

RISE

SOP for UB Intake Visits

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Purpose:

This SOP describes the procedure for both in-person and remote Intake visits for the RISE study.

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✳ On Visit days:

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

Procedures for Running In-Person RISE Intake Visits

Preparation for In-Person Intake Visits

1. Preparations should be done about 30 minutes prior to your scheduled Intake visit (just in case your participant (PPT) arrives early)
2. Prepare PPT Room
 - a. In-person Intakes 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. Care Pack 1 - Quit Kit, US Bank payment card, iCO device + guide, and printed visit reminder sheet for both In-Person (IP) and Remote (R) visits
 - i. You don't yet know whether your PPT will be randomized to in-person (IP) or remote (R) visits, so have everything with you so you are prepared for either option
 1. IP Care Pack 1 = Quit Kit, US Bank payment card, IP visit reminder sheet
 2. R Care Pack 1 = Quit Kit, US Bank payment card, iCO device + guide, R visit reminder sheet
 - c. Printed referral sheets for 211 (in case they score high on the AUDIT or PHQ) and smoking cessation (in case they are ineligible)
 - d. Get the CO monitor from the left cabinet in Rm 308A
 - i. If the symbol below shows up on the screen, then the CO monitor needs to be calibrated; do the calibration if you have time, or switch to the other monitor if you don't have time right then; be sure to come back and calibrate after your visit using the "Covita Micro+™basic, baby, & pro Smokerlyzer Calibration Guide" downloaded from the Covita.net website



- ii. If the symbol below shows up on the screen, then the plastic mouthpiece (i.e., D-piece) needs to be changed; get one out of the left cabinet in Rm 308; Be sure to tell the coordinator when there is only one D-piece left in the cabinet so they can order more



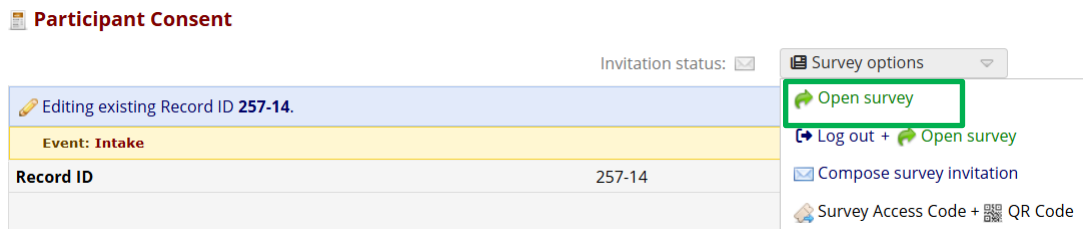
- e. Set the CO monitor and a wrapped plastic mouthpiece on the cabinet or table – be sure to keep the wrapping on the mouthpiece until the PPT is in the room so they can see you’re using a new mouthpiece

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 PPT facing consent form and survey sets
 - i. Open the “Participant Consent” form
 - ii. Click on “Survey options” in the upper right of the form



- iii. Select “Open survey”



- iv. After the survey opens in new window, make sure to leave the survey without saving changes in the original window
- v. Repeat this process for “Smoking History and Demographics” (1st Survey Set)
- vi. Repeat this process for “Phenx Health Literacy for Participant” (2nd Survey Set)
- vii. Minimize the windows for these survey sets and open the window for “Participant Consent”, then press F11 to make full screen and leave this page set up on the PPT’s computer

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. Set up TLFB
 - i. Under “Intake” 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”

6. Check the PPT’s name so you can greet them correctly when they arrive

7. Open the Intake Record Form and use it as a checklist and procedure guide as you proceed with the visit

Running In-Person Intake Visits

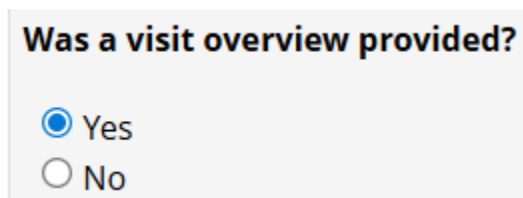
1. PPTs have been instructed to call the study line ...
 - a. ... after they've parked in either a clinic spot or the Diefendorf Lot (if they are driving)
 - b. ... OR when they arrive on the ground floor of Diefendorf Hall (if they took public transportation, walked, or were dropped off)
2. If the PPT 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 voice message (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 by 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, take a parking pass down to them and make sure they put it on the dashboard (if they drove), then escort the PPT up to the 3rd floor via the elevator
 - a. When you see the PPT (**IF they are 21 years or older**) ask them if they brought a pack with them – MAKE SURE NOBODY CAN OVERHEAR YOU ASKING THEM
4. Go to the room you've reserved for your Intake visit:
 - a. Have the PPT sit in the chair facing the desktop computer
 - b. You can sit in the other chair

Confirm PPT Cigarettes

1. Say: "**We asked that you have a pack of your usual brand of cigarettes available at this visit. Could you please show it to me?**"
2. If PPT **does** have a pack of cigarettes available:
 - a. Thank PPT for bringing them
 - b. Document the "Cigarette brand" and "Flavor" in the Record Form; any additional information (e.g., 100's, King size, etc.) can be noted in the "Cigarette Comments" box
 - c. Proceed with the visit overview
3. If PPT **does not** have a pack of cigarettes (even an empty pack):
 - a. Ask if they have one in their car
 - b. If they don't have one available, the visit needs to be rescheduled
 - c. Emphasize the importance of having their pack of cigarettes at the next visit, then work with the PPT to find a day/time to reschedule the visit to

Study Overview and Informed Consent

1. With REDCap opened up to the Intake Record Form, review with the PPT what will be happening at the Intake Visit. Say: **“Today we will be doing several things with you. First, we will have you read the consent form. We will answer any questions you have then you can sign the form if you are interested in participating in this study. Then, we will ask you questions about your use of nicotine products and about the medications you take. Finally, you will answer survey questions electronically and be asked to provide a breath sample.”**
 - 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 Intake Record Form
 - b. After answering any questions the PPT has, update the Intake Record Form



Was a visit overview provided?

Yes

No

- c. Say: **“As I just mentioned, I will first have you read the consent form on the device in front of you. Please read the form carefully and let me know if you have any questions. As you progress through the form, you will click boxes to view the next section. Once you have reached the bolded red letters saying, "wait for Research Assistant", wait there and do NOT check the box, just let me know that you've reached that point. At this point, I will ask if you have any questions about what you read, and then I will ask you some questions to make sure you fully understand your participation in this study. If you decide you'd like to participate, I will have you provide your signature on the form. Do you have any questions?”**
 - i. Sit in chair away from PPT and wait for them to read through the consent form
2. While they read, open the “Consent Overview” form on your computer
 - a. Once participant is at the “Wait for the Research Assistant” prompt, ask if they have any questions about the consent
 - i. Say: **“Now that you've had a chance to read through the full consent form, do you have any questions about what you read?”**
 - ii. If the participant has any questions, record them verbatim in the “Consent Overview” form as well as your answer to the question
3. Then, administer questions stated below:
 - a. Approximately how many weeks will your participation in this entire study last? **(This visit and the next 5 will be completed in 3-4 months.)**
 - b. Can you decide to not participate in this study at any point during your participation? **(YES)**
 - c. How long is each treatment and assessment visit? **(30-60 minutes)**

- d. How will you receive payment for participation in this study? (**Reloadable US Bank Visa Debit Card**)
 - e. What kind of nicotine replacement therapy will you receive in this study? (**Patches and lozenges**)
4. If any of the questions have been answered incorrectly, make sure to explain the answers and point the PPT back to the applicable section in the consent
- a. If you have doubts about the PPT’s comprehension of the consent form, please consult with the coordinator before proceeding. [For example, you can say to the PPT: **“I am going to pause here to check in with the study coordinator. I will be back in a few minutes. Please relax while I’m gone.”**]
5. After administering questions:
- a. Say: **“You can now check the box that says, “All questions have been answered.”**
6. Guide PPT through signing the consent form:
- a. Say: **“Below the “Signature Box for Capable Adult”, please read and answer the first question that asks if you still want to participate.”**
 - i. If PPT answers “No” they don’t want to participate, a box will pop up asking them to “Please explain why:”
 - ii. If PPT answers “Yes” they want to participate, say: **“Now, answer the next question that asks if you want a copy of the consent form emailed to you.”**
 - b. Say: **“Please enter your email if applicable, then your legal first and last name and provide your signature and the date.”**

The screenshot shows a digital consent form with the following fields and content:

- First Name:** * must provide value. Input field contains "Monica".
- Last Name:** * must provide value. Input field contains "Mary".
- Signature of Subject:** * must provide value. Contains a handwritten signature image and a file name "signature_2023-01-22_1935.png (0.01 MB)". Below the signature is a "Remove signature" button.
- Today's Date:** * must provide value. Input field contains "01-18-2023" with a calendar icon and "Today" button. The format "M-D-Y" is indicated.

At the bottom of the form is a "Next Page >>" button.

- i. After filling out that box, PPT should hit “Next Page>>”
- c. Say: **“Please scroll down to the bottom of the page (pdf) and carefully review that your information is correct, then check the box to certify this is true.”**

I certify that all of my information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

<< Previous Page Submit

i. PPT should click “Submit” and close the survey page

d. Say: **“Please give me a moment to check over everything and to add my signature to the consent.”**

i. Save the “Consent Overview” as “Unverified” so you can check over the PPT consent

ii. Open the “Participant Consent” form and ensure that the PPT’s signature and date are observable; if the signature and date don’t show up, have the PPT redo the consent form from the beginning (they can skip through and just check the boxes to move on since they already read the form once)

iii. **NOTE: AT THIS TIME, FILL OUT THE STAFF CONSENT FORM!!!**

7. Open the “Staff Consent” form

a. In the Consent form Version Date, enter the date on which the consent form was most recently updated. [Found at the top of page 1 of the consent form]

Title of research study: Remote vs. In-Person Study Evaluation (RISE T Smoking)
Version Date: 03/27/2025
Investigators: Larry W. Hawk, Jr., PhD, and Martin Mahoney, MD, PhD

b. Save as “Complete” once all fields were completed

8. Go back to the “Consent Overview” form and answer the last 3 questions, then save as “Complete”

9. Go to “Intake Record Form” and answer questions under the “Consent” section

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 phone screen?”**

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 TLFB

Administer TLFB

1. Navigate to “TLFB Setup” on your laptop

2. At Intake, 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 [Appendix A](#)
4. Save TLFB form as “Complete”

Survey Set #1

1. Set up survey set #1 on the PPT computer by maximizing the earlier minimized “Smoking History and Demographics” 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’m going to go into the other room to prepare your care pack. Please let me know if you have any questions as you go through.”**
3. The first set of surveys includes:
 - a. Smoking History & Demographics [compiled primarily from PhenX toolkit; data will allow us to characterize our research sample]
 - b. FTCD [The Fagerström Test for Cigarette Dependence) is a six-item survey that measures cigarette dependence]
 - c. PPT Cost Measure [created for the RISE study; PPT survey of time, productivity loss, transportation cost and any other forgone resources for participation]
 - d. Perceived Stress Scale [helps to understand how different situations affect PPT’s feelings and perceived stress]
 - e. 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. 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
 - a. If there is anything to review with the coordinator, do that now
 - b. You can follow the PPT’s survey progress on REDCap
5. Ensure that the “Intake Record Form” is fully updated during this downtime

Preparing Payment Card

IMPORTANT NOTE – PREPARE PAYMENT CARD WHILE PPT IS WORKING ON SURVEYS

1. Write PPT ID# and date on the right side between the blue banner and the QR code on the payment card envelope (see example below)
2. Take a photo of the envelope
3. Save the photo using the PPT ID (e.g., RISE 198-1356 Payment Card) as the name of the photo
4. Upload the photo to REDCap in the Intake Record Form



Side Effect Tracking

1. After PPT completes Survey Set 1, open the Side Effect Tracking form (see below)
2. Side effects that have to be reported will be listed after the section "Code 3 Side Effect Endorsements"; the first side effect is usually **bolded** and highlighted in **GREEN** and subsequent side effects are bolded and appear below that
 - a. If no side effects are listed in bold, select "No" in the STAFF field, save the form as "Complete", and move on to Medications
3. If side effects are listed **in bold**, select "Yes" in the appropriate STAFF field ("Are there any symptoms listed above for the current visit?")
 - a. You can quickly see the extent of severity reported, regardless of symptom, by looking at the field "Max Side Effect Intensity reported by patient was:" at the top of the form
 - i. If this field is blank, the PPT reported no side effects
 - b. ANY side effect whose severity the PPT marks as "No normal activities are possible" will be categorized as a Code 3 Side Effect Endorsement
 - i. These codes must be reported to the study physician, PI, and study coordinator immediately after the visit
 - ii. The study physician must reply with a plan of action within 24 hours
 - c. Certain side effects (listed in the REDCap form) will be categorized as a Code 2 Side Effect Endorsement when the PPT marks their severity as "Interferes with some activities". These side effects are potentially related to nicotine medications
 - i. These codes must be reported to the study physician, PI, and study coordinator immediately after the visit
 - ii. The study physician must reply with a plan of action within 48 hours
 - d. Never interact with the radio buttons next to a bolded side effect. These are meant solely for Dr. Mahoney / Dr. Hawk

Max Side Effect Intensity reported by patient was:	<input type="radio"/> 1 <input checked="" type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <small>If a Code 3, this is a possible SAE and must be reviewed by the HCP immediately.</small>	View equation	
Code 2 Side Effect Endorsements (symptom interferes with some daily activities) Code 2 events limited to: -cardiac symptoms (irregular heartbeat or palpitations, increased heart rate, chest pain), -dermatologic symptoms (skin swelling, skin rash or redness (not sunburn)), -depressed mood, -specific gastrointestinal symptoms (vomiting, indigestion), and -specific sleep problems (insomnia, abnormal dreams)			
Code 3 Side Effect Endorsements (no normal activities are possible) -any symptom			
Depressed Mood In: and interferes with some activities V1: _____ V2: _____ V3: _____ V4: _____ V5: _____			<input checked="" type="radio"/> None <input type="radio"/> Does not interfere with daily activities <input type="radio"/> Interferes with some activities <input type="radio"/> No normal activities are possible <small>reset</small> The HCP can recode the symptom using the radio buttons above
Insomnia In: and interferes with some activities V1: _____ V2: _____ V3: _____ V4: _____ V5: _____			<input type="radio"/> None <input type="radio"/> Does not interfere with daily activities <input type="radio"/> Interferes with some activities <input type="radio"/> No normal activities are possible <small>reset</small> The HCP can recode the symptom using the radio buttons above
STAFF: Are there any symptoms listed above for the current visit?			<input type="radio"/> No <input type="radio"/> Yes

4. Then, go through each symptom indicated and ask the PPT the questions that appear above the box in the Side Effect Tracking form, and record their answers in the text field provided:
 - a. **“You just indicated that you’re having moderate depressed mood symptoms. What would you attribute that to?”, “How long have you been experiencing the symptom?”, “Anything done to treat this symptom?”, “What normal daily activities have been impacted and how?”**
 - b. After recording their answers for each symptom, list the date and your initials in the text field.
 - c. See visual example below:

Depressed Mood
In: and interferes with some activities
 V1: _____
 V2: _____
 V3: _____
 V4: _____
 V5: _____

None
 Does not interfere with daily activities
 Interferes with some activities
 No normal activities are possible

The HCP can recode the symptom using the radio buttons above reset

Insomnia
In: and interferes with some activities
 V1: _____
 V2: _____
 V3: _____
 V4: _____
 V5: _____

None
 Does not interfere with daily activities
 Interferes with some activities
 No normal activities are possible

The HCP can recode the symptom using the radio buttons above reset

STAFF: Are there any symptoms listed above for the current visit?
 * must provide value

No
 Yes

If NO, submit the form as complete. If YES, save as unverified and send the link to HCP/PI per the EvarQuit SE and SAE manual. reset

STAFF: You just indicated that you're having [moderate/severe... symptoms noted above].

What would you attribute this to? How long have you been experiencing the symptom? Anything done to treat this symptom? What normal daily activities have been impacted and how?

Depressed Mood: Attributed to recent financial struggles, rumination. Experiencing current episode for about a week. PPT is going for walks and journaling for tx. Social activities mainly affected, PPT has low motivation to engage with others. "My social battery, is just low right now".

Insomnia: Attributed to stress related to job and familial problems. Experiencing sx for about 3 days. PPT is taking nightly melatonin for tx. Activity affected globally, "everything is harder when I'm tired."

AH 2/26/26 @15:45

Please add your name, the date, and time once you complete this field. Save the instrument as unverified after you are done. Then email Dr. Mahoney to inform him that this participant has a SEC/SAE to be reviewed.

5. After gathering more information about the symptoms reported by the PPT, answer the two questions that appear below the text box (see below)
 - a. Verify their smoking status based on TLFB completed earlier
 - b. Since this is an Intake, you know that the PPT is not taking study medication so the answer to the next question should be "No"

STAFF: Is participant currently smoking?

Note: For the fields below, a value of 1 indicates that cigarettes have been used in the past 7 days of the visit, according to the TLFB Set-Up form

Intake: Check if used Yes
 No

T/A 1: _____
T/A 2: _____
T/A 3: _____
T/A 4: _____
T/A 5: _____

STAFF: Is participant currently taking study medication?

Note: For the fields below, a value of 1 indicates that NRT patches have been used in the past 7 days, according to the TLFB Set-Up form

Intake: _____
T/A 1: _____
T/A 2: _____
T/A 3: _____
T/A 4: _____
T/A 5: _____

Yes
 No

Note: For the fields below, a value of 1 indicates that NRT lozenges have been used in the past 7 days, according to the TLFB Set-Up form

Intake: _____
T/A 1: _____
T/A 2: _____
T/A 3: _____
T/A 4: _____
T/A 5: _____

6. After the visit, you will need to email a link to the “Side Effect Tracking” form to the study physician/PI/study coordinator (See “SOP for Handling Participant Side Effects” for details)

Medications

1. Ask about any allergies to medications
 - a. If the answer is “Yes”, a text box pops up where the medication and the reaction they have can be documented
2. Next, say: “**Do you use or take any medications prescribed by a Health Care Provider on a regular basis?**”
3. If “No”, the survey ends and you can move on to the next task
4. If “Yes”, work with the participant to build a list of their prescription medications in REDCap
 - a. Start typing the medication name in the box and the ontology will open so you can select the appropriate one
 - b. Note whether the information is from direct observation of the medication packaging, a picture, a list OR from PPT report

- c. If PPT cannot remember exact date they started a medication:
 - i. Ask about how many years ago they started and what time of year. The aim is to be as accurate as possible. However, if a PPT is struggling to remember, focus on just estimating the year and month
 - ii. If only have year, use July 15th
 - iii. If have year and month, use 15th of the month
 - iv. If PPT does not know the purpose of a medication they take, you can Google it and confirm the usage with the PPT
 - v. If PPT stopped the medication in the past two weeks, record the stop date
5. Save form as “Unverified” as a helpful reminder to review this record at each subsequent visit
 - a. This form in REDCap should only be saved as “Complete” when the PPT has ended their participation

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 or regularly 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 project coordinator after the visit
2. Record the reading in the Intake Breath CO form
3. Save form as “Complete”

Px270401 Phenx Health Literacy

1. Set up the “Phenx Health Literacy for Participant” form (survey set #2) on the PPT computer by maximizing the earlier minimized window
2. Open “Px270401 Phenx Health Literacy” on your computer as a data entry form
3. Ensure that the PPT says the top word and you then say: **“Between [bottom word one] and [bottom word two], which is most similar to the top word?”**
 - a. If PPT is picking up on the process and wants to read the top word then immediately give their answer, they are allowed to do that – you do not have to read the two answer choices
4. As the PPT provides their verbal responses, you will record their answers in the “Px270401 Phenx Health Literacy” version of the form
 - a. The PPT will not be asked to enter any data on their version of the survey
 - b. PPT will just need to select “Next Page” after giving each response until the survey is completed

5. When done with the word sets, ask final question “**How confident are you filling out medical forms by yourself?**” and record answer in REDCap
6. Save “Px270401 Phenx Health Literacy” as “Complete”

Survey Set #2

1. Let PPT know they can continue by clicking “Submit” to begin second survey set
2. Also let the PPT know:
 - a. The first two questionnaires (CPQ-12 and MDPQ-16) have similar questions, but the first questionnaire is asking about *computers* and the second one is asking about *mobile devices* (like cell phones and tablets)
 - b. Emphasize that the NIDA (the final survey about drug use), is asking about two things:
 - i. Medications you have taken for reasons or in doses OTHER THAN PRESCRIBED by a medical professional
 - ii. And illicit or illegal drugs you have taken
3. 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.**”
4. The second set of surveys includes:
 - a. CPQ-12 - Computer Proficiency Questionnaire (The Computer Proficiency Questionnaire (CPQ) is a survey that measures someone's ability to use a computer to accomplish different tasks)
 - b. MDPQ-16 (The Mobile Device Proficiency Questionnaire is a 16-question survey that evaluates a person's ability to use a mobile device)
 - c. Trust Medical Care Research 4 Item (Trust in medical researchers is a measurable single-factor construct including trust in safety, researcher fidelity, and honesty)
 - d. Discrimination in Health Care (The DHC scale is a 7-item instrument that assesses a person's prior experiences of mistreatment while getting health care that were attributed to race, ancestry, national origin, sex, disability, or age)
 - e. AUDIT (The Alcohol Use Disorders Identification Test (AUDIT) is a 10-item screening tool developed by the World Health Organization (WHO) to assess alcohol consumption, drinking behaviors, and alcohol-related problems)
 - f. PHQ 8 (Patient Health Questionnaire is one of the self-reported questionnaires most frequently used worldwide for the screening and severity assessment of depression)
 - g. NIDA QS1 (The NIDA Quick Screen is designed to assess high risk involvement with illicit or nonmedical prescription drugs)
5. Once again, during this time, 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
 - a. If there is anything to review with the coordinator, do that now
 - b. You can follow the PPT's survey progress on REDCap
6. Ensure that the “Intake Record Form” is fully updated during this downtime

RA Task During Survey Set 2

1. As stated before, you don't yet know whether your PPT will be randomized to in-person (IP) or remote (R) visits, so have everything organized so you can take the correct Care Pack 1 contents with you when you return to the PPT room
 - a. IP Care Pack 1 = Quit Kit, US Bank payment card, IP visit reminder sheet
 - b. R Care Pack 1 = Quit Kit, US Bank payment card, iCO device + guide, R visit reminder sheet

Intake Eligibility Summary

1. After Survey Set #2 is complete, go to the "Intake Eligibility Summary" to determine if the PPT is eligible to continue in the study (0 = Eligible; 1 = Ineligible)
2. For this study, there are two eligibility criteria assessed at Intake:
 - a. Ability/willingness to provide informed consent, follow directions, and respond appropriately – this is based on RA experience with PPT during consent and during the visit
 - b. NIDA QS1 – the following will result in the PPT being deemed Ineligible
 - i. A score of 27+ for Cannabis, Cocaine, Prescription Stimulants, Methamphetamine, Inhalants, Sedatives/Sleeping Pills, Street Opioids, Prescribed Opioids, Hallucinogens
 - ii. If someone scores over one or more cutoffs for the NIDA, they are deemed ineligible AND we will offer them referrals at the end of the visit
 - c. Although the AUDIT and PHQ 8 are not exclusionary for this study, we will offer referral information at the end of the visit if the PPT's score exceeds the following cutoffs:
 - i. AUDIT score >13 for females and >15 for males
 - ii. PHQ 8 score >11
3. Complete the "Randomization 2 at Intake" form in REDCap
 - a. Go to the form and click "Randomize"
 - b. Save "Intake Eligibility Summary" as "Complete"
4. IF **INELIGIBLE**:
 - a. Say "**Because this is a research study, we are looking for people with very particular characteristics. Unfortunately, it looks like you are ineligible for this study. However, we really do appreciate your time today. You will receive \$30 for your time.**"
 - i. Give referrals if indicated
 - ii. IF the PPT asks why they are ineligible, you may tell them
 1. If we feel they couldn't consent, say: "**It is our responsibility to follow good practice guidelines set by federal policy, and when reviewing the consent form, we were unable to confirm that you completely understood what the consent form was describing. This is standard eligibility criteria across all research studies currently enrolling participants.**"
 2. If NIDA is too high, say: "**Your degree of use of X drug is above the set limits for this study.**"
 3. If inappropriate behavior, giving careless answers, or unable to follow directions, say: "**We want to enroll people who are going to take care and**

give accurate and thoughtful answers, and we have found that not to be the case.”

5. IF ELIGIBLE:

- a. Once you have confirmed eligibility:
 - i. Complete randomization
 - ii. Finalize contents of Care Pack 1 depending on whether the PPT was randomized to IP or R T/A visits
 - iii. Return to PPT room
- b. Say: **“Thank you for providing consent and answering those questions. You are eligible to continue in the study! Like we did at the end of the phone screen, a computer determines whether your five treatment and assessment visits take place in-person or remotely, like the flip of a coin. I completed this just now, and the computer determined that the rest of your visits in this study will all be [INSERT IN-PERSON or REMOTE here].”**
- c. Ask if the PPT has any questions about this; answer them accordingly before moving forward
- d. Proceed to “Scheduling Treatment and Assessment (T/A) Visits”

Scheduling Treatment and Assessment (T/A) Visits

1. Open the “T/A Visit Scheduler” and proceed to schedule all 5 T/A visits
 - a. Say: **“Let’s get your visits scheduled. We will start with the date when you want to quit smoking [this is known as the Target Quit Date (TQD)].”**
 - i. The TQD, also known as T/A visit 2, should be between 2 and 5 weeks away from Intake date
 - ii. Once PPT chooses TQD, tell them that we will keep their visits on the same day of the week and at the same time as T/A 2, whenever possible
 - iii. Then schedule the rest of the visits as follows:
 1. T/A visit 1 will be one week BEFORE T/A visit 2 (TQD)
 2. T/A visit 2 will be *the Target Quit Date*
 3. T/A visit 3 will be 2 weeks AFTER T/A visit 2
 4. T/A visit 4 will be 6 weeks AFTER T/A visit 3
 5. T/A visit 5 will be 4 weeks AFTER T/A visit 4
2. Once all visits are scheduled, fill out the printed visit reminder form and include it in the PPT’s Care Pack 1

Review Care Pack 1

- * After scheduling T/A visits, IF PPT was randomized to remote T/A visits, go into the adjacent room and take a picture of the entire Care Pack 1, including the completed visit reminder form

FOR IN-PERSON INTAKE randomized to IN-PERSON T/A VISITS

1. Say **“I’m now going to review your first Care Pack.”**
2. Take out Care Pack 1 and review contents:

- a. Payment Card
 - i. Say as you show the payment card to the PPT: **“Here is the US Bank Visa card onto which we will be loading your study payments. You should register the card and set up a PIN if you want to use an ATM. Payments should appear 1-2 BUSINESS DAYS after your visit. Our study staff will add the payment to your card then the US Bank Card administrator at UB will have to approve the payment before it will show up on your card. If you have questions about your payment, please call us on our study line at 716-829-2323.”**
 - b. Quit Kit
 - i. Say as you hand Quit Kit to PPT: **“This booklet reviews some of the best resources out there for quitting smoking and includes a section that walks you through some of the most important parts of a good quit plan. We will talk more about this Kit at your first Treatment and Assessment visit. You are welcome to review the contents of the booklet prior to your next visit, if you are interested.”**
3. Place the payment card and the Visit Reminder handout into the Quit Kit folder and hand everything over to the PPT
 4. Remind PPT of next visit date and time before showing them to the elevators
 - a. Proceed to Post-Visit tasks

FOR IN-PERSON INTAKE randomized to **REMOTE T/A VISITS**

1. First, review the PPT’s familiarity with using video-conferencing platforms, namely Zoom
 - a. Depending on the PPT’s comfort level and past use, help them install the app to their phone and/or make a plan to have the PPT complete their visits from a computer or laptop
2. Take out Care Pack 1 and review contents:
 - a. iCOquit Smokerlyzer and Guide
 - i. Say as you hand the iCOquit Smokerlyzer to PPT: **“This device will allow us to measure the amount of carbon monoxide in your lungs at each visit. You will need to download an app onto your smartphone. To make sure we are all set for the next visit, we will do that now.”**
 1. Depending on the PPT’s OS, instruct them to open the App Store or Google Play and search for “iCOquit”
 2. Select install, and once it has been installed, ask them to open the app
 - a. Follow all procedures to register an account for the iCO
 - b. The PPT should use the email that they provided to us in their Contact Info
 - c. We will provide the password (e.g. RISE198-XXXX)
 3. PPT will have to “verify” the account via a link sent to their email (if they don’t see the link, ask them to check their Junk/Spam folder)
 4. Once you have confirmed that they can log in successfully, write the email address and password used to register on the iCO guide handout

5. If time permits:
 - a. Point out the main features that will be used for the study, especially “New Breath Test”
 - b. Have the ppt turn on their Bluetooth and connect the device to their smartphone to ensure functionality
6. For more details and/or troubleshooting tips, refer to the RISE_iCO SOP

b. Payment Card

- i. Say as you show the payment card to the PPT: **“Here is the US Bank Visa card onto which we will be loading your study payments. You should register the card and set up a PIN if you want to use an ATM. Payments should appear 1-2 BUSINESS DAYS after your visit. Our study staff will add the payment to your card then the US Bank Card administrator at UB will have to approve the payment before it will show up on your card. If you have questions about your payment, please call us on our study line at 716-829-2323.”**

c. Quit Kit

- i. Say as you hand Quit Kit to PPT: **“This booklet reviews some of the best resources out there for quitting smoking and includes a section that walks you through some of the most important parts of a good quit plan. We will talk more about this Kit at your first Treatment and Assessment visit. You are welcome to review the contents of the booklet prior to your next visit, if you are interested.”**

- d. Place the payment card, Visit Reminder handout, and iCO guide handout into the Quit Kit folder and hand everything over to the PPT

3. Remind PPT of next visit date and time before showing them to the elevators

4. Proceed to Post-Visit tasks

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

Care Pack

1. If PPT was assigned to Remote T/A visits: 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

Serial Number	Pre-calibrated by COVita?	Test Result (expected = 20+/- 3 ppm)	Date Tested	Tested	Distributed By	Date of Distribution	Record ID	Visit	R or IP visit
CQ10009438	Yes				CGD	6/9/2025	198-1210	Intake	R

Cleaning the Visit Room:

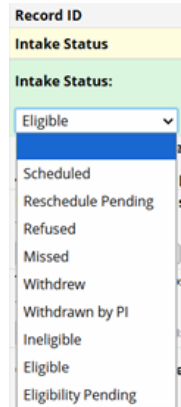
1. Log out of the desktop computer
2. Wipe down the keyboard, mouse, computer desk, and chair with 70% isopropyl alcohol solution
3. Sanitize the CO Monitor with a Covita wipe

- 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, unused Care Pack materials)

Completing Post-Intake Record Form:

1. Update Milestones

- a. If the visit went according to protocol and PPT is eligible to continue:
 - i. The overall Study Status should remain as “Pre-ITT Pending”
 - ii. Change the Intake Visit Status to “Eligible”
 - iii. Update the “Date of most recent update to Intake Status” to the date the Intake was completed and add any notes about what occurred during the visit, if applicable
 - iv. Update all T/A Visit Statuses to “Scheduled” and input Date and Time of each visit, adding that this is the “1st time scheduling”; be sure to note your initials and the current date at the bottom of each Status form
- b. Add all scheduled visits to the Google calendar



T/A 1 Status:

Achieved

45 Day Deadline to complete T/A 1 based on intake date:

07-31-2025 [View equation](#)

Date and Time of T/A 1 scheduled during Intake:
02-26-2025 at 12:00

Date of T/A 1 from most recent scheduling:
* must provide value
06-16-2025 [Today](#) M-D-Y

Time of T/A 1 from most recent scheduling:
* must provide value
15:37 [Now](#) H:M

Current T/A 1 schedule number:

1st time scheduling
 1st time rescheduling
 2nd time rescheduling (or beyond)

Actual Date & Time of T/A 1 from T/A 1 Record Form:
02-19-2025 at 11:45

T/A 1 Status Notes:

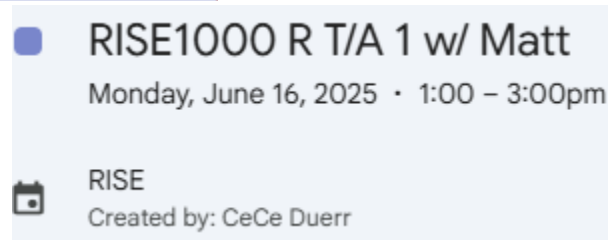
Date of most recent update to T/A 1 Status:

02-19-2025 [Today](#) M-D-Y

Staff username:

CGD

RISE1000 R T/A 1 w/
Matt
1 – 3pm

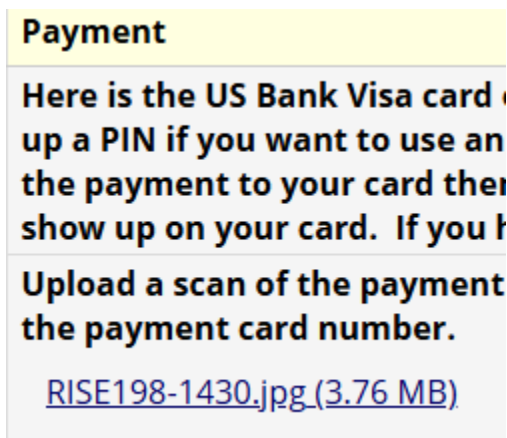


- 2. If the PPT was deemed Ineligible, voluntarily Withdrew, or Refused before signing consent:

- a. Update both the Visit Status and Study Status forms to indicate this outcome and add a comment explaining why they were deemed IE or the reason that the PPT did not complete the visit
 - b. The Study Status should be marked as the “Pre-ITT” version of whatever outcome occurred
 - c. All future T/A Visit Status Forms will be left blank
3. Side Effects and AEs
- a. (If applicable) See SOP for Handling Participants Side Effects for instructions on emailing the study physician, principal investigator, and project coordinator
 - b. Insert the date and time the email was sent out
4. Ad Hoc AE form
- a. (If applicable) See SOP for Handling Participants Side Effects for instructions on emailing the study physician, principal investigator, and project coordinator

Payment

1. Participant payments are made in the US Bank Prepaid Administrative Website by the study coordinator or their designee
2. Log in to the US Bank website
3. Payment cards must be registered after being distributed at Intake
 - a. Click on “Cardholders”
 - b. Click on “Register New Cardholder”
 - c. Go to Intake Record form → “Payment” section " → click on the file to get the card number



- d. Enter the 10-digit Card ID
 - e. Click “Find Card”
 - f. Enter first and last name in the “Cardholder Information” section
 - g. Enter address in “Account Contact Information” section
 - h. Enter ONLY birthdate in “Personal Information” section
 - i. At the bottom of the form, enter the grant number and select the state from the drop-down list
4. To make a payment:

- a. Click on “View Cardholder Details” → “Account Management” → “Funds Transfer”
- b. Make sure “Transfer to Cardholder” is checked

Please select your Transfer Option

Transfer to Cardholder Transfer from Cardholder

- c. Enter the following in the “Memo for Selected Card (optional):” box: **RISE IN on [date]**
 - d. Enter “Transfer amount”
5. Click “Submit Request”

Procedures for Running Remote RISE Intake Visits

Preparation for Remote Intake Visits

1. Zoom meeting link:

- a. On the morning of the visit, schedule a meeting for the established Intake 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

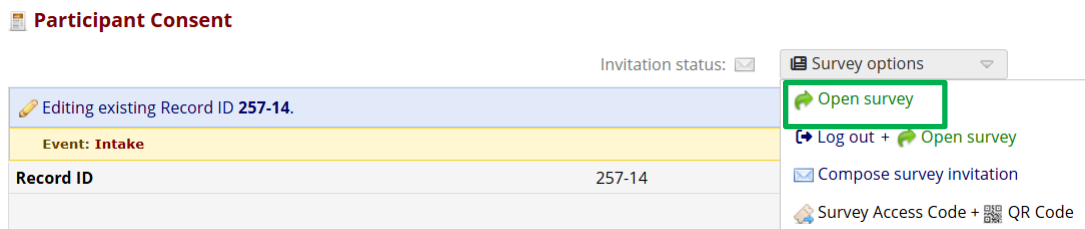
- Enable language interpretation
- Select sign language interpretation video channels below. You can assign interpreters at any time.

- Preparations should be done about 30 minutes prior to your scheduled Intake visit (just in case your PPT joins the Zoom call early)
 - Remote Intakes should happen primarily in Rooms 304B, 307A & 307B
- Have the following available for during and at the end of the visit:
 - TLFB substance definition pdf

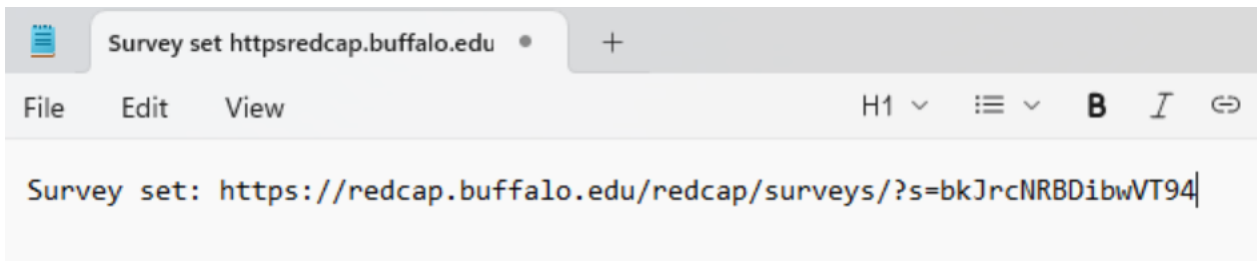
- b. Care Pack 1 - Quit Kit, US Bank payment card, iCO device + guide, and printed visit reminder sheet for both In-Person (IP) and Remote (R) visits
 - i. You don't yet know whether your PPT will be randomized to in-person (IP) or remote (R) visits, so have everything with you so you are prepared for either option
 - 1. IP Care Pack 1 = Quit Kit, US Bank payment card, IP visit reminder sheet
 - 2. R Care Pack 1 = Quit Kit, US Bank payment card, iCO device + guide, R visit reminder sheet
 - c. Referral sheet pdfs for 211 (in case they score high on the AUDIT or PHQ) and smoking cessation (in case they are ineligible)
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. Set up TLFB
 - i. Under "Intake" 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. Prepare PPT facing consent form and survey sets
- a. Open the "Participant Consent" form
 - b. Click on "Survey options" in the upper right of the form



- c. Select "Open survey"



- d. After the survey opens in new window, copy survey set URL into notepad on computer - make sure to leave the survey without saving changes in the original window



- e. Repeat this process for “Smoking History and Demographics” (1st Survey Set)
 - f. Repeat this process for “Phenx Health Literacy for Participant” (2nd Survey Set)
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

A screenshot of the iCoQuit app's sign-in form. It features two input fields: "Email Address" and "Password". Below the password field, there is a checkbox labeled "Remember Email" and a link for "Forgotten Password?". At the bottom, there are three buttons: a dark blue "Sign In" button, a white "OR" button, and another dark blue "Register" button.

7. Check the PPT’s name so you can greet them correctly when they arrive on the Zoom call
8. Open the Intake Record Form and use it as a checklist and procedure guide as you proceed with the visit

Running Remote Intake Visits

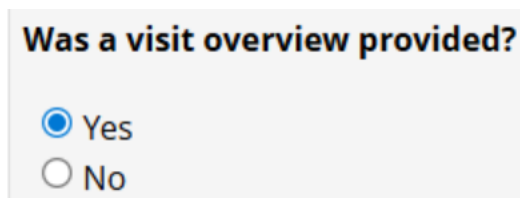
1. About 10 minutes prior to the scheduled appointment time, start the Zoom call
2. If the PPT hasn’t joined the Zoom meeting or called by 10 minutes after the scheduled visit time, call the PPT to get an update on their status or leave a voice message (VM) if they do not answer; refer to the Rescheduling 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 join Zoom 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”

Confirm PPT Cigarettes

1. Once the PPT joins the Zoom call, greet them and say (if 21 years or older): **“We asked that you have a pack of your usual brand of cigarettes available at this visit. Could you please hold it up to the camera so I can see it?”**
 - a. If PPT **does** have a pack of cigarettes available:
 - i. Thank PPT for bringing them
 - ii. Document the “Cigarette brand” and “Flavor” in the Record Form; any additional information (e.g., 100’s, King size, etc.) can be noted in the “Cigarette Comments” box
 - iii. Proceed with the visit overview
 - b. If PPT **does not** have a pack of cigarettes (even an empty pack), you will need to reschedule the visit
 - i. Emphasize the importance of having their pack of cigarettes at the next visit, then work with the PPT to find a day/time to reschedule the visit

Study Overview and Informed Consent

1. With REDCap opened up to the Intake Record Form, review with the PPT what will be happening at the Intake Visit. Say: **“Today we will be doing several things with you. First, we will have you read the consent form. We will answer any questions you have then you can sign the form if you are interested in participating in this study. Then, we will ask you questions about your use of nicotine products and about the medications you take. Finally, you will answer survey questions electronically.”**
 - 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 Intake Record Form
 - b. After answering any questions the PPT has, update the Intake Record Form



Was a visit overview provided?

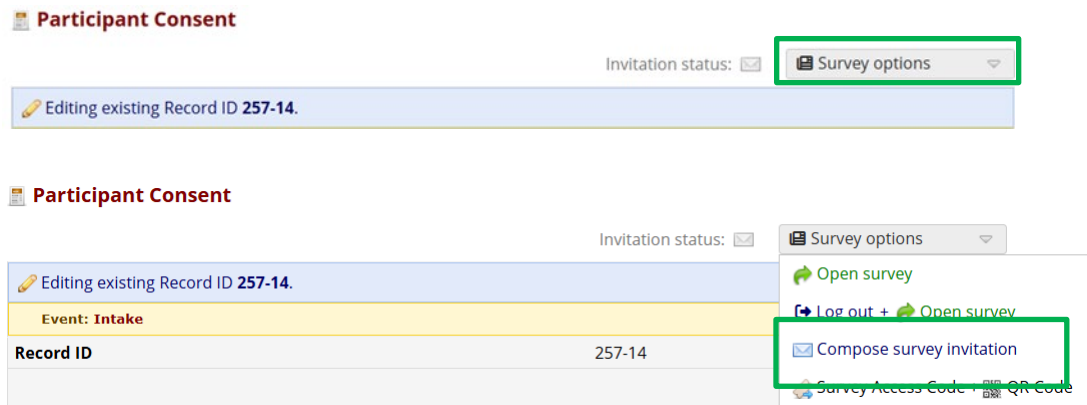
Yes

No

- c. Say: **“As I just mentioned, I will first have you read the consent form that you will receive via a link sent to you. You can click on the link when you receive it. Please read the form carefully and let me know if you have any questions. I will be here in the meeting with my camera and mic off, so if you have any questions as you read the form, you can ask me or put it in the chat. As you progress through the form, you will click boxes to view the next section. Once you have reached the bolded red letters saying, "wait for Research Assistant," wait there and do NOT check the box, just let me know that you've reached**

that point. At this point, I will ask if you have any questions about what you read, and then I will ask you some questions to make sure you fully understand your participation in this study. If you decide you'd like to participate, I will have you provide your signature on the form. Do you have any questions?"

- i. If consent URL was previously copied into Notepad, copy the link into the Zoom chat and send to PPT
- ii. Alternatively, the link can be sent via text or email depending on the PPT's preference, by using the drop-down in the top right labeled "Survey Options" select "Compose survey invitation". Inform them that a text will come from a phone number with area code 716 or the email will come from bhealth@buffalo.edu



2. While they read, open the "Consent Overview" form on your computer
 - a. Once participant is at the "Wait for the Research Assistant" prompt, ask if they have any questions about the consent
 - i. Say: **"Now that you've had a chance to read through the full consent form, do you have any questions about what you read?"**
 - ii. If the participant has any questions, record them verbatim in the "Consent Overview" form as well as your answer to the question
3. Then, administer questions stated below
 - a. Approximately how many weeks will your participation in this entire study last? **(This visit and the next 5 will be completed in about 3-4 months)**
 - b. Can you decide to not participate in this study at any point during your participation? **(YES)**
 - c. How long is each treatment and assessment visit? **(30-60 minutes)**
 - d. How will you receive payment for participation in this study? **(Reloadable US Bank Visa Debit Card)**
 - e. What kind of nicotine replacement therapy will you receive in this study? **(Patches and lozenges)**
4. If any of the questions have been answered incorrectly, make sure to explain the answers and point the PPT back to the applicable section in the consent

- a. If you have doubts about the PPT’s comprehension of the consent form, please consult with the coordinator before proceeding. [For example, you can say to the PPT: **“I am going to pause here to check in with the study coordinator. I will be back in a few minutes. Please relax while I’m muted for a moment.”**]
5. After administering questions:
 - a. Say: **“You can now check the box that says, “All questions have been answered.”**
6. Guide PPT through signing the consent form:
 - a. Say: **“Below the “Signature Box for Capable Adult”, please read and answer the first question that asks if you still want to participate. Please notify me of your choice so I can guide you through the next steps.”**
 - i. If PPT answers “No” they don’t want to participate, a box will pop up asking them to “Please explain why:”
 - ii. If PPT answers “Yes” they want to participate, say: **“Now, answer the next question that asks if you want a copy of the consent form emailed to you.”**
 - b. Say: **“Please enter your email if applicable, then your legal first and last name and provide your signature and the date.”**

The screenshot shows a digital consent form with the following sections:

- First Name:** A text input field containing "Monica". Above the field is a red asterisk and the text "* must provide value".
- Last Name:** A text input field containing "Mary". Above the field is a red asterisk and the text "* must provide value".
- Signature of Subject:** A green-shaded area containing a handwritten signature "Ae" in blue ink. Below the signature is a blue link: "signature_2023-01-22_1935.png (0.01 MB)". Below the link is a red "X" icon and the text "Remove signature".
- Today's Date:** A date input field containing "01-18-2023". To its right is a "Today" button and the text "M-D-Y". Above the field is a red asterisk and the text "* must provide value".

At the bottom of the form is a button labeled "Next Page >>" in red text.

- i. After filling out that box, PPT should hit “Next Page>>”
 - c. Say: **“Please scroll down to the bottom of the page (pdf) and carefully review that your information is correct, then check the box to certify this is true.”**

I certify that all of my information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

<< Previous Page Submit

- i. PPT should click “Submit” and close the survey page
- d. Say: **“Please give me a moment to check over everything and to add my signature to the consent.”**
 - i. Save the “Consent Overview” as “Unverified” so you can check over the PPT consent
 - ii. Open the “Participant Consent” form and ensure that the PPT’s signature and date are observable; if the signature and date don’t show up, have the PPT redo the consent form from the beginning (they can skip through and just check the boxes to move on since they already read the form once)
 - iii. **NOTE: AT THIS TIME, FILL OUT THE STAFF CONSENT FORM!!!**

7. Open the “Staff Consent” form

- a. In the Consent form Version Date, enter the date on which the consent form was most recently updated. [Found at the top of page 1 of the consent form]

Title of research study: Remote vs. In-Person Study Evaluation (RISE) T
Smoking)
Version Date: 03/27/2025
Investigators: Larry W. Hawk, Jr., PhD, and Martin Mahoney, MD, PhD

- b. Save as “Complete” once all fields were completed

8. Go back to the “Consent Overview” form and answer the last 3 questions, then save as “Complete”

9. Go to “Intake Record Form” and answer the questions under the “Consent” section

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 phone screen?”**
 - 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 TLFB

Administer TLFB

1. Navigate to “TLFB Setup” on your laptop
2. At Intake, 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 pdf via Zoom chat or screenshare
3. Administer TLFB using instructions in [Appendix A](#)
4. Save TLFB form as “Complete”

Survey Set #1

1. Like you did for “PPT Consent”, if survey set #1 URL was previously copied into Notepad, copy the link into the Zoom chat and send to PPT OR open the “Smoking History and Demographics” drop-down in the top right by clicking on “Survey Options”, select “Open Survey” and send the URL to the ppt via email or text
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 here with my camera and mic turned off to prepare your care pack. Please let me know if you have any questions as you go through.”**
3. The first set of surveys includes:
 - a. Smoking History Demographics [compiled primarily from PhenX toolkit; data will allow us to characterize our research sample]
 - b. FTCD [The Fagerström Test for Cigarette Dependence) is a six-item survey that measures cigarette dependence]
 - c. PPT Cost Measure
 - d. Perceived Stress Scale
 - e. SE Checklist V20 (Side Effect Checklist)
4. 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
 - a. If there is anything to review with the coordinator, do that now
 - b. You can follow the PPTs survey progress on REDCap
5. Ensure that the “Intake Record Form” is fully updated during this downtime

Preparing Payment Card

IMPORTANT NOTE – PREPARE PAYMENT CARD WHILE PPT IS WORKING ON SURVEYS

1. Write PPT ID# and date on the right side between the blue banner and the QR code on the payment card envelope (see example below)
2. Take a photo of the envelope
3. Save the photo using the PPT ID (e.g., RISE 198-1356 Payment Card) as the name of the photo
4. Upload the photo to REDCap in the Intake Record Form



Side Effect Tracking

1. After PPT completes Survey Set 1, open the "Side Effect Tracking" form (see below)
2. Side effects that have to be reported will be listed after the section "Code 3 Side Effect Endorsements"; the first side effect is usually **bolded** and highlighted in **GREEN** and subsequent side effects are bolded and appear below that
 - a. If no side effects are listed in bold, select "No" in the STAFF field, save the form as "Complete", and move on to Medications
3. If side effects are listed **in bold**, select "Yes" in the appropriate STAFF field ("Are there any symptoms listed above for the current visit?")
 - a. You can quickly see the extent of severity reported, regardless of symptom, by looking at the field "Max Side Effect Intensity reported by patient was:" at the top of the form
 - i. If this field is blank, the PPT reported no side effects
 - b. ANY side effect whose severity the PPT marks as "No normal activities are possible" will be categorized as a Code 3 Side Effect Endorsement
 - i. These codes must be reported to the study physician, PI, and study coordinator immediately after the visit
 - ii. The study physician must reply with a plan of action within 24 hours
 - c. Certain side effects (listed in the REDCap form) will be categorized as a Code 2 Side Effect Endorsement when the PPT marks their severity as "Interferes with some activities". These side effects are potentially related to nicotine medications
 - i. These codes must be reported to the study physician, PI, and study coordinator immediately after the visit
 - ii. The study physician must reply with a plan of action within 48 hours
 - d. Never interact with the radio buttons next to a bolded side effect. These are meant solely for Dr. Mahoney / Dr. Hawk

Max Side Effect Intensity reported by patient was: 2 [View equation](#)
If a Code 3, this is a possible SAE and must be reviewed by the HCP immediately.

Code 2 Side Effect Endorsements
 (symptom interferes with some daily activities)

Code 2 events limited to:
 -cardiac symptoms (irregular heartbeat or palpitations, increased heart rate, chest pain),
 -dermatologic symptoms (skin swelling, skin rash or redness (not sunburn)),
 -depressed mood,
 -specific gastrointestinal symptoms (vomiting, indigestion), and
 -specific sleep problems (insomnia, abnormal dreams)

Code 3 Side Effect Endorsements
 (no normal activities are possible)

-any symptom

Depressed Mood
 In: and interferes with some activities

V1: _____ None
 V2: _____ Does not interfere with daily activities
 V3: _____ Interferes with some activities
 V4: _____ No normal activities are possible
 V5: _____ [reset](#)

The HCP can recode the symptom using the radio buttons above

Insomnia
 In: and interferes with some activities

V1: _____ None
 V2: _____ Does not interfere with daily activities
 V3: _____ Interferes with some activities
 V4: _____ No normal activities are possible
 V5: _____ [reset](#)

The HCP can recode the symptom using the radio buttons above

STAFF: Are there any symptoms listed above for the current visit? No Yes

4. Then, go through each symptom indicated and ask the PPT the questions that appear above the box in the Side Effect Tracking form, and record their answers in the text field provided:
 - a. **“You just indicated that you’re having moderate depressed mood symptoms. What would you attribute that to?”, “How long have you been experiencing the symptom?”, “Anything done to treat this symptom?”, “What normal daily activities have been impacted and how?”**
 - b. After recording their answers for each symptom, list the date and your initials in the text field
 - c. See visual example below:

Depressed Mood
In: and interferes with some activities
V1: _____
V2: _____
V3: _____
V4: _____
V5: _____

None
 Does not interfere with daily activities
 Interferes with some activities
 No normal activities are possible

The HCP can recode the symptom using the radio buttons above reset

Insomnia
In: and interferes with some activities
V1: _____
V2: _____
V3: _____
V4: _____
V5: _____

None
 Does not interfere with daily activities
 Interferes with some activities
 No normal activities are possible

The HCP can recode the symptom using the radio buttons above reset

STAFF: Are there any symptoms listed above for the current visit?
* must provide value

No
 Yes

If NO, submit the form as complete. If YES, save as unverified and send the link to HCP/PI per the EvarQuit SE and SAE manual. reset

STAFF: You just indicated that you're having [moderate/severe... symptoms noted above].

What would you attribute this to? How long have you been experiencing the symptom? Anything done to treat this symptom? What normal daily activities have been impacted and how?

Depressed Mood: Attributed to recent financial struggles, rumination. Experiencing current episode for about a week. PPT is going for walks and journaling for tx. Social activities mainly affected, PPT has low motivation to engage with others. "My social battery, is just low right now".

Insomnia: Attributed to stress related to job and familial problems. Experiencing sx for about 3 days. PPT is taking nightly melatonin for tx. Activity affected globally, "everything is harder when I'm tired."

AH 2/26/26 @15:45

Please add your name, the date, and time once you complete this field. Save the instrument as unverified after you are done. Then email Dr. Mahoney to inform him that this participant has a SEC/SAE to be reviewed.

5. After gathering more information about the symptoms reported by the PPT, answer the two questions that appear below the text box (see below)
 - a. Verify their smoking status based on TLFB completed earlier
 - b. Since this is an Intake, you know that the PPT is not taking study medication so the answer to the next question should be "No"

STAFF: Is participant currently smoking?

Note: For the fields below, a value of 1 indicates that cigarettes have been used in the past 7 days of the visit, according to the TLFB Set-Up form

Intake: Check if used Yes
 No

T/A 1: _____
T/A 2: _____
T/A 3: _____
T/A 4: _____
T/A 5: _____

STAFF: Is participant currently taking study medication?

Note: For the fields below, a value of 1 indicates that NRT patches have been used in the past 7 days, according to the TLFB Set-Up form

Intake: _____
T/A 1: _____
T/A 2: _____
T/A 3: _____
T/A 4: _____
T/A 5: _____

Yes
 No

Note: For the fields below, a value of 1 indicates that NRT lozenges have been used in the past 7 days, according to the TLFB Set-Up form

Intake: _____
T/A 1: _____
T/A 2: _____
T/A 3: _____
T/A 4: _____
T/A 5: _____

- After the visit, we will need to send a link to the “Side Effect Tracking” form to the study physician/PI/study coordinator. (See SOP for Handling Participant Side Effects for details)

Medications

- Ask about any allergies to medications
 - If the answer is “Yes”, a text box pops up where the medication and the reaction they have can be documented
- Next, say: **“Do you use or take any medications prescribed by a Health Care Provider on a regular basis?”**
- If “No”, the survey ends and you can move on to the next task
- If “Yes”, work with the participant to build a list of their prescription medications in REDCap
 - Start typing the medication name in the box and the ontology will open so you can select the appropriate one
 - Note whether the information is from direct observation of the medication packaging, a picture, a list OR from PPT report
 - If PPT cannot remember exact date they started a medication:
 - Ask about how many years ago they started and what time of year. The aim is to be as accurate as possible. However, if a PPT is struggling to remember, focus on just estimating the year and month

- ii. If only have year, use July 15th
 - iii. If have year and month, use 15th of the month
 - iv. If PPT does not know the purpose of a medication they take, you can Google it and confirm the usage with the PPT
 - v. If PPT stopped the medication in the past two weeks, record the stop date
5. Save form as “Unverified” as a helpful reminder to review this record at each subsequent visit
 - a. This form in REDCap should only be saved as “Complete” when the PPT has ended their participation

Breath CO

1. We do not collect Breath CO at Intake for Remote visits
 - a. Go into the “Breath CO” form and check the box (see below)

Event: **Intake**

Record ID 198-1420

Check off the box below to confirm that the PPT will not complete CO since they are completing a remote intake. H

* must provide value

No CO reading at this visit.

Save form as "Complete".

Final CO Reading H [View equation](#) H

* must provide value

2. Save form as “Complete”

Px270401 Phenx Health Literacy

1. Send invite or link (see previous instructions for consent or survey set #1 about this process) of “Phenx Health Literacy for Participant” to PPT to complete as a survey
2. Open “Px270401 Phenx Health Literacy” on your computer as a data entry form
3. Ensure that the PPT says the top word and you then say: **“Between [bottom word one] and [bottom word two], which is most similar to the top word?”**
 - a. If PPT is picking up on the process and wants to read the top word then immediately give their answer, they are allowed to do that – you do not have to read the two answer choices
4. As the PPT provides their verbal responses, you will record their answers in the “Px270401 Phenx Health Literacy” version of the form
 - a. The PPT will not be asked to enter any data on their version of the survey
 - b. PPT will just need to select “Next Page” after giving each response until the survey is completed
5. When done with the word sets, ask final question **“How confident are you filling out medical forms by yourself?”** and record answer in REDCap
6. Save “Px270401 Phenx Health Literacy” as “Complete”

Survey Set #2

1. Let PPT know they can continue by clicking “Submit” to begin second survey set
2. Also let the PPT know:
 - a. The first two questionnaires (CPQ-12 and MDPQ-16) have similar questions, but the first questionnaire is asking about *computers* and the second one is asking about *mobile devices* (like cell phones and tablets)
 - b. Emphasize that the NIDA (the final survey about drug use), is asking about two things:
 - i. Medications you have taken for reasons or in doses OTHER THAN PRESCRIBED by a medical professional
 - ii. And illicit or illegal drugs you have taken
3. 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.”**
4. The second set of surveys includes:
 - a. CPQ-12 - Computer Proficiency Questionnaire (The Computer Proficiency Questionnaire (CPQ) is a survey that measures someone's ability to use a computer to accomplish different tasks)
 - b. MDPQ-16 (The Mobile Device Proficiency Questionnaire is a 16-question survey that evaluates a person's ability to use a mobile device)
 - c. Trust Medical Care Research 4 Item (Trust in medical researchers is a measurable single-factor construct including trust in safety, researcher fidelity, and honesty)
 - d. Discrimination in Health Care (The DHC scale is a 7-item instrument that assesses a person’s prior experiences of mistreatment while getting health care that were attributed to race, ancestry, national origin, sex, disability, or age)
 - e. AUDIT (The Alcohol Use Disorders Identification Test (AUDIT) is a 10-item screening tool developed by the World Health Organization (WHO) to assess alcohol consumption, drinking behaviors, and alcohol-related problems)
 - f. PHQ 8 (Patient Health Questionnaire is one of the self-reported questionnaires most frequently used worldwide for the screening and severity assessment of depression.)
 - g. NIDA QS1 (The NIDA Quick Screen is designed to assess high risk involvement with illicit or nonmedical prescription drugs)
5. Once again, during this time, you should turn your camera off, mute yourself, and follow the PPT’s survey progress in their REDCap record
 - a. If you need to step out for any reason, make sure the PPT is informed and that you let them know once you’ve returned
 - b. You can follow the PPT’s survey progress on REDCap
6. Ensure that the “Intake Record Form” is fully updated during this downtime

RA Task During Survey Set 2

1. As stated before, you don't yet know whether your PPT will be randomized to in-person (IP) or remote (R) visits, so have everything organized so you can refer to the correct Care Pack 1 if PPT is deemed eligible
 - a. IP Care Pack 1 = Quit Kit, US Bank payment card, IP visit reminder sheet
 - b. R Care Pack 1 = Quit Kit, US Bank payment card, iCO device + guide, R visit reminder sheet

Intake Eligibility Summary

1. After Survey Set #2 is complete, go to the "Intake Eligibility Summary" to determine if the PPT is eligible to continue in the study (0 = Eligible; 1 = Ineligible)
2. For this study, there are two eligibility criteria assessed at Intake:
 - a. Ability/willingness to provide informed consent, follow directions, and respond appropriately – this is based on RA experience with PPT during consent and during the visit
 - b. NIDA QS1 – the following will result in the PPT being deemed Ineligible
 - i. A score of 27+ for Cannabis, Cocaine, Prescription Stimulants, Methamphetamine, Inhalants, Sedatives/Sleeping Pills, Street Opioids, Prescribed Opioids, Hallucinogens
 - ii. If someone scores over one or more cutoffs for the NIDA, they are deemed ineligible AND we will offer them referrals at the end of the visit
 - c. Although the AUDIT and PHQ 8 are not exclusionary for this study, we will offer referral information at the end of the visit if the PPT's score exceeds the following cutoffs:
 - i. AUDIT score >13 for females and >15 for males
 - ii. PHQ 8 score >11
3. Complete the "Randomization 2 at Intake" form in REDCap
 - a. Go to the form and click "Randomize"
 - b. Save "Intake Eligibility Summary" as "Complete"
4. **IF INELIGIBLE:**
 - a. Say **"Because this is a research study, we are looking for people with very particular characteristics. Unfortunately, it looks like you are ineligible for this study. However, we really do appreciate your time today. You will receive \$30 for your time."**
 - i. Give referrals if indicated
 - ii. IF the PPT asks why they are ineligible, you may tell them
 1. If we feel they couldn't consent, say: **"It is our responsibility to follow good practice guidelines set by federal policy, and when reviewing the consent form, we were unable to confirm that you completely understood what the consent form was describing. This is standard eligibility criteria across all research studies currently enrolling participants."**
 2. If NIDA is too high, say: **"Your degree of use of X drug is above the set limits for this study."**
 3. If inappropriate behavior, giving careless answers, or unable to follow directions, say: **"We want to enroll people who are going to take care and**

give accurate and thoughtful answers, and we have found that not to be the case.”

5. IF ELIGIBLE:

- a. Once you have confirmed eligibility:
 - i. Complete randomization
 - ii. Finalize contents of Care Pack 1 depending on whether the PPT was randomized to IP or R T/A visits
 - iii. Turn your video back on
- b. Say: **“Thank you for providing consent and answering those questions. You are eligible to continue in the study! Like we did at the end of the phone screen, a computer determines whether your five treatment and assessment visits take place in-person or remotely, like the flip of a coin. I completed this just now, and the computer determined that the rest of your visits in this study will all be [INSERT IN-PERSON or REMOTE here].”**
- c. Ask if the PPT has any questions about this; answer them accordingly before moving forward
- d. Proceed to “Scheduling Treatment and Assessment (T/A) Visits”

Scheduling Treatment and Assessment (T/A) Visits

1. Open the “T/A Visit Scheduler” and proceed to schedule all 5 T/A visits
 - a. Say: **“Let’s get your visits scheduled. We will start with the date when you want to quit smoking [this is known as the Target Quit Date (TQD)].”**
 - i. The TQD, also known as T/A visit 2, should be between 2 and 5 weeks away from Intake date
 - ii. Once PPT chooses TQD, tell them that we will keep their visits on the same day of the week and at the same time as T/A 2, whenever possible
 - iii. Then schedule the rest of the visits as follows:
 1. T/A visit 1 will be one week BEFORE T/A visit 2 (TQD)
 2. T/A visit 2 will be *the Target Quit Date*
 3. T/A visit 3 will be 2 weeks AFTER T/A visit 2
 4. T/A visit 4 will be 6 weeks AFTER T/A visit 3
 5. T/A visit 5 will be 4 weeks AFTER T/A visit 4
2. Once all visits are scheduled, fill out the printed Appointment Reminder handout and include it in the PPT’s Care Pack 1

Review of Care Pack 1

FOR REMOTE INTAKE randomized to IN-PERSON T/A VISITS

1. Say: **“I’m now going to review your first Care Pack. You will receive it when you come to your first Treatment and Assessment visit. I’ll review each item with you now.”**
2. Take out each item and hold it up to the camera while reviewing with PPT:
 - a. Payment Card

- i. Hold up payment card and say: **“Here is the US Bank Visa card onto which we will be loading your study payments. You should register the card and set up a PIN if you want to use an ATM. Payments should appear 1-2 BUSINESS DAYS after your visit. Our study staff will add the payment to your card then the US Bank Card administrator at UB will have to approve the payment before it will show up on your card. If you have questions about your payment, please call us on our study line at 716-829-2323.”**
 - b. Quit Kit
 - i. Hold up Quit Kit and say: **“This booklet reviews some of the best resources out there for quitting smoking and includes a section that walks you through some of the most important parts of a good quit plan. We will talk more about this Kit at your first Treatment and Assessment visit. You are welcome to review the contents of the booklet prior to your next visit, if you are interested.”**
3. Ask: **“Are you okay with getting your payment card at your next visit, which will be in-person, or do you want us to mail it to you?”**
 - a. Document in REDCap Intake Record form
4. Remind PPT of next visit date and time that will be in-person
 - a. Review instructions of how to get to our Center and answer any questions related to In-Person visits or the next steps of the study.
 - b. Once the Zoom call has ended, proceed to the Post-Visit tasks

FOR REMOTE INTAKE randomized to **REMOTE T/A VISITS**

1. Say **“I’m now going to review your first Care Pack. You will receive it by mail within the next 2-5 days. I’ll review each item with you now.”**
2. Take out each item and hold it up to the camera while reviewing with PPT:
 - a. iCOquit Smokerlyzer and Guide
 - i. Hold up iCOquit Smokerlyzer and say: **“This device will allow us to measure the amount of carbon monoxide in your lungs at each visit. You will need to download an app onto your smartphone. To make sure we are all set for the next visit, we will do that now.”**
 1. Depending on the PPT’s OS, instruct them to open the App Store or Google Play and search for “iCo Quit”
 2. Select install, and once it has been installed, ask them to open the app.
 - a. Follow all procedures to register an account for the iCO
 - b. The PPT should use the email that they provided to us in their Contact Info
 - c. We will provide the password (e.g. RISE198-XXXX)
 3. PPT will have to “verify” the account via a link sent to their email (if they don’t see the link, ask them to check their Junk/Spam folder)

4. Once you have confirmed that they can log in successfully, write the email address and password used to register on the iCO guide
5. If time permits:
 - a. Point out the main features that will be used for the study especially “New Breath Test”
 - b. Have the ppt turn on their Bluetooth and connect the device to their smartphone to ensure functionality
6. For more details and/or troubleshooting tips, refer to the RISE_iCO SOP

b. Payment Card

- i. Hold up payment card and say: **“Here is the US Bank Visa card onto which we will be loading your study payments. You should register the card and set up a PIN if you want to use an ATM. Payments should appear 1-2 BUSINESS DAYS after your visit. Our study staff will add the payment to your card then the US Bank Card administrator at UB will have to approve the payment before it will show up on your card. If you have questions about your payment, please call us on our study line at 716-829-2323.”**

c. Quit Kit

- i. Hold up Quit Kit and say: **“This booklet reviews some of the best resources out there for quitting smoking and includes a section that walks you through some of the most important parts of a good quit plan. We will talk more about this Kit at your first Treatment and Assessment visit. You are welcome to review the contents of the booklet prior to your next visit, if you are interested.”**

d. Confirm the address that we are shipping their Care Pack to

3. Remind PPT of next visit date and time and to expect a new Zoom link ahead of the visit as well as the package
4. Once the Zoom call has ended, proceed to Post-Visit tasks

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. **Care Pack**
 - a. If PPT was assigned to Remote T/A visits: update the RISE Inventory + Tracking spreadsheet with the PPT’s ID, date of distribution, RA initials in the row of the iCO device being assigned to this PPT

Serial Number	Pre-calibrated by COVita?	Test Result (expected = 20+/- 3 ppn)	Date Tested	Tested	Distributed By	Date of Distribution	Record ID	Visit	R or IP visit
CQ10009438	Yes				CGD	6/9/2025	198-1210	Intake	R

Cleaning the Visit Room:

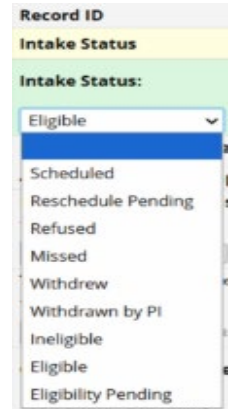
1. Log out of the desktop computer

2. Ensure that all materials from the visit are returned to their proper location (e.g., TLFB Sheets, unused Care Pack materials)

Completing Post-Intake Record Form:

1. Update Milestones

- a. If the visit went according to protocol and PPT is eligible to continue:
 - i. The overall Study Status should remain as “Pre-ITT Pending”
 - ii. Change the Intake Status to “Eligible”
 - iii. Update the “Date of most recent update to Intake Status” to the date the Intake was completed and add any notes about what occurred during the visit, if applicable
 - iv. Update all T/A Visit Statuses to “Scheduled” and input Date and Time of each visit, adding that this is the “1st time scheduling”; be sure to note your initials and the current date at the bottom of each Status form
- b. Add all scheduled visits to the Google calendar



Intake Status:
 Eligible

Date and Time of Intake scheduled during the Phone Screen: 06-16-2025 15:00

45 Day Deadline to complete Intake based on Phone Screen on 06-09-2025 14:38: 07-24-2025

Date of Intake from most recent scheduling:
* must provide value
 06-16-2025 Today M-D-Y

Time of Intake from most recent scheduling:
* must provide value
 09:30 Now H:M

Current Intake schedule number:

1st time scheduling
 1st time rescheduling
 2nd time rescheduling (or beyond)

Actual Date & Time of Intake from Intake Record Form:
 06-16-2025 at 09:30

Intake Status Notes:

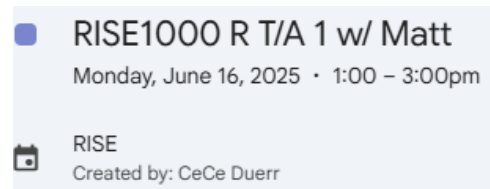
03/03/2025 MG: IP T/A 1 scheduled for 3/7 at 12:30p
 02/25/2025 MG: R IN scheduled for 3/3 at 9:30a

Were there any technical difficulties during this visit?

Yes
 No

Date of most recent update to Intake Status:
 06-16-2025 Today M-D-Y

Staff username:
 CGD



2. If the PPT was deemed Ineligible, voluntarily Withdrew, or Refused before signing consent:

- a. Update both the Visit Status and Study Status forms to indicate this outcome and add a comment explaining why they were deemed IE or the reason that the PPT did not complete the visit
 - b. The Study Status should be marked as the “Pre-ITT” version of whatever outcome occurred
 - c. All future T/A Visit Status Forms will be left blank
3. Side Effects and AEs
- a. (If applicable) See SOP for Handling Participants Side Effects for instructions on emailing the study physician, principal investigator, and project coordinator
 - b. Insert the date and time the email was sent out
4. Ad Hoc AE form
- a. (If applicable) See SOP for Handling Participants Side Effects for instructions on emailing the study physician, principal investigator, and project coordinator
5. T/A Appointment Doc
- a. If PPT was randomized from R Intake to R T/A visits, the visit schedule should be emailed to them after the visit
 - b. Fill in the “Date and Time that T/A Appointment Doc was Sent” section of the Post-Intake Record Form

Care Pack 1:

1. Finalize the contents of Care Pack 1 depending on whether the iCO Device/Guide is included
2. Take a photo of the full open Care Pack 1 and upload this to REDCap in the Intake Record Form
3. If PPT was randomized to **R T/A Visits**, prep the package to be shipped with the following included:
 - a. US Bank Card
 - b. Quit Kit
 - c. Completed Remote Visit Reminder Form
 - d. iCO device and guide
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; additionally, place a UB RISE return sticker at the top left
6. Update the Post-Intake Record Form in REDCap with the photo of the sealed Care Pack package
7. 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
8. 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

Serial Number	Pre-calibrated by COVita?	Test Result (expected = 20+/- 3 ppn)	Date Tested	Tested	Distributed By	Date of Distribution	Record ID	Visit	R or IP visit
CQ10009438	Yes				CGD	6/9/2025	198-1210	Intake	R

9. If PPT was randomized to **IP T/A Visits:**

- a. Email the completed Appointment Reminder handout + directions on how to get to our lab

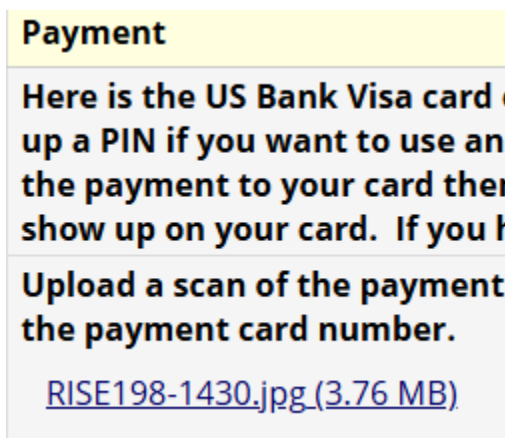
10. Print a copy of the Appointment Reminder handout to be included in their Care Pack

11. Solo Payment Card

- a. You may need to send the US Bank Card to a PPT who completed a Remote Intake if the PPT:
 - i. Was deemed ineligible
 - ii. Requested that their payment card be sent before their IP T/A 1
 - iii. Withdrew after randomization to R or IP T/A visits
 - iv. Was eligible AND was randomized to T/A visits BUT then withdrew from the study before they could receive a payment card
- b. If you are sending the US Bank Card to the PPT before their scheduled T/A 1
 - i. Grab an envelope and place the payment card in it
 - ii. Write the PPT's address on the outside of the envelope and place a UB RISE return address sticker at the top left
 - iii. Place a stamp at the top right and put it in the USPS dropbox
 - iv. Take a photo of the sealed envelope and upload it to the Post-Intake Record Form in REDCap

Payment

1. Participant payments are made in the US Bank Prepaid Administrative Website by the study coordinator or their designee
2. Log in to the US Bank website
3. Payment cards must be registered after being distributed at Intake
 - a. Click on "Cardholders"
 - b. Click on "Register New Cardholder"
 - c. Go to Intake Record form → "Payment" section" → click on the file to get the card number



- d. Enter the 10-digit Card ID
- e. Click "Find Card"

- f. Enter first and last name in the “Cardholder Information” section
 - g. Enter address in “Account Contact Information” section
 - h. Enter ONLY birthdate in “Personal Information” section
 - i. At the bottom of the form, enter the grant number and select the state from the drop-down list
4. To make a payment:
- a. Click on “View Cardholder Details” → “Account Management” → “Funds Transfer”
 - b. Make sure “Transfer to Cardholder” is checked
- Please select your Transfer Option**
- Transfer to Cardholder Transfer from Cardholder
- c. Enter the following in the “Memo for Selected Card (optional):” box: **RISE IN on [date]**
 - d. Enter “Transfer amount”
5. Click “Submit Request”

APPENDIX A: TIMELINE FOLLOWBACK (TLFB)

Instructions for Setup:

1. Open TLFB Setup in REDCap
2. Make sure to have the product definition sheets with you or a PDF version of them
3. “Calendar Start Date” should be **one day before** the Intake Visit (e.g., visit is on 2/19/25, select 2/18/25)

The screenshot shows the 'TLFB Setup' form in REDCap. The form is titled 'TLFB Setup' and is for editing an existing record with ID 198-1025. The event is 'Intake'. The record ID is 198-1025. The lab visit name is 'Intake'. The calendar start date is set to 02-18-2025, with a note that data collection will go back 7 days. There are radio buttons for 'Today' and 'M-O-Y'.

4. Introduce the assessment
 - a. Say: **“Next, we are going to ask you whether you’ve used certain products (including cigarettes, e-cigarettes/vapes, other tobacco/nicotine products, and combustible marijuana) over the past 7 days as well as today. Then, for the products you’ve used, we will go through and record the number of times or whether or not you’ve used each product on each of the last 7 days.”**
 - b. Assess which products were used in the past 7 days and record answers in TLFB Setup on your desktop computer
 - i. Say: **“Did you use any of the following over the past 7 days?”**
 - ii. Read the products one by one and wait for PPT to answer “Yes” or “No”
 1. As you are reviewing the types of products listed, refer back to the product definition sheet or PDF for each product the PPT indicated using in the past 7 days
 2. Take a moment to review product usage definitions on the sheets with the PPT
 3. If the PPT endorsed using marijuana over the past week, make sure to point out that we are only interested in combustible marijuana, not any other kind of marijuana use [if they ask why, explain that only combustible marijuana will affect their expired air carbon monoxide readings when we do them at the Treatment and Assessment visits]
 - a. If In-Person – hand the sheets to the PPT
 - b. If Remote – use the screen share method, or send the definitions PDF in the Zoom chat, to review definitions with the PPT about each product.
 - iii. Mark appropriate answer in TLFB Setup form
 1. If PPT answers Yes – Select the radio button under “Check if used”
 2. If PPT answers No – leave the radio button blank

- iv. For each product endorsed “Yes” by the PPT, a corresponding question about use “**So far today (meaning from midnight until right now), how many...**” will pop up under the yellow banner (see below)

****For each product the PPT has used in past 7 days, ask about use earlier today since this will not be captured on the following calendar.****

So far today (meaning from midnight until right now), how many...

...cigarettes have you smoked? Enter # of cigarettes.

...times have you vaped nicotine using an e-cigarette, where 1 "time" equals around 15 puffs or lasts around 10 minutes"? enter # of 'times', using PSECDI definition

So far today (meaning from midnight until right now), have you used other nicotine and tobacco products (cigars, cigarillos, pipe tobacco, smokeless tobacco, nicotine pouches, etc.)? Yes No reset

Enter #

So far today (meaning from midnight until right now), have you used marijuana: combustible (includes bowls, spliffs, joints, blunts, etc.)? Yes No reset

Enter #

- v. Ask about use for each product that was endorsed above

Conducting the Assessment:

- Once Calendar Start Date has been entered in TLFB Setup you will see those dates in TLFB underlined in **RED** (they will stay red until you enter number of products used, then they turn **GREEN**. If a date is partially completed, it will be underlined in **YELLOW**)
 - If there was a holiday, click on the date and enter the holiday under “List important dates” (in the example below, Valentine’s Day was entered on February 14)
 - Note that you will also ask the PPT if there were any important events on each day you go through with them
- Say: **“Now, we are going to review your use of those products over the past 7 days. We will start with yesterday and work our way back over the past week. We will go over important or notable events from each day to help you remember, and then I will ask how many cigarettes you smoked and about your use of other nicotine products on that day. We realize that it is hard for anyone to recall things with 100% accuracy, but we want to try to be as accurate as possible. If you can’t recall exactly how much product you used on a particular day, we will help you use your patterns and recollections to arrive at a best educated guess. Our job is to record your best daily estimate using this calendar. I am not judging you in any way for your [smoking, vaping, or marijuana] habits. Our goal is simply to get the most accurate information possible. Keep in mind that each day is considered Midnight to 11:59PM. Do you have any questions?”**
 - NOTE – it does not matter what time the PPT goes to bed or wakes up. If they work nights and sleep in the day, you still consider one day as 12:00AM to 11:59PM
- Start with yesterday and go one day at a time asking about use of each product on each day

- a. Start by asking the PPT what events happened yesterday (this will help anchor the day for the PPT)
 - i. Note that you should always enter something into the “List important events” box even if it’s just “work” or something similar
 - ii. If that field is left blank, the line under the date will be yellow instead of green
 - iii. In the example below, you can see that everything was entered for 2/18, 2/17 is incomplete, and 2/12-2/16 haven’t been done yet

FEBRUARY							Questions
S	M	T	W	T	F	S	
26	27	28	29	30	31	1	List important events <input type="text"/>
2	3	4	5	6	7	8	Cigarettes <input type="text"/>
9	10	11	12	13	14	15	Electronic Cigarettes <input type="text"/>
16	17	18	19	20	21	22	All other nicotine and tobacco products (pipe tobacco, hookah, smokeless tobacco, dissolvable tobacco, etc.) <input type="radio"/> Yes <input type="radio"/> No
23	24	25	26	27	28	1	Marijuana: combustible (includes bowls, spliffs, joints, vaporized flower etc. GRAMS PER DAY) <input type="radio"/> Yes <input type="radio"/> No
2	3	4	5	6	7	8	

- b. Instruct the PPT to consider typical patterns or recollect anchoring events (i.e., holidays, special events, sporting events, etc.) to assist with memory
 - i. Emphasize importance of remembering what they did each day to assist with reporting
 - ii. If needed to help remember, say: ***“Do you have any typical patterns in your [product] use?”*** (Some examples would be smoking with morning coffee, having smoke breaks at work, vaping when you’re drinking alcohol, etc.)
 1. Confirm if the pattern is the same for the entire week of the assessment period
 - iii. On days where there is a holiday or special event, say ***“As you can see [holiday/special event] occurred on this day. Sometimes people change their [product] use patterns during holidays and special occasions. Did you alter your [product] use on that day at all? How many times did you use [product] on that day?”***
 - iv. Probe for any days of abstinence
 1. Enter “0” for days of abstinence for a given product
 2. Don’t assume if they were abstinent for one product that they were abstinent for all products. Ask about each separately for each day

3. If the PPT reports being abstinent for the entire assessment period confirm by asking about any exceptions. Say **“So, you reported not using [product] even once between ___ and ___ (insert dates of assessment). Is that correct?”**
- c. Save TLFB form as “Complete”

Important Techniques and Points to Remember

1. Exaggeration technique:
 - a. Participant- “I don’t remember how many cigarettes I smoked, but it was a lot.”
 - b. Interviewer- **“By a lot, do you mean 5 cigarettes or 60 cigarettes?”**
2. Narrowing the range:
 - a. Participant- “I smoked 2 or 3 cigarettes.”
 - b. Interviewer- **“If you had to choose one number between 2 and 3, what do you think would be most accurate?”**
3. Remaining neutral
 - a. Do not react to how much or how little the PPT reports using
 - b. Do not act surprised if the PPT reports smoking or other use on a given day
4. Additional probe questions during interview
 - a. For high usage, for example large numbers of cigarettes, clarify with... **“How are you coming up with that number?”**
 - b. If they confirm the large number, you can say, **“So, you feel comfortable with me putting down that you smoked X cigarettes?”**
5. Be aware of rushing
 - a. If a participant seems like they are rushing or finding the task frustrating, validate the difficulty of the assessment, but reiterate the importance of accuracy
 - i. Say **“I understand that this can be tiresome or difficult, but it is important that we get the most accurate information as possible. Perhaps there were some days when you used [product] a bit more or less than XXX?”**
 - b. Still confirm with the participant the number you are putting for each day
 - i. “So, you think it was “XX” on this day as well?”
6. Always thank the PPT for completing the assessment

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