

RISE

SOP for Running Treatment and Assessment Visit 1

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Purpose:

This SOP describes the procedures for running in-person (pages 2-10) and remote (pages 11-21) Treatment and Assessment (T/A) Visit 1 for the RISE project.

[In-Person Procedure](#)

[Remote Procedure](#)

✳ On Visit days:

- Dress appropriately: business casual; no cut-off shorts, shirts that show your tummy, etc.

Procedures for Running IN-PERSON T/A Visit 1

Preparations for In-Person T/A Visit 1

1. Preparations should be done about 30 minutes prior to your scheduled T/A 1 visit (just in case your participant (PPT) arrives early)
2. Prepare PPT Room
 - a. In-person T/A Visits should happen primarily in Rooms 304B & 319
3. Have the following available for during and at the end of the visit:
 - a. Printed TLFB substance definition sheets
 - b. *If intake was remote, and Care Pack 1 was not mailed out:* Care Pack 1 with the Quit Kit, printed visit reminder sheet, and US Bank Card (unless it was shipped to the PPT already)
 - c. *If intake was in-person:* Have a Quit Kit to review with the ppt in case they don't have the one from Intake with them
 - d. Care Pack 2 (including Nicotine Patches and Lozenges with blank labels)
 - i. At the end of the visit, these materials will be placed in one of the poly envelopes (that are stored in the right file cabinet in Room 308A) and handed to the PPT
 - e. Get the CO monitor from the left cabinet in Rm 308A (see more detailed information in the Intake SOP on Page 2, Section 3d)
 - i. Ensure the CO monitor does NOT need to be calibrated; if it does, calibrate if time allows or switch to the other monitor if no time to calibrate
 - ii. Check to see if the plastic mouthpiece (i.e., D-piece) needs to be changed
 - iii. Set the CO monitor and a wrapped plastic mouthpiece on the cabinet or table – be sure to keep the wrapping on the mouthpiece until the PPT is in the room so they can see you're using a new mouthpiece
4. Set up PPT desktop
 - a. Use your UB credentials to log in to REDCap and open the RISE project
 - b. Navigate to the PPT's Record ID using "Add / Edit Records"
 - c. Prepare the PPT facing survey set
 - i. Open the "QSU Phenx" form
 - ii. Click on "Survey options" in the upper right of the form (see image below)

The screenshot shows the REDCap interface for editing an existing record. At the top right, there is a label 'Invitation status:' followed by an envelope icon and a dropdown menu. The dropdown menu is open, showing 'Survey options' with a downward arrow. Below this, there is a blue header bar that says 'Editing existing Record ID 198-1030.' followed by a yellow bar that says 'Event: Intake'. At the bottom, there is a table with two columns: 'Record ID' and '198-1030'.

- iii. Select "Open survey"

The screenshot shows a REDCap record edit form for Record ID 198-1030. The form includes fields for 'Event: Intake', 'Record ID', 'Cigarettes', and a question 'What brand of cigarettes do you usually smoke?'. A dropdown menu titled 'Survey options' is open, showing options: 'Open survey' (highlighted with a green box), 'Log out + Open survey', 'Compose survey invitation', 'Survey Access Code + QR Code', and 'Survey Queue'.

- iv. After the survey opens in a new window, make sure to leave the survey without saving changes in the original window
 - v. Minimize the window for this survey set
5. Set up your laptop
- a. Use your UB credentials to log in to REDCap and open the RISE project
 - b. Navigate to the PPT's Record ID using "Add / Edit Records"
 - c. TLFB Setup
 - i. Under "T/A V1" column, open "TLFB Setup" form and set the "Calendar Start Date" to yesterday's date, then Save as "Unverified"
 - ii. Open "TLFB" form and put any major holidays that occurred within the TLFB period into that day's "List important events" field, then Save as "Unverified"
 1. If T/A 1 happens exactly one week after Intake, make sure to list the visit as an important event for the week
6. Check the PPT's name so you can greet them correctly when they arrive
7. Open the T/A 1 Record Form and use it as a checklist and procedure guide as you proceed with the visit

Running In-Person T/A 1 Visits

1. PPTs have been instructed to call the study line ...
 - a. ... after they've parked in either a clinic spot or the Diefendorf Lot (if they are driving)
 - b. ... OR when they arrive on the ground floor of Diefendorf Hall (if they took public transportation, walked, or were dropped off)
2. If the PPT hasn't arrived or called by 10 minutes after the scheduled visit time, call the PPT to get an update on their status or leave a voicemail (VM) if they do not answer; refer to the Rescheduling SOP for more information and for scripts
 - a. If the PPT shares that they will be 30 minutes late or more, check the calendar to determine if we have staff availability to run the visit; reschedule if needed
 - i. If we are able to accommodate, stress the importance of arriving on time to the PPT and share that we will likely be unable to accommodate lateness in the future
 - b. If the PPT doesn't answer or is running late, wait in the visit room; if the PPT does not show up either within 20 minutes of the original visit time or the new time they shared, milestone as "Reschedule Pending" OR "Missed" depending on the situation
 - c. If the PPT is not going to attend the visit that day, proceed to "In-Person Post Visit Tasks"

3. When your PPT calls, ask if they need a new parking pass; make sure their parking pass is prominently displayed on the dashboard of their car
4. When you see the PPT:
 - a. If you have already met them, say: **“Hi [PPT name]. It’s good to see you. Please follow me to the visit room.”**
 - b. If it is your first time meeting them, say: **“Are you [PPT name]? My name is [Name] and I will be working with you today. It’s very nice to meet you. Please follow me.”**
5. Go to the room you’ve reserved for your T/A 1 visit:
 - a. Have the PPT sit in the chair facing the desktop computer
 - b. You can sit in the other chair

Visit Overview and Quit Kit Explanation/Walkthrough

1. Review with PPT what will be happening at the T/A 1 Visit, say: **“I’m going to start with an overview of today’s visit. First, we will review the contents of Care Pack 1 that you received [at/after] your Intake appointment. Then I’ll ask you questions about your use of nicotine and other tobacco products as well as about any medications you use. You will also complete surveys and do a breath sample. At the end of the visit, we will review Care Pack 2.”**
 - a. After explaining visit overview, ask PPT: **“Do you have any questions about the visit today?”**
 - i. Note any questions asked by the PPT as well as your answers in the “Notes” box at the bottom of the T/A 1 Record Form
 - b. After answering any questions the PPT has, update the T/A 1 Record Form
2. Take out Care Pack 1
 - a. If PPT received Care Pack 1 at Intake, ask them to take it out now
 - i. If the PPT forgot it, offer another printed copy of the Quit Kit to review at this time which they won’t keep (unless they have lost the other one)
 - b. If PPT completed a Remote Intake, show them Care Pack 1 now
 - c. Say **“As you read in the consent form last time, the treatment in this study is nicotine replacement therapy patches and lozenges along with self-help materials to help you reach your quit smoking goal. You will receive those medications at the end of this visit and you will begin using them on the morning of your T/A visit 2 - also known as your Target Quit Date – the date you plan to stop smoking.”**
 - i. [RA – Hold up Quit Kit] Ask **“Have you already read through the Quit Kit?”** [If yes, RA can congratulate them and thank them for doing so!]
 - ii. [If no, say] **“It would be super helpful for you to read through this Quit Kit BEFORE the morning of your Target Quit Date, which will be your next visit.”**
 - d. Say, **“The most important things to know today are:**
 - i. **WHEN IS YOUR QUIT DAY?** [RA let them answer] **AND**
 - ii. **WHEN WILL YOU START USING YOUR STUDY MEDICATION?”** [RA let them answer but confirm that they know to start first thing in the morning when they wake up on their TQD]

- e. Say, **“This Kit has several sections that will help you along the way during your quit smoking journey. The first 3 sections include an introduction and information about what you will be doing throughout the study.”**
- f. Say, **“The 4th section on page 5 reviews Nicotine Replacement Therapy (NRT) treatment basics, directions for use of patches and lozenges, and a short section on Side Effects of using NRT. You'll put your patch on first thing in the morning when you wake up and you'll use the lozenges to help you deal with stronger cravings throughout the day. We will talk more about this at the end of the visit when I give you your patches and lozenges.”**
- g. Say, **“On page 10, you will find quit-smoking resources, including a comprehensive quit smoking website, a text messaging program, an app, and a quit line number. These resources are there for you IF you want to use them – they are not required.”**
- h. Say, **“Starting on page 11, you will find strategies and worksheets to help you prepare for your quit day and to stay on track during your quit attempt.”**
- i. Say, **“We hope you will use whatever resources and strategies you think will help you.”**
- j. Click “Yes” that you went through the Quit Kit and a text box will pop up
- k. Ask PPT if they have any questions about the Quit Kit
 - i. Record Quit Kit-related questions, as well as the answers you provide, in the text box that popped up in the Record Form
 - ii. If the PPT does not have any questions about the Quit Kit, type “N/A” in the text box

Did you go through the Quit Kit?

☒ Yes
☐ No

What questions did Matt have about the Quit Kit?

Administer TLFB

1. Navigate to “TLFB Setup” on your laptop
2. At T/A 1, we are asking about cigarettes, e-cigarettes, any other tobacco/nicotine product, and combustible marijuana
 - a. If PPT says they use e-cigarettes, any other tobacco/nicotine products or combustible marijuana, provide them with the definition card(s)

3. Administer “TLFB” using instructions in REDCap and Appendix A in the Intake SOP
 - a. You may use a shortened script to introduce TLFB: **“Just like we’ve done before, we are now going to review your use of those products over each of the past 7 days, starting with yesterday. Each day we will review what you did as well as what products you used. Our purpose is to get the most accurate information for each day but if you’re not sure of the exact number for a particular day, give your best guess. Keep in mind that each day is considered Midnight to 11:59pm. Do you have any questions?”**
4. Save “TLFB” form as “Complete”

Medications

1. Say, **“Have there been any changes to your prescription medications since your last visit?”**
 - a. If yes, open the “Medications” form (in the “Intake” column) and make any necessary changes
 - i. Click “Updates were made in the Medications form”
 - ii. Save “Unverified”
 - b. If no, click “There was nothing to update in the Medications form”
 - i. Save “Unverified”

Contact Info

1. Go to “Contact Info” form (under Phone Screen) and confirm that nothing has changed with their contact info saying, **“Have there been any changes to your name, address, phone number or email since your last visit?”**
 - a. If yes, update info as necessary
 - i. Copy and paste the old information into a text box in the “Contact info” form so we have a record of what was changed and when the change was made (e.g., 2026.02.25 CGD: PPT’s phone number was changed from 716-555-5555 to 716-777-7777 today)
 - b. If no changes, move on to Survey Set

Survey Set

1. Set up the survey set on the PPT computer by maximizing the earlier minimized “QSU Phenx” window
2. Remind PPT, **“There are several different surveys that you will fill out. Please pay attention to any instructions that appear at the beginning of each one. I’ll be in the other room preparing your care pack. Please let me know if you have any questions and I’ll come back over. I can see your survey list on my laptop and will know when you are done; I’ll come back into the room then.”**
 - a. If you need to step out of the visit room for any reason, make sure the PPT is informed and that you let them know once you’ve returned
3. The survey set includes:
 - a. QSU [Questionnaire of Smoking Urges; consists of 10 statements about the respondent’s feelings and thoughts about his or her desire to smoke cigarettes as he or she is completing the questionnaire (i.e., right now)]

- b. MNWS [Minnesota Nicotine Withdrawal Scale; now known as the Minnesota (Tobacco) Withdrawal Scale is a self-report protocol which reviews symptoms of withdrawal]
 - c. TOES and AbstSE [Treatment Outcome Expectancies using the Stanford Expectations of Treatment Scale with one question at the end measuring Abstinence Self Efficacy; an instrument for measuring positive and negative treatment expectancies]
 - d. PPT Cost Measure [created for the RISE study; PPT survey of time, productivity loss, transportation cost and any other forgone resources for participation]
 - e. Perceived Stress Scale [helps to understand how different situations affect PPT's feelings and perceived stress]
 - f. SE Checklist V20 [Side Effect Checklist; 25 item-checklist of symptoms; PPTs check each one experienced in the previous month then rate the severity]
4. While PPT is completing the survey set, begin preparing Care Pack 2 (CP2)

Target Quit Day (T/A 2)

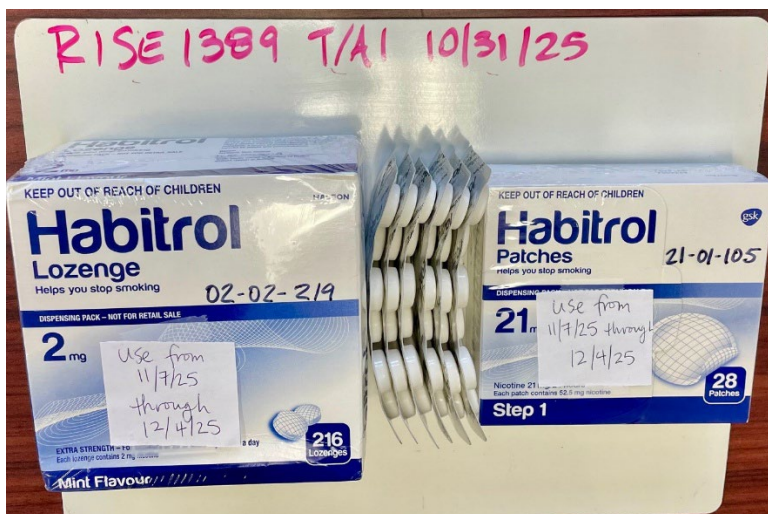
03-12-2025  M-D-Y

By hand, write on both stickers:
"Use from 03-12-2025 to..."

04-08-2025 [View equation](#)

Then, stick 1 sticker on a box of patches and the other on a box of lozenges.

- a. Write down the range of use dates as indicated in the T/A 1 Record Form on 2 pieces of white paper
 - b. Tape one to the front of the patches package and the other to the front of the lozenges package
5. Once CP2 is prepared, take a picture of the entire care pack, with the patches package (w/ date range), lozenges package (w/ date range), and the 6 lozenge blister packs all visible



- a. Upload this picture to the appropriate section of the T/A 1 Record Form

- b. If time permits, update the “UB RISE Inventory + Tracking” Excel file, now

Pack #	LOT	Expiration	Dose (mg)	# of Patches	Date Labeler	Labeled By	Study ID	Visit	R or IP?	Initials of Distributor	Date of Distribution	Notes
21-09-145	685700B	09/2026	21	28	2/21/2025	MG 1193	T/A 1	R		CGD	6/9/2025	06/13/2025 CGD: Care Pack 2 delivered

Box #	Batch	Expiration	Dose (mg)	# of Lozenges	Date Labeler	Labeled By	Study ID	Visit	R or IP?	Initials of Distributor	Date of Distribution	Notes (how many sleeves/bottles left)
02-07-183	2401391	07/2026	2	216	5/15/2025	MG 1193	T/A 1	R		CGD	6/9/2025	06/13/2025 CGD: Care Pack 2 delivered

Side Effect Tracking

- After PPT completes the Survey Set, open the Side Effect Tracking form
- Follow instructions in the Intake SOP AND the SOP for Handling Participant Side Effects to determine if there are any symptoms that meet criteria for review and should be discussed with the PPT
- If there are symptoms to report to the study physician:
 - Collect additional information from PPT about each symptom
 - After gathering more information about the symptoms reported by the PPT, answer the two questions that appear below the text box
 - Verify their smoking status based on TLFB completed earlier
 - Since this is the first T/A visit and the PPT has not received study medication yet, you know that the answer to the next question should be “No” but ask anyway
 - You will need to send an email to send to the study physician, et al, after the visit
 - Save the form as “Unverified”
- If there are NO symptoms to report to the study physician, save the form as “Complete”
- Move on to Breath CO

Breath CO

- Collect breath CO according to the instructions in the REDCap form
 - If PPT asks more about the carbon monoxide reading, say: **“Carbon Monoxide is a colorless, odorless gas produced from the incomplete burning of virtually any combustible product. It may accumulate indoors as a result of tobacco smoking, poorly ventilated appliances, and attached garages.”**
 - If PPT asks for feedback about their reading, you can tell them that people who smoke daily generally fall into the 10-60 ppm range; if reading is >60 there may be additional factors in the environment influencing the reading
 - If a participant has a reading >60, please consult with the PI or Coordinator after the visit
- Record the reading in the T/A 1 Breath CO Form
- Save the form as “Complete”

Review of Care Pack 2

- Take out Care Pack 2
- Take out patches

- a. Remind PPT to apply the patch as soon as they wake up on the Target Quit Day and wear it until replacing with a new patch the next morning
- b. Review important directions for use, including:
 - i. Recommended application locations
 - ii. Application area should be completely dry and free from body care products
 - iii. Application location should be rotated such that the same spot is not used more than once per week
3. Take out lozenges
 - a. Remind the PPT to use them to help with strong cravings throughout the day
 - b. Review important directions for use, including:
 - i. Recommended daily quantity of 5 – 15 lozenges
 - ii. Placement between gum and cheek
4. Remind the PPT to review the instructions on pages 5 – 8 of the Quit Kit for using NRT
5. Place NRT in the gray poly envelope and hand it to PPT

Ending the visit

1. Say “**Payment for today’s visit will be available on your US Bank card in 1-2 business days**”
2. Remind PPT of the date and time of next visit which is the Target Quit Day
3. Ensure PPT has all of the materials from Care Pack 2 (and Care Pack 1 if they received it at this visit) with them when they leave the visit
4. Thank PPT for their time today and end the visit
5. Complete final fields in T/A 3 Record Form, noting PPT’s use of nicotine and/or tobacco product(s) during the visit, and any significant distractions that diverted PPT’s attention from the visit

In-Person Post Visit Tasks

1. Change the color of the event on the RISE Google calendar from lavender to sage green to indicate that the PPT attended the visit
2. If not done previously, update the “UB RISE Inventory + Tracking” Excel file with the “pack” number of the patches and the “box” number of the lozenges that were dispersed to this PPT (refer to pictures above in Section 5b on Page 7)

Cleaning the Visit Room:

1. Log out of the desktop computer
2. Wipe down the keyboard, mouse, computer desk, and chair with 70% isopropyl alcohol solution
3. Sanitize the CO Monitor with a Covita wipe
 - a. Make sure to squeeze out extra liquid before wiping down the monitor
 - b. Dry the monitor with a tissue
4. Ensure that all materials from the visit are returned to their proper location (e.g., CO monitor, TLFB Sheets)

Completing Post-T/A 1 Record Form:

1. Update Milestones

- a. If the visit went according to protocol and the PPT achieved the visit and wants to continue:
 - i. The overall Study Status should be updated to “ITT Ongoing”
 - ii. Change the T/A 1 visit status to “Achieved”
 - iii. Update the “Date of most recent update to T/A 1 Status” to the date the T/A 1 was completed and add any notes about what occurred during the visit, if applicable

Study status:

ITT Ongoing ▼

- Pre-ITT Never screened for eligibility
- Pre-ITT Refused before signing consent
- Pre-ITT Ineligible
- Pre-ITT Withdrew
- Pre-ITT Withdrawn by PI
- Pre-ITT Pending
- Pre-ITT LTFU at Intake
- Pre-ITT LTFU at T/A 1
- ITT Ongoing**
- ITT Withdrew
- ITT Withdrawn by PI
- ITT LTFU at T/A 2
- ITT LTFU at T/A 3
- ITT LTFU at T/A 4
- ITT LTFU at T/A 5
- ITT Finished

T/A 1 Status:

Achieved ▼

- Scheduled
- Reschedule Pending
- Missed
- Withdrew
- Withdrawn by PI
- Partial visit achieved
- Achieved**

- iv. All other milestone options can be found in the dropdown menu – refer to the Milestoning SOP if you have questions about what status to select

2. Complete the sections on “Side Effects and AEs” as well as “Ad Hoc AE”

- a. Follow the SOP for Handling Participant Side Effects to determine if there is anything that needs to be reported to the study physician

3. Save “Complete” and exit the record

4. For info on “Payment” refer to page 43 in the SOP for Intake Visits

Procedures for Running REMOTE T/A 1 Visit

Preparations for Remote T/A 1 Visit

1. Zoom meeting link

- a. On the morning of the visit, schedule a meeting for the established T/A 1 time in Zoom, and send the meeting invitation to the PPT via text and/or email depending on preference discussed at Phone Screen
 - i. Ensure that the following meeting settings are enabled (see pictures below):
 1. Set Meeting Security to “Waiting Room” (Passcode is enabled by default)
 2. Set Video for both Host & Participant to be “On”
 3. Under Advanced, select “Allow participants to join anytime” and deselect “Mute participants upon entry”

Schedule Meeting

* Topic

[+ Add Description](#)

When

Duration hr min

Time Zone

☐ Recurring meeting

Invitees

Registration ☐ Required

Meeting ID ☒ Generate Automatically ☐ Personal Meeting ID 583 805 6475

Template

Whiteboard

Docs

Security ☐ Passcode
Only users who have the invite link or passcode can join the meeting

☒ Waiting Room
Only users admitted by the host can join the meeting

☒ Follow Zoom web portal setting

☐ Select who should go into the waiting room for this meeting

☐ Require authentication to join

AI Companion

AI Companion

- ☐ Automatically start AI Companion ⓘ
- ☐ Automatically start meeting questions
- ☐ Automatically start meeting summary

Meeting summary template

General template ▼

[Change default summary template ↗](#)

Video

- Host ☒ on ☐ off
- Participant ☒ on ☐ off

Audio

- ☐ Telephone
- ☐ Computer Audio
- ☒ Both

Dial from **United States** and other 3 countries 

Options

[Hide](#)

- ☒ Allow participants to join anytime
- ☐ Q&A
- ☐ Mute participants upon entry
- ☐ Breakout Room pre-assign
- ☐ Automatically record meeting
- ☐ Enable focus mode when meeting starts
- ☐ Enable additional data center regions for this meeting
- ☐ Approve or block entry to users from specific regions/countries

Alternative Hosts

Enter user name or email addresses ▼

Allow the alternative host to manage this meeting's assets as co-owner after the meeting. ⓘ

- ☒ Meeting summary
- ☒ Meeting cloud recording
- ☒ Add or edit polls

Student Life Tracking (pilot)

Select ▼

Interpretation

- ☐ Enable language interpretation
- ☐ Select sign language interpretation video channels below. You can assign interpreters at any time.

2. Preparations should be done about 30 minutes prior to your scheduled T/A 1 visit (just in case your PPT joins the Zoom call early)
 - a. Remote T/A visits should happen primarily in Rooms 304, 307A, & 307B
3. Have the following available for the visit:
 - a. Printed TLFB substance definition sheets
 - b. Quit Kit to review with the PPT
 - c. Care Pack 2 (including Nicotine Patches and Lozenges with blank labels)

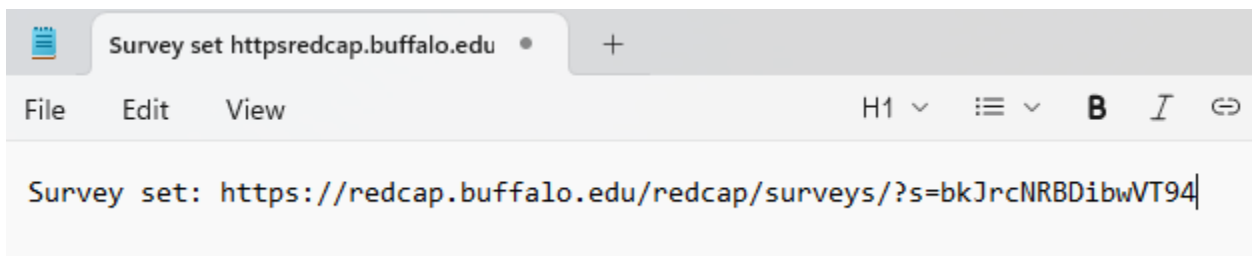
d. Instructions for the iCO monitor:

- i. RISE_iCO SOP – the steps are in REDCap but the SOP contains extra information plus troubleshooting tips
- ii. “The Quit Kit’s Guide to Your CO Monitor” is a truncated version of the steps for creating and registering an account and for collecting a sample

4. Set up REDCap

- a. Use the desktop computer for the Zoom meeting and your laptop for REDCap OR use a split screen layout on the desktop computer so that Zoom and REDCap can be used at the same time
- b. Use your UB credentials to log in to REDCap and open the RISE project
- c. Navigate to the PPT’s Record ID using “Add / Edit Records”
- d. TLFB Setup
 - i. Under “T/A V1” column, open “TLFB Setup” form and set the “Calendar Start Date” to yesterday’s date, then save as “Unverified”
 - ii. Open “TLFB” form and put any major holidays that occurred within the TLFB period into that day’s “List important events” field, then save as “Unverified”

5. Open and copy survey set link into notepad on computer



6. To save time later, you can enter PPT’s username and password into the iCOquit App (if account was registered together at Intake) so that after the PPT collects their CO sample, you can sign in to get the screenshot of their reading

Sign In

☐ Remember Email [Forgotten Password?](#)

OR

7. Check the PPT’s name so you can greet them correctly when they arrive on the Zoom call

8. Open the T/A 1 Record Form and use it as a checklist and procedure guide as you proceed with the visit

Running Remote T/A 1 Visit

1. About 10 minutes prior to the scheduled visit time, start the Zoom call
2. If the PPT hasn't joined the Zoom meeting or called by 10 minutes after the scheduled visit time, call the PPT to get an update on their status or leave a voicemail (VM) if they do not answer. Refer to the Rescheduling SOP for more information and for scripts
 - a. If the PPT shares that they will be 30 minutes late or more, check the calendar to determine if we have staff availability to run the visit; reschedule if needed
 - i. If we are able to accommodate, stress the importance of arriving on time to the PPT and share that we will likely be unable to accommodate lateness in the future
 - b. If the PPT doesn't answer or is running late, return to the visit room. If the PPT does not show up either within 20 minutes after the scheduled visit time or the new time they shared - milestone as "Reschedule Pending" OR "Missed" depending on the situation
 - c. If the PPT is not going to attend the visit that day, proceed to "Remote Post Visit Tasks"
3. When the PPT joins the Zoom meeting ...
 - a. Introduce yourself and welcome the PPT
 - b. Ensure that PPT is in a private, distraction-free space
 - i. Ask **"Are you in a private area where you feel comfortable talking and no one will disturb you?"**
 1. If PPT is not in a private area and is unable/unwilling to move to a private area, ask if they would like to reschedule the appointment to a day/time when they can be in a private area
 2. It is up to the PPT to decide whether to continue if they are not in a private area

Visit Overview

1. Review with PPT what will be happening at the T/A 1 Visit, say: **"I'm going to start with an overview of today's visit. First, we will review the contents of Care Pack 1 that you received [at your Intake appointment/in the mail after your Intake appointment]. Then I'll ask you questions about your use of nicotine and other tobacco products as well as about any medications you use. You will also complete surveys and do a breath sample. At the end of the visit, we will review Care Pack 2."**
 - a. After explaining visit overview, ask PPT: **"Do you have any questions about the visit today?"**
 - i. Note any questions asked by the PPT as well as your answers in the "Notes" box at the bottom of the T/A 3 Record Form
 - b. After answering any questions the PPT has, update the T/A 2 Record Form
2. Take out sample Care Pack 1
 - a. Ask PPT to take out their Care Pack 1 now

- b. Say **“As you read in the consent form last time, the treatment in this study is nicotine replacement therapy patches and lozenges along with self-help materials to help you reach your quit smoking goal. You will receive those medications at the end of this visit, and you will begin using them on the morning of your second visit - also known as your Target Quit Date – the date you plan to stop smoking.”**
 - i. [RA – Hold up Quit Kit] Ask, **“Have you already read through the Quit Kit?** [If yes, RA can congratulate them and thank them for doing so!]
 - ii. [If no, say] **“It would be super helpful for you to read through this Quit Kit BEFORE the morning of your Target Quit Date, which will be your next visit.”**
- c. Say, **“The most important things to know today are:**
 - i. **WHEN IS YOUR QUIT DAY?** [RA let them answer] **AND**
 - ii. **WHEN WILL YOU START USING YOUR STUDY MEDICATION?”** [RA let them answer but confirm that they know to start first thing in the morning when they wake up on their Quit Day]
- d. Say **“This Kit has several sections that will help you along the way during your quit smoking journey. The first 3 sections include an introduction and information about what you will be doing throughout the study.”**
- e. Say, **“The 4th section on page 5 reviews Nicotine Replacement Therapy (NRT) treatment basics, directions for use of patches and lozenges, and a short section on Side Effects of using NRT. You'll put your patch on first thing in the morning when you wake up and you'll use the lozenges to help you deal with stronger cravings throughout the day. We will talk more about this at the end of the visit when I give you your patches and lozenges.”**
- f. Say, **“On page 10, you will find quit-smoking resources, including a comprehensive quit smoking website, a text messaging program, an app, and a quit line number. These resources are there for you IF you want to use them – they are not required.”**
- g. Say, **“Starting on page 11, you will find strategies and worksheets to help you prepare for your quit day and to stay on track during your quit attempt.”**
- h. Say, **“We hope you will use whatever resources and strategies you think will help you.”**
- i. Click “Yes” that you went through the Quit Kit and a text box will pop up
- j. Ask PPT if they have any questions about the Quit Kit
 - i. Record Quit Kit-related questions, as well as the answers you provide, in the text box that popped up in the Record Form
 - ii. If the PPT does not have any questions about the Quit Kit, type “N/A” in the text box

Administer TLFB

1. Navigate to “TLFB Setup” on your laptop
2. At T/A 1, we are asking about cigarettes, e-cigarettes, any other tobacco/nicotine product, and combustible marijuana
 - a. If PPT says they use e-cigarettes, any other tobacco/nicotine products or combustible marijuana, provide them with the definition card(s)

3. Administer “TLFB” using instructions in REDCAP and Appendix A in the Intake SOP
 - a. You may use a shortened script to introduce TLFB: **“Just like we’ve done before, we are now going to review your use of those products over the past 7 days, starting with yesterday. Each day we will review what you did as well as what products you used. And remember, if you’re not sure what the exact number was for a particular day, you can just give your best guess. Keep in mind that each day is considered Midnight to 11:59pm. Do you have any questions?”**
4. Save TLFB form as “Complete”

Medications

1. Say, **“Have there been any changes to your prescription medications since your last visit?”**
 - a. If yes, open the “Medications” form (in the “Intake” column) and make any necessary changes
 - i. Click “Updates were made in the Medications form”
 - ii. Save “Unverified”
 - b. If no, click “There was nothing to update in the Medications form”

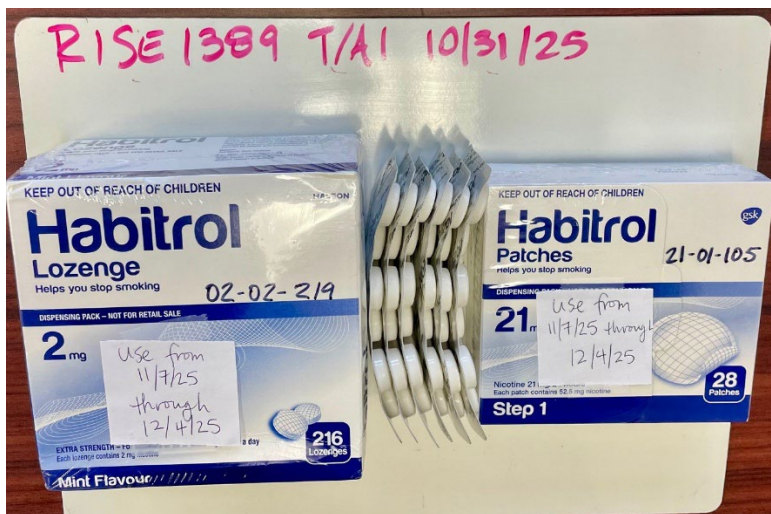
Contact Info

1. Go to “Contact Info” form (under Phone Screen) and confirm that nothing has changed with their contact info saying, **“Have there been any changes to your name, address, phone number or email since your last visit?”**
 - a. If yes, update info as necessary
 - i. Copy and paste the old information into a text box in the “Contact info” form so we have a record of what was changed and when the change was made (e.g., 2026.02.25 CGD: PPT’s phone number was changed from 716-555-5555 to 716-777-7777 today)
 - b. If no changes, move on to Survey Set

Survey Set

1. Send PPT a link to the QSU survey (effectively, the link for the whole survey set)
 - a. You may opt to send via Zoom chat, email, or access code based on your evaluation of what is best for that individual PPT
2. Remind PPT, **“There are several different surveys you will fill out. Please pay attention to any instructions that appear at the beginning of each one. I will have my camera and microphone off while I prepare your care pack. Please let me know if you have any questions as you go through. I can see your survey list on my laptop and will know when you are done; I’ll turn my camera and microphone back on then.”**
 - a. If you need to step out of the visit room for any reason, make sure the PPT is informed and that you let them know once you’ve returned
3. The survey set includes:

- a. QSU [Questionnaire of Smoking Urges; consists of 10 statements about the respondent's feelings and thoughts about his or her desire to smoke cigarettes as he or she is completing the questionnaire (i.e., right now)]
 - b. MNWS [Minnesota Nicotine Withdrawal Scale; now known as the Minnesota (Tobacco) Withdrawal Scale is a self-report protocol which reviews symptoms of withdrawal]
 - c. TOES and AbstSE [Treatment Outcome Expectancies using the Stanford Expectations of Treatment Scale with one question at the end measuring Abstinence Self Efficacy; an instrument for measuring positive and negative treatment expectancies]
 - d. PPT Cost Measure [created for the RISE study; PPT survey of time, productivity loss, transportation cost and any other forgone resources for participation]
 - e. Perceived Stress Scale [helps to understand how different situations affect PPT's feelings and perceived stress]
 - f. SE Checklist V20 [Side Effect Checklist; 25 item-checklist of symptoms; PPTs check each one experienced in the previous month then rate the severity]
3. While PPT is completing the survey set, begin preparing Care Pack 2 (CP2)
 - a. Write down the range of use dates as indicated in the T/A 1 Record Form on 2 pieces of white paper
 - b. Tape one to the front of the patches package and the other to the front of the lozenges package
 4. Once CP2 is prepared, take a picture of the entire care pack, with the patches package (w/ date range), lozenges package (w/ date range), and the 6 lozenge blister packs all visible



- a. Upload this picture to the appropriate section of the T/A 1 Record Form
- b. If time permits, update the "UB RISE Inventory + Tracking" Excel file, now

Pack #	LOT	Expiration	Dose (mg)	# of Patch	Date Label	Labeled E	Study ID	Visit	R or IP	Initials of Distributor	Date of Distribution	Notes
21-09-145	685700B	09/2026	21	28	2/21/2025	MG 1193	T/A 1	R	CGD	6/9/2025	06/13/2025 CGD: Care Pack 2 delivered	

Box #	Batch	Expiration	Dose (mg)	# of Lozenges	Date Labeled	Labeled By	Study ID	Visit	R or IP?	Initials of Distributor	Date of Distribution	Notes (how many sleeves/bottles left)
02-07-183	2401391	07/2026	2	216	5/15/2025	MG 1193		T/A 1	R	CGD	6/9/2025	06/13/2025 CGD: Care Pack 2 delivered

Side Effect Tracking

1. After PPT completes the Survey Set, open the Side Effect Tracking form
2. Follow instructions in the Intake SOP AND the SOP for Handling Participant Side Effects to determine if there are any symptoms that meet criteria for review and should be discussed with the PPT
3. If there are symptoms to report to the study physician:
 - a. Collect additional information from PPT about each symptom from the PPT
 - b. You will need to send an email to send to the study physician, et al, after the visit
 - c. Save the form as “Unverified”
4. If there are NO symptoms to report to the study physician, save the form as “Complete”
5. Move on to Breath CO

Breath CO

1. Open the “Breath CO” form in REDCap
 - a. Say, **“Now we are going to collect a breath sample using the iCOquit device you received in Care Pack 1. Do you have your iCoQuit device with you?”**
 - i. If Yes, select the matching radio button in REDCap and proceed with steps below.
 - ii. If No, select the matching radio button in REDCap and read the script that is displayed there, essentially letting PPT know they can submit the reading within 12hrs to receive the \$10 breath sample payment
2. When you see that the PPT has their iCO device and instructions out, say **“You can go ahead and log into your iCOquit account on your smartphone. Do you remember your username and password?”**
 - a. If needed, refer to the top of the Breath CO form and remind PPT of their login information
 - b. If PPT did not register their iCOQuit account, refer to page 39 #2.a.1 (FOR REMOTE INTAKE randomized to REMOTE T/A VISITS) of the Intake SOP to help them register their account
3. Guide PPT through collection of CO sample using instructions in REDCap
4. Do your best to ensure that PPT is visible from the chest up during the collection process
 - a. If they’re using their smartphone for Zoom, their camera feed may stop once they enter the iCO app:
 - i. If this happens, first let them log in
 - ii. Then ask them to return to Zoom
 - iii. Then go back into the iCO app
 - b. If the camera is still not working with the app, you will have to record that the collection could not be observed in the appropriate field of the REDCap Breath CO form
5. If PPT asks more about the carbon monoxide reading, say: **“Carbon Monoxide is a colorless, odorless gas produced from the incomplete burning of virtually any combustible product. It may**

accumulate indoors as a result of tobacco smoking, poorly ventilated appliances, and attached garages.”

6. If PPT asks for feedback about their reading, you can tell them that people who smoke regularly generally fall into the 10-60 ppm range; if reading is >60 there may be additional factors in the environment influencing the reading
 - a. If a PPT has a reading >60, please consult with the PI or Coordinator after the visit
7. Record the reading in the T/A 1 Breath CO Form

Review of Care Pack 2

1. Take out Care Pack 2
2. Take out patches
 - a. Remind PPT to apply the patch as soon as they wake up on the Target Quit Day and wear it until replacing with a new patch the next morning
 - b. Review important directions for use, including:
 - i. Recommended application locations
 - ii. Application area should be completely dry and free from body care products
 - iii. Application location should be rotated such that the same spot is not used more than once per week
3. Take out lozenges
 - a. Remind the PPT to use them to help with strong cravings throughout the day
 - b. Review important directions for use, including:
 - i. Recommended daily quantity of 5 – 15 lozenges
 - ii. Placement between gum and cheek
4. Remind the PPT to review the instructions on pages 5 – 8 of the Quit Kit for using NRT
5. Confirm the address that Care Pack 2 will be shipped to and mark “Yes” under “Care Pack 2” in the T/A 1 Record Form

Ending the visit

1. Say **“Payment for today’s visit will be available on your US Bank card in 1-2 business days”**
2. Remind PPT of the date and time of next visit, which is the Target Quit Day
3. Thank PPT for their time today and end the visit
4. Complete final fields in T/A 3 Record Form, noting PPT’s use of nicotine and/or tobacco product(s) during the visit, and any significant distractions that diverted PPT’s attention from the visit

Remote Post Visit Tasks

1. Change the color of the event on the RISE Google calendar from blueberry to basil green to indicate that the PPT attended the visit
2. If not done previously, update the “UB RISE Inventory + Tracking” Excel file with the “pack” number of the patches and the “box” number of the lozenges that were dispersed to this PPT (refer to pictures above in Section 5b on Page 7)

Cleaning the Visit Room:

1. Log out of the desktop computer
2. Ensure that all materials from the visit are returned to their proper location (e.g., CO monitor, TLFB Sheets)

Completing Post-T/A 1 Visit Record Form:

1. Update Milestones
 - a. If the visit went according to protocol and the PPT achieved the visit and wants to continue:
 - i. The overall Study Status should be updated to “ITT Ongoing”
 - ii. Change the T/A 1 visit status to “Achieved”
 - iii. Update the “Date of most recent update to T/A 1 Status” to the date the T/A 1 was completed and add any notes about what occurred during the visit, if applicable

Study status:

ITT Ongoing

Pre-ITT Never screened for eligibility

Pre-ITT Refused before signing consent

Pre-ITT Ineligible

Pre-ITT Withdrew

Pre-ITT Withdrawn by PI

Pre-ITT Pending

Pre-ITT LTFU at Intake

Pre-ITT LTFU at T/A 1

ITT Ongoing

ITT Withdrew

ITT Withdrawn by PI

ITT LTFU at T/A 2

ITT LTFU at T/A 3

ITT LTFU at T/A 4

ITT LTFU at T/A 5

ITT Finished

T/A 1 Status:

Achieved

Scheduled

Reschedule Pending

Missed

Withdrew

Withdrawn by PI

Partial visit achieved

Achieved

- iv. All other milestone options can be found in the dropdown menu – refer to the Milestoning SOP if you have questions about what status to select
2. Complete the sections on “Side Effects and AEs” as well as “Ad Hoc AE”
 - a. Follow the SOP for Handling Participant Side Effects to determine if there is anything that needs to be reported to the study physician
3. Save “Complete” and exit the record
4. For info on “Payment” refer to page 43 in the SOP for Intake Visit

Care Pack 2

1. Finalize the contents of Care Pack 2
2. Take a photo of the full open Care Pack 2 and upload this to REDCap in the T/A 1 Record Form
3. Prep the package to be shipped with the following included:
 - a. 1 box of 28 patches
 - i. If PPT smokes 11 or more cigarettes per day they will receive 21 mg patches
 - ii. If PPT smokes 10 or fewer cigarettes per day they will receive 14 mg patches
 - b. 1 box of 216 2 mg lozenges PLUS 6 sleeves of 12 lozenges each for a total of 288 lozenges
4. Grab a blue poly bubble mailer and pack the contents securely inside, taping over the top flap to make sure the seal is secure
5. Write the PPT's name and mailing address onto a blank address sticker and place this on the outside center of the package
6. Place a UB RISE return address sticker at the top left
7. Update the Post T/A 1 Record Form in REDCap with the photo of the sealed Care Pack package
8. Inform the project coordinator you have a package that needs to be mailed so they can print out a Campus Mail form
 - a. Tape Campus Mail form to front of package, take to D1EF 114, and put in the RISE outgoing mail spot
9. If not done already, update the RISE Inventory + Tracking spreadsheet with the PPT's ID, date of distribution, and RA initials in the row of the iCO device being assigned to this PPT

REVISION HISTORY		
Date	Staff member	Brief description of revision(s)
04/02/2026	CGD	Updated for website
2/26/26	AH	Copied over edits from T/A 1 after meeting with CeCe, fixed formatting for TLFB setup appendix
2/19/26	AH	Accepted edits, updated scripts to match previous visit SOPs + REDCap
11/06/2025	MKP	Updated scripts & procedure throughout document to match current RISE protocol