

# RISE

## Milestone SOP

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### **TABLE OF CONTENTS**

|    |                                        |                      |
|----|----------------------------------------|----------------------|
| 1. | Study Status Milestones                | <a href="#">p. 2</a> |
| 2. | Phone Screen Milestones                | <a href="#">p. 4</a> |
| 3. | Intake Milestones                      | <a href="#">p. 5</a> |
| 4. | T/A Visit Milestones                   | <a href="#">p. 6</a> |
| 5. | Milestoning Active vs Passive Refusals | <a href="#">p. 7</a> |
| 6. | General Procedures for Milestones      | <a href="#">p. 8</a> |

### **Purpose:**

**Milestones are assigned in REDCap to identify a person's status at every phase of their participation in the RISE Above Smoking study. This SOP describes the RISE milestoning procedures.**

### **Glossary of terms:**

CO – breath carbon monoxide

GCal – Google calendar for RISE

IN – intake visit

IP – in person

ITT – intent to treat

LVM – left voice message

PI – principal investigator

PPT – participant

PS – phone screen

R – remote

SOP – standard operating procedures

**STUDY STATUS MILESTONES**

- ITT:
  - A PPT falls in the Intent to Treat (ITT) category upon completion of Treatment and Assessment visit # 1
  - “Pre-ITT” refers to anything that occurs before the completion of T/A 1
  - “ITT” refers to anything after completion of T/A 1

| Visit                       | Status                                 | Definition                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------------|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>OVERALL STUDY STATUS</b> | Pre-ITT Never screened for eligibility | PPT never completed a phone screen, and they are no longer being contacted for screening. If the PPT contacts us later, we can restart the process.                                                                                                                                                                                                                                                                                                                                          |
|                             | Pre-ITT Refused before signing consent | Used for individuals who say they do not want to continue for any reason before, during, or after the phone screen (unless you’ve already deemed them ineligible), and even during Intake but before signing the consent form                                                                                                                                                                                                                                                                |
|                             | Pre-ITT Ineligible                     | Ineligible at either Phone screen or Intake <ul style="list-style-type: none"> <li>• Once a PPT has been deemed ineligible, they will always be ineligible for RISE</li> </ul>                                                                                                                                                                                                                                                                                                               |
|                             | Pre-ITT Withdrew                       | PPT decided to stop participating after signing consent form, but before completing T/A 1                                                                                                                                                                                                                                                                                                                                                                                                    |
|                             | Pre-ITT Withdrawn by PI                | PPT was withdrawn by the PI/Study Physician before completing T/A 1 visit                                                                                                                                                                                                                                                                                                                                                                                                                    |
|                             | Pre-ITT Pending                        | Placeholder for Pre-ITT PPTs who have not completed T/A 1 and do not have another Pre-ITT status. Use this status for: <ul style="list-style-type: none"> <li>• PPTs who are in progress from phone screen through Intake (ongoing participation before T/A 1)</li> <li>• PPTs who need to be contacted for reasons other than a visit reminder, including individuals whose eligibility at phone screen or Intake is under review</li> <li>• This cannot be a final Study Status</li> </ul> |
|                             | Pre-ITT LTFU at Intake                 | PPT was eligible at phone screen but they stopped responding to contact attempts thereafter and Intake deadline has passed                                                                                                                                                                                                                                                                                                                                                                   |
|                             | Pre-ITT LTFU at T/A 1                  | PPT was eligible at Intake but they stopped responding to contact attempts thereafter and T/A 1 deadline has passed                                                                                                                                                                                                                                                                                                                                                                          |
|                             | ITT Ongoing                            | This is a placeholder for PPTs who have completed a T/A 1 visit and do not fall under another ITT status (ongoing participation after T/A 1, has not completed the study)                                                                                                                                                                                                                                                                                                                    |
|                             | ITT Withdrew                           | After completing T/A 1 (criterion for ITT), PPT <b>actively</b> decided to stop participating in the study. We will not follow up with the PPT for subsequent visits.                                                                                                                                                                                                                                                                                                                        |

|  |                     |                                                                                                                                                                                                                                                                                                                                                                                                            |
|--|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | ITT Withdrawn by PI | After completing T/A 1 (criterion for ITT), PPT was withdrawn by the PI/Study Physician for some reason (e.g., inappropriate behavior)                                                                                                                                                                                                                                                                     |
|  | ITT LTFU at T/A 2   | PPT became ITT but then they stopped responding to contact attempts thereafter and T/A 2 - 5 deadlines have <i>all</i> passed                                                                                                                                                                                                                                                                              |
|  | ITT LTFU at T/A 3   | PPT attended through T/A 2, but stopped responding to contact attempts thereafter and T/A 3 – 5 deadlines have <i>all</i> passed                                                                                                                                                                                                                                                                           |
|  | ITT LTFU at T/A 4   | PPT attended through T/A 3, but stopped responding to contact attempts thereafter and T/A 4 & 5 deadlines have <i>both</i> passed                                                                                                                                                                                                                                                                          |
|  | ITT LTFU at T/A 5   | PPT attended through T/A 4, but stopped responding to contact attempts thereafter and T/A 5 deadline has passed                                                                                                                                                                                                                                                                                            |
|  | ITT Finished        | <ul style="list-style-type: none"> <li>• PPT completed T/A 5, regardless of whether they completed all T/A 2 – 4 visits</li> <li>• Although we were in communication with PPT trying to get visit rescheduled, the time window for T/A 5 passed and the PPT did not complete the visit</li> <li>• PPT was never ITT Withdrew or ITT Withdrawn by PI</li> <li>• PPT did NOT become LTFU at T/A 5</li> </ul> |

- Study Status = Withdrawn
  - a. RAs will **NEVER** assign an Overall Study Status of “Withdrawn”
  - b. If the RA believes the Study status should be updated to one of the two below, they should discuss the situation with the project coordinator
  - c. After a decision is made, the coordinator will update the status:
    - i. Pre-ITT Withdrawn by PI
    - ii. ITT Withdrawn by PI

**PHONE SCREEN MILESTONES**

| Visit               | UB Status                      | Definition                                                                                                                                                                                                                                                                                                                                                                                             |
|---------------------|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PHONE SCREEN</b> | Never Screened for Eligibility | <p>Potential PPT never completed a phone screen because:</p> <ul style="list-style-type: none"> <li>5 contact attempts, with mixed means (call, email, and text) on different days of the week, were made and the PPT was never reached (also called “Maxed Out”) OR</li> <li>started phone screen but did not finish</li> </ul> <p>Use only if PPT never <b>refused</b> participation in any way.</p> |
|                     | Refused                        | PPT indicated they were not interested in completing a phone screen for the study whether by direct communication or hanging up on an outreach call                                                                                                                                                                                                                                                    |
|                     | Pending                        | <p>This is a temporary status used when:</p> <ul style="list-style-type: none"> <li>PPT is scheduled for a PS OR</li> <li>PPT completed a phone screen, but awaiting consultation with PI/Study Physician/Coordinator to determine eligibility</li> </ul>                                                                                                                                              |
|                     | Ineligible                     | <p>Used when:</p> <ul style="list-style-type: none"> <li>PPT was deemed ineligible after completing the phone screen OR</li> <li>PPT revealed info before starting the screen that makes them IE</li> </ul>                                                                                                                                                                                            |
|                     | Eligible                       | PPT was deemed eligible at the phone screen                                                                                                                                                                                                                                                                                                                                                            |

- Contact attempts after Phone Screen:
  - All contact attempts after the Phone Screen but prior to the Intake visit should be logged in the “Intake Status notes” paragraph box, in the Intake Visit Status form
    - In the rare circumstance that the PPT is unable to schedule Intake after completing PS, note that in PS Visit Status notes
  - Update **the top** of the box with **the date of the update + initials of the staff member making the note**, followed by the update (see example below)

**Intake Status Notes:**

03/04/2025 MP: RC - PPT confirmed  
 03/03/2025 CGD: PPT called to R/S Intake to 3/5/2025  
 02/25/2025 CGD: IP IN scheduled for 3/4/2025

**INTAKE MILESTONES**

- Do not begin updating “Intake Status” until Intake has been scheduled for the first time

| Visit         | Status              | Definition                                                                                                                                                                                                                                                                                                                 |
|---------------|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>INTAKE</b> | Scheduled           | PPT has scheduled an Intake visit but it has not yet occurred                                                                                                                                                                                                                                                              |
|               | Reschedule Pending  | PPT did not attend an Intake visit and has yet to reschedule it. Once rescheduled, the status would return to “Scheduled” until they receive a different status (e.g., Eligible, Ineligible, Refused, etc)                                                                                                                 |
|               | Refused             | PPT is eligible at phone screen then actively refuses to participate <b>before signing the consent</b> form (could happen during phone screen but after eligibility determination, before intake, or during intake but before signing consent)                                                                             |
|               | Missed              | PPT missed/canceled their Intake visit and it was not rescheduled before visit deadline                                                                                                                                                                                                                                    |
|               | Withdrew            | PPT <b>signed consent</b> but decided, before completing Intake, not to participate further                                                                                                                                                                                                                                |
|               | Withdrawn by PI     | PPT was withdrawn by the PI or study physician after signing the consent form                                                                                                                                                                                                                                              |
|               | Ineligible          | PPT signed the consent form, then was deemed ineligible based on their Intake questionnaire responses or inability/unwillingness to provide informed consent                                                                                                                                                               |
|               | Eligible            | PPT signed the consent form, then was deemed eligible based on their Intake questionnaire responses<br><br>They also scheduled all their T/A visits, so <b><u>go fill out the T/A 1 status and the rest of the T/A statuses as “Scheduled”!</u></b>                                                                        |
|               | Eligibility Pending | PPT signed consent form and completed baseline questionnaires, but their eligibility was indeterminable based on their questionnaire responses. <ul style="list-style-type: none"> <li>Document the situation and that you are consulting with the project coordinator/PI/study physician regarding eligibility</li> </ul> |

- Once Intake status is “Achieved” all 5 T/A visit statuses should be updated to “Scheduled”
- All contact attempts after the Intake Visit Status is “Eligible” through completion of T/A 1 should be documented in the “T/A 1 status notes” paragraph box in the T/A 1 Visit Status form

- Update **the top** of the box with **the date of the update + initials of the staff member making the note**, followed by the update

### **T/A VISIT MILESTONES**

- Do not begin updating a T/A visit status until that visit has been scheduled for the first time
- Similarly, contact attempts from when a T/A visit is complete until the completion of the next T/A visit, should be documented in the upcoming visit status notes
  - For example, T/A 1 is complete so all of the contact attempt notes for the next visit should be documented in T/A 2 visit notes

#### **T/A 2 Status Notes:**

03/13/2025 MG: IP T/A 2 R/S for 3/13 at 12:30p. In room 304.  
 03/10/2025 MG: IP T/A 2 still on for 3/12 at 3:30p  
 03/03/2025 MG: IP T/A 2 scheduled for 3/12 at 3:30p

| Visit                       | Status             | Definition                                                                                                                                                                                                                     |
|-----------------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>T/A Visits<br/>(1-5)</b> | Scheduled          | PPT has scheduled the T/A visit                                                                                                                                                                                                |
|                             | Reschedule Pending | PPT did not attend T/A visit and has yet to reschedule it: once the visit has been rescheduled, the status goes back to “Scheduled”                                                                                            |
|                             | Missed             | PPT did not attend T/A visit within the visit window <ul style="list-style-type: none"> <li>• For T/A 1, this means the PPT did not become Intent-To-Treat (ITT) and they are no longer eligible to be in the study</li> </ul> |
|                             | Withdrew           | After completing the previous visit but before completing current visit, PPT decided to not participate further                                                                                                                |
|                             | Withdrawn by PI    | After completing the previous visit but before completing current visit, PPT was withdrawn by PI or study physician                                                                                                            |
|                             | Achieved           | PPT has completed T/A visit                                                                                                                                                                                                    |

**MILESTONING ACTIVE VS PASSIVE REFUSALS**

|                           |                                                            | <b>ACTIVE</b>                          | <b>PASSIVE</b>                                                                                                                                         |
|---------------------------|------------------------------------------------------------|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>BEFORE<br/>CONSENT</b> | Before Phone Screen                                        | Pre-ITT Refused before signing consent | Pre-ITT Never Screened for Eligibility                                                                                                                 |
|                           | During Phone Screen                                        | Pre-ITT Refused before signing consent | It's not possible for there to be passive refusal <u>during</u> the phone screen (if they hang up or say not interested, that would be active refusal) |
|                           | After Phone Screen but before signing consent at Intake    | Pre-ITT Refused before signing consent | Pre-ITT LTFU at Intake                                                                                                                                 |
| <b>AFTER<br/>CONSENT</b>  | After signing consent at Intake but before Achieving T/A 1 | Pre-ITT Withdrew                       | Pre-ITT LTFU at T/A 1                                                                                                                                  |
|                           | After Achieving T/A 1                                      | ITT Withdrew                           | ITT LTFU (@ visit at which they stopped attending)                                                                                                     |

LTFU = Lost to Follow Up

- Some Overall Study Statuses can be classified as active or passive, as well as before or after consent
- We use these terms to refer to individuals whose participation in RISE ended before study completion for a reason other than ineligibility
- ACTIVE = PPT said or did something to indicate they don't want to participate
  - Examples include:
    - Hanging up on us
      - After we state who we are when calling
      - During an initial outreach call
      - During a phone screen
    - Stating they aren't interested via phone call, email, or text
    - Walking out of the Intake or a visit
- PASSIVE = PPT stopped communicating with study team; they didn't say/do anything to indicate they no longer want to participate but they stopped responding to our calls, texts, and emails

## **GENERAL PROCEDURES FOR MILESTONES**

1. Log into UB REDCap, select the “RISE” project, and navigate to a specific record from “Add/Edit Records” or the “Record Status Dashboard”
2. Select the “Study Status” form under the “Tracking” arm
3. Review the “Study Status at a Glance” at the top of the form for an overview of the record’s progress throughout the study
4. Confirm that you should milestone an event by considering if recently:
  - a. A potential PPT has completed a phone screen
  - b. A PPT or potential PPT has rescheduled a visit
  - c. A PPT has completed a visit
  - d. A PPT or potential PPT has maxed out their contact attempts
  - e. A PPT or potential PPT has reached the reschedule limit
  - f. A PPT or potential PPT has missed the latest possible date of a visit
  - g. A PPT or potential PPT has actively refused to continue with the study
  - h. A PPT has withdrawn from the study
  - i. **If none of the above are true, do not change any milestones;** however, you may add an update to the relevant Status Notes paragraph box
5. The Study Status form should only be opened AFTER:
  - a. a phone screen, T/A 1 visit, or T/A 5 visit is complete, regardless of outcome,
  - b. a potential PPT maxes out contact attempts to complete a phone screen (PS),
  - c. a potential PPT refuses to complete a PS, or,
  - d. a potential PPT is clearly ineligible for the study before beginning the PS
6. Anytime you milestone an event:
  - a. Fill out “Status date” to reflect **the date the milestone was achieved**
    - i. This may NOT be the date you are filling out the Study Status form!
  - b. Assume that a researcher will rely on the “Status notes” in conjunction with the categorical “Study Status” to pinpoint a PPT’s exact status in the RISE study
  - c. Sign the entry with your REDCap username (which will be filled in automatically)
  - d. “Quality control check is complete” will only be completed by the study coordinator once Quality Control has been done for that form
  - e. Save the Study Status as “Unverified” (If the study coordinator has checked the box for “Quality control check is complete”, make sure this form is saved as “Complete”)
7. If you update a status that is not best illustrated through the drop-down choices, always include as much detail as reasonably possible in the “Status notes” paragraph box

- 8.** For all cases discussed in this SOP, “No-show” refers to a PPT who misses a visit without giving the research team at least 48 hours’ notice
  - a. We will work to reschedule no-shows within the window for the visit