with a one-time payment of \$100 during their Week 13 appointment. If participants complete 80% of the EMAs, they will be compensated with a one-time payment of \$75 during their Week 13 appointment. If participants complete 50% of the EMAs, they will be compensated with a one-time payment of \$50 during their Week 13 appointment.

## Data Entry

Includes all aspects of data planning, handling, analysis, documentation, and storage, and takes place during all stages of a study. The objective is to create a reliable data base containing high quality data. Management is a too often neglected part of study design, and includes:

- Planning the data needs of the study
- Data collection
- Data entry
- Data validation and checking
- Data manipulation
- Data files backup
- Data documentation

Each of these processes requires thought and time; each requires painstaking attention to detail. The main elements of data management are database files. The data will be managed via REDCap.

## Data Collection Parameters

Below is a guide to best understand the forms we are using within this study and how they should be collected in the most efficient manner:

- **CO Level:** Based on reading from CO Machine and entered in REDCap. **Completed at all visits.**
- **Cotinine Test:** Based on result from cotinine strip test and entered in REDCap. **Completed at Baseline and as needed for all other visits.**
- **Medication Given:** Select the dosage of patch and gum/lozenge/inhaler/nasal spray that the participant is receiving at the session that day. Select N/A for either or both medication types if the participant is not receiving medication. **Completed at all visits.**
- **Tobacco/NRT Calendars (Weekly/Monthly):** While the participant fills out the questionnaires in REDCap through the Survey Queue, you will bring up REDCap on the desktop computer and enter in the information from the calendars into the proper REDCap forms. **Completed at each session visit.**
- **Demographics Form:** Subject fills out form within REDCap survey cue. Verify form is completed before allowing participant to leave. **Only completed at Baseline.**
- **Minnesota Nicotine Withdrawal Scale:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. **Completed at all visits.**
- **Questionnaire of Smoking Urges-Short Form (QSU):** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. **Completed at all visits.**
- **Smoking History Form:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. **Only completed at Baseline.**
- **Weekly Smoking Behavior:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. **Completed at all visits.**
- **Thoughts About Abstinence:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. **Completed at all visits.**
- **Fagerström Test for Nicotine Dependence (FTND):** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. **Completed at Baseline, Week 5, Week 6, Week 9, Week 13, and Month 1 Follow-up.**
- **Perceived Stress Scale (PSS):** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. **Completed at all visits.**
- **Wisconsin Inventory of Smoking Dependence Motives:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. **Completed at Baseline, Week 5, Week 6, Week 9, Week 13, and Month 1 Follow-up.**

- **Attitudes About Nicotine Replacement Therapy:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed at all visits.
- **Abstinence-Related Motivational Engagement (ARME):** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed at all visits.
- **Smoking Abstinence Questionnaire (SAQ):** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed only at Baseline, Week 5, Week 6, Week 9, Week 13, and Month 1 Follow-up.
- **Symptoms/Side Effects Scale:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed at all visits, except Month 1 Follow-up.
- **Treatment Expectations:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed at all visits.
- **Treatment Satisfaction Survey:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed only at Week 5, Week 13, and Month 1 Follow-up.
- **Credibility Expectancy Questionnaire (CEQ):** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed only at Week 5, Week 13, and Month 1 Follow-up.
- **Minnesota Nicotine Withdrawal Scale 2:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed only at Week 1, Week 2, Week 3, Week 4, and Week 5.
- **Questionnaire of Smoking Urges-Short Form 2 (QSU):** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed only at Week 1, Week 2, Week 3, Week 4, and Week 5.
- **Alliance Questionnaire:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed only at Week 5.
- **Alliance Questionnaire-Therapist:** The staff fills out this questionnaire in REDCap after the conclusion of the appointment. This can be filled out after the participant has left. Completed only at Week 5.
- **Mini International Neuropsychiatric Interview (M.I.N.I):** This is a paper interview that is given by the staff and is entered into REDCap at the completion of the study visit. Completed only at Baseline.
- **Pittsburgh Sleep Quality Index:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed at all visits.
- **Barratt Impulsivity Scale:** Subject fills out form within REDCap Survey Queue. Verify form is completed before allowing participant to leave. Completed only at Baseline.
- **Group Assignment:** This form in REDCap randomizes the participants into one of the Intervention or Control groups for the remainder of the study. Completed only at Baseline.
- **Audio Recording Length (Counseling Session):** This is the length of the counseling session for each weekly session appointment and will be recorded in REDCap at the conclusion of the study visit. Completed only at Week 1, Week 2, Week 3, Week 4, and Week 5.

## **Amendments/Protocol Changes**

- 7-17-18 - This amendment clarified errors to reflect the protocol; added a compensation of \$5 for baseline failures, method of compensation, EMA compensation, removed documenting distributed compensation section, revised materials, procedures, and therapy protocol sections.
- 8-6-19- For this amendment, we added amendment dates to the Amendments/Protocol Changes section and made changes to correctly reflect our existing protocol.