

# **RISE**

## **SOP for Running Treatment and Assessment Visit 2**

**Author(s): C. Duerr & A. Hassan**

**Original RISE Date: 2025.03.26**

**Most Recent Updates: 2.27.2026**

**Purpose:**

**This SOP describes the procedures for running in-person and remote Treatment and Assessment (T/A) Visit 2 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 2

### Preparations for In-Person T/A Visit 2

1. Preparations should be done about 30 minutes prior to your scheduled T/A 2 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. 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)

Invitation status: **Survey options** ▼

Editing existing Record ID **198-1030**.

**Event: Intake**

|                  |          |
|------------------|----------|
| <b>Record ID</b> | 198-1030 |
|------------------|----------|

iii. Select “Open survey”

Invitation status: **Survey options** ▼

Editing existing Record ID **198-1030**.

**Event: Intake**

|                                                       |          |
|-------------------------------------------------------|----------|
| <b>Record ID</b>                                      | 198-1030 |
| <b>Cigarettes</b>                                     |          |
| <b>What brand of cigarettes do you usually smoke?</b> |          |

\* must provide value

Open survey  
 Log out + Open survey  
 Compose survey invitation  
 Survey Access Code + QR Code  
 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 V2" 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 2 happens exactly one week after T/A 1, 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 2 Record Form and use it as a checklist and procedure guide as you proceed with the visit

### **Running In-Person T/A 2 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 session 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 session; 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 you have NOT already met them, say: **“Are you [PPT name]? My name is [Name] and I will be working with you during your time in this study. It’s very nice to meet you. Please follow me.”**
5. Go to the room you’ve reserved for your T/A 2 visit:
  - a. Have the PPT sit in the chair facing the desktop computer
  - b. You can sit in the other chair

### **Check-in About Target Quit Day**

1. We are doing this first to show that the participant’s experience is important to us
2. Remember that today is the day the PPT picked to quit smoking, and they could be experiencing a range of emotions
3. Your role is to support them but not counsel them; you can validate that what they are attempting to do is hard and gently refer them to resources in their Quit Kit when needed
4. Start with - **“Today is your quit smoking day. People can experience a variety of emotions on their quit day. How are things going for you today?”**
5. If they say they put on their patch in the morning, are using lozenges, and have not smoked today: say **“That’s great! Keep up the good work. And remember to continue using the patches and lozenges as instructed to improve your chances of staying quit for the long term.”**; then move on to the next topic
6. Other example PPT responses:
  - a. They say they are struggling with quitting: say **“That’s a common challenge people face. It might help to look back at your Quit Kit and explore the resources there.”**
  - b. They say they intended to quit today but something stressful happened and they grabbed a cigarette: say **“That sounds really challenging. I would recommend you review the Quit Kit to plan how best to get back on track.”**
  - c. They are struggling with cravings or withdrawal: say **“Your Quit Kit has information and tips for dealing with that. But one of the most important things is to continue using your patches every day and using the lozenges when you feel a cigarette craving coming on.”**
  - d. They have a slip or a lapse: say **“Lots of people have a hard time quitting smoking but don’t let that stop you! This is a good time to go back to your Quit Kit for ideas on how to successfully handle these things.”**

### **Visit Overview**

1. Review with PPT what will be happening at the T/A 2 Visit, say: **“Now I’m going to ask you questions about your use of nicotine and other tobacco products, as well as about any changes to the medications you take. You will also complete surveys and do a breath sample. Do you have any questions for me?”**
  - 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 2 Record Form

- b. After answering any questions the PPT has, update the T/A 2 Record Form

### **Administer TLFB**

1. Navigate to “TLFB Setup” on your laptop
2. At T/A 2, we are asking about cigarettes, e-cigarettes, Nicotine Replacement Therapy patches, Nicotine Replacement Therapy lozenges, 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. After TLFB Setup is complete, 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 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, please let me know if you have any questions as you go through.”**
  - 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. Quit Kit survey [created for the RISE study to determine if PPTs used the Kit and if so, what parts were most helpful]
  - a. 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]

### **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
  - b. After gathering more information about the symptoms reported by the PPT, answer the two questions that appear below the text box
    - i. Verify their smoking status based on TLFB completed earlier
    - ii. Since this is the second T/A visit – Target Quit Date - you know that the answer to the next question should be “Yes”, ask PPT to confirm
  - c. You will need to send an email to send to the study physician, et al, after the visit
  - d. 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. Collect breath CO according to the instructions in the REDCap form
  - a. 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.”**
  - b. 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
  - c. If a participant has a reading >60, please consult with the PI or coordinator after the visit
2. Record the reading in the T/A 2 Breath CO Form
3. Save the form as “Complete”

## **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:
  - a. Of date and time of next visit
  - b. To have their remaining NRT medication on hand for their next visit
3. Thank PPT for their time today and end the visit
4. Complete final fields in T/A 2 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

## **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 session are returned to their proper location (e.g., CO monitor, TLFB Sheets).

## **Completing Post-T/A 2 Visit Record Form:**

1. Update Milestones
  - a. If the session went according to protocol and the PPT achieved the visit and wants to continue:
    - i. The overall Study Status will remain “ITT Ongoing” until the PPT finishes the study UNLESS the PPT withdraws or is withdrawn
    - ii. Change the T/A 2 visit status to “Achieved”

- iii. Update the “Date of most recent update to T/A 2 Status” to the date the T/A 2 was completed and add any notes about what occurred during the session, if applicable
  - iv. All other 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 2 Visit

### Preparations for Remote T/A 2 Visit

#### 1. Zoom meeting link

- a. On the morning of the visit, schedule a meeting for the established T/A 2 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      | <input type="text" value="RISE1212 T/A 1"/>                                                                                                          |                                    |                                 |
|              | <a href="#">+ Add Description</a>                                                                                                                    |                                    |                                 |
| When         | <input type="text" value="02/26/2026"/>                                                                                                              | <input type="text" value="3:00"/>  | <input type="text" value="PM"/> |
| Duration     | <input type="text" value="1"/> hr                                                                                                                    | <input type="text" value="0"/> min |                                 |
| Time Zone    | <input type="text" value="(GMT-5:00) Eastern Time (US and Canada)"/>                                                                                 |                                    |                                 |
|              | <input type="checkbox"/> Recurring meeting                                                                                                           |                                    |                                 |
| Invitees     | <input type="text" value="Enter user names or email addresses"/>                                                                                     |                                    |                                 |
| Registration | <input type="checkbox"/> Required                                                                                                                    |                                    |                                 |
| Meeting ID   | <input checked="" type="radio"/> Generate Automatically <input type="radio"/> Personal Meeting ID 583 805 6475                                       |                                    |                                 |
| Template     | <input type="text" value="Select a template"/>                                                                                                       |                                    |                                 |
| Whiteboard ⓘ | <input type="button" value="Add Whiteboard"/>                                                                                                        |                                    |                                 |
| Docs         | <input type="button" value="Add Docs"/>                                                                                                              |                                    |                                 |
| Security     | <input type="checkbox"/> Passcode<br>Only users who have the invite link or passcode can join the meeting                                            |                                    |                                 |
|              | <input checked="" type="checkbox"/> Waiting Room<br>Only users admitted by the host can join the meeting                                             |                                    |                                 |
|              | <input checked="" type="radio"/> Follow Zoom web portal setting<br><input type="radio"/> Select who should go into the waiting room for this meeting |                                    |                                 |
|              | <input type="checkbox"/> Require authentication to join                                                                                              |                                    |                                 |

|                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AI Companion                  | <b>AI Companion</b><br><input type="checkbox"/> Automatically start AI Companion ⓘ<br><input type="checkbox"/> Automatically start meeting questions<br><input type="checkbox"/> Automatically start meeting summary<br><br><b>Meeting summary template</b><br><div style="border: 1px solid #ccc; padding: 2px; display: inline-block;">General template ▼</div><br><a href="#">Change default summary template ↗</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Video                         | Host <input checked="" type="radio"/> on <input type="radio"/> off<br>Participant <input checked="" type="radio"/> on <input type="radio"/> off                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Audio                         | <input type="radio"/> Telephone <input type="radio"/> Computer Audio <input checked="" type="radio"/> Both<br>Dial from <b>United States</b> and other 3 countries ✎                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Options                       | <a href="#">Hide</a><br><input checked="" type="checkbox"/> Allow participants to join anytime<br><input type="checkbox"/> Q&A<br><input type="checkbox"/> Mute participants upon entry<br><input type="checkbox"/> Breakout Room pre-assign<br><input type="checkbox"/> Automatically record meeting<br><input type="checkbox"/> Enable focus mode when meeting starts<br><input type="checkbox"/> Enable additional data center regions for this meeting<br><input type="checkbox"/> Approve or block entry to users from specific regions/countries<br><br><b>Alternative Hosts</b><br><div style="border: 1px solid #ccc; padding: 2px; display: inline-block;">Enter user name or email addresses ▼</div><br>Allow the alternative host to manage this meeting's assets as co-owner after the meeting. ⓘ<br><input checked="" type="checkbox"/> Meeting summary<br><input checked="" type="checkbox"/> Meeting cloud recording<br><input checked="" type="checkbox"/> Add or edit polls |
| Student Life Tracking (pilot) | <div style="border: 1px solid #ccc; padding: 2px; display: inline-block;">Select ▼</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Interpretation                | <input type="checkbox"/> Enable language interpretation<br><input type="checkbox"/> 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 2 visit (just in case your PPT joins the Zoom call early)
  - a. Remote T/A visits should happen primarily in Rooms 304B, 307A, & 307B
3. Have the following available for the visit:
  - a. TLFB substance definition pdf file

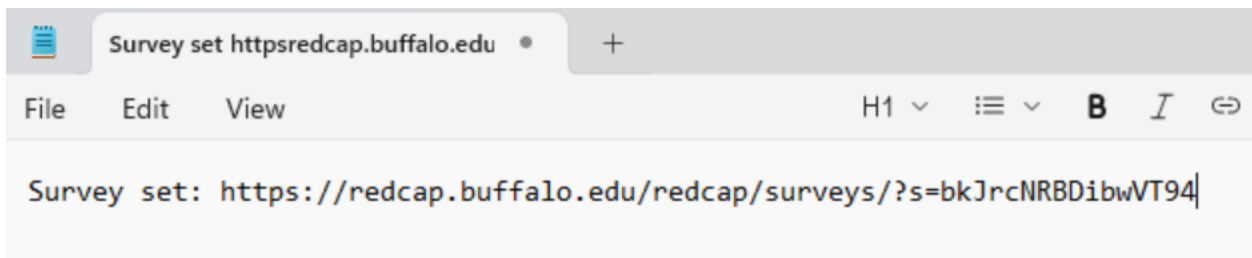
b. Instructions for the iCO monitor:

- 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 V2” 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 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 2 Record Form and use it as a checklist and procedure guide as you proceed with the visit

## **Running Remote T/A 2 Visit**

1. About 10 minutes prior to the scheduled appointment time, start the Zoom call
2. If the PPT hasn't joined or called by 10 minutes after the scheduled session 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 session; 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

## **Check-in about Target Quit Day**

1. We are doing this first to show that the participant's experience is important to us
2. Remember that today is the day the PPT picked to quit smoking, and they could be experiencing a range of emotions
3. Your role is to support them but not counsel them. You can validate that what they are attempting to do is hard and gently refer them to resources in their Quit Kit
4. Start with **"Today is your quit smoking day. People can experience a variety of emotions on their quit day. How are things going for you today?"**
5. If they say they put on their patch in the morning, are using lozenges, and have not smoked today: say **"That's great! Keep up the good work. And remember to continue using the patches and lozenges as instructed to improve your chances of staying quit for the long term."** Then move on to the next topic
6. Other example PPT responses:
  - a. They say they are struggling with quitting: say **"That's a common challenge people face. It might help to look back at your Quit Kit and explore the resources there."**

- b. They say they intended to quit today but something stressful happened and they grabbed a cigarette: say **“That sounds really challenging. I would recommend you review the Quit Kit to plan how best to get back on track.”**
- c. They are struggling with cravings or withdrawal: say **“Your Quit Kit has information and tips for dealing with that. But one of the most important things is to continue using your patches every day and using the lozenges when you feel a cigarette craving coming on.”**
- d. They have a slip or a lapse: say **“Lots of people have a hard time quitting smoking but don’t let that stop you! This is a good time to go back to your Quit Kit for ideas on how to successfully handle these things.”**

### **Visit Overview**

1. Review with PPT what will be happening at the T/A 2 Visit, say: **“Now I’m going to ask you questions about your use of nicotine and other tobacco products as well as about any medications you take. You will also complete surveys and do a breath sample. Do you have any questions for me?”**
  - 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 2 Record Form
  - b. After answering any questions the PPT has, update the T/A 2 Record Form

### **Administer TLFB**

1. Navigate to “TLFB Setup” on your laptop
2. At T/A 2, we are asking about cigarettes, e-cigarettes, Nicotine Replacement Therapy patches, Nicotine Replacement Therapy lozenges, 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. After TLFB Setup is complete, 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
    - ii. Click “Updates were made in the Medications form”

- iii. 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,
  - a. **“There are several different surveys you will fill out. Please pay attention to any instructions that appear at the beginning of each one. While you go through these surveys, I will have my camera off but please send a message/let me know if you have a question.”** [Be sure to let the ppt know if you will be leaving the room/when you are back.]
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]

### **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
  - b. After gathering more information about the symptoms reported by the PPT, answer the two questions that appear below the text box
    - i. Verify their smoking status based on TLFB completed earlier
    - ii. Since this is the second T/A visit – Target Quit Date – you know that the answer to the next question should be “Yes”, ask PPT to confirm
  - c. You will need to send an email to send to the study physician, et al, after the visit
  - d. 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, **“Next I'll be collecting a breath sample from you. 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 **“Great! Do you remember the process?”**
  - a. If yes, say, **“Okay, you can go right ahead then. I'm here to help as needed.”**
  - b. If no, guide PPT through the collection steps using the instructions in the REDCap Breath CO Form
    - i. When you see that the PPT has their iCO device and instructions out, say **“You can also go ahead and log into your iCOquit account on your smartphone. Do you remember your username and password?”**
    - ii. If needed, look at the top of the Breath CO form OR in the Intake Record Form and remind PPT of their login information
3. 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

4. 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.”**
5. 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 participant has a reading >60, please consult with the PI/Coordinator
6. Record the reading in the T/A 2 Breath CO 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:
  - a. Of the date and time of next visit
  - b. To have their remaining NRT medication on hand for their next visit
3. Thank PPT for their time today and end the visit
4. Complete final fields in T/A 2 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

### **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. Ensure that all materials from the session are returned to their proper location (e.g., TLFB Sheets)

### **Completing Post-T/A 2 Visit Record Form:**

1. Update Milestones
  - a. If the session went according to protocol and the PPT achieved the visit and wants to continue:
    - i. The overall Study Status will remain “ITT Ongoing”
    - ii. Change the T/A 2 visit status to “Achieved”
    - iii. Update the “Date of most recent update to T/A 2 Status” to the date the T/A 2 was completed and add any notes about what occurred during the session, if applicable
    - iv. All other milestone options can be found in the dropdown menu – refer to the Milestones 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

| <b>REVISION HISTORY</b> |                     |                                                                                                |
|-------------------------|---------------------|------------------------------------------------------------------------------------------------|
| <b>Date</b>             | <b>Staff member</b> | <b>Brief description of revision(s)</b>                                                        |
| 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                 |