

QUICK GUIDE FOR THE R2R PROCESS FOR INITIAL SUBMISSIONS IN RUTH

CREATE NEW SUBMISSION

IF NUMBER

- Always CAPITALIZE the IF
- If BRANY is the IRB of record and negotiating the contract, type BRANY in the IF field.

BASIC STUDY INFORMATION

- #2 SHORT TITLE: Add a short title, as this will be the visible title in the dashboard spaces
- #4 WHAT KIND OF STUDY IS THIS: Always single-site study, regardless of the number of external sites or Sinai locations that the study will be conducted at.
- #7 ATTCH THE PROTOCOL: Attach the sponsor protocol or grant application

EXTERNAL IRB

- #1 EXTERNAL IRB: Choose the external IRB from the list
- #2 EXTERNAL STUDY ID: List the external study number if known
- #3 SPECIFY THE REASON: Explain why this study should be reviewed by an external IRB (i.e., industry-sponsored multi-site clinical trial, NIH sIRB mandate)

STUDY FUNDING SOURCES

- Confirm that the sponsor pulled correctly from the Sinai Central via the IF listed.
- If BRANY is negotiating the contract, add the sponsor

LOCAL STUDY TEAM MEMBERS

- Confirm that study team members pulled correctly from Sinai Central
- You can add additional Administrative staff that are not listed on the IF at this time.
 - Role must be listed as “Administrative Staff (non-FCOI)”
 - These individuals cannot be involved in the consent process

STUDY SCOPE

- Click the [Ancillary Review Form](#)
- This is required for all studies
- Attach the completed form to RUTH submission
- Assign all Ancillary Reviews indicated in the form by clicking the Manage Ancillary Reviews button prior to submission

LOCAL RESEARCH LOCATIONS

- Add all Sinai locations where the research will be conducted

LOCAL SITE DOCUMENTS

- Consent Forms: Attach all study consent forms
- Recruitment Materials: Not required for R2R submissions
- Other Attachments: Attach all other applicable documents indicated in the HRP-232 that have not been uploaded
 - Attach as Reliance – External IRB Document
- Click FINISH

SUBMISSION WORKSPACE

- Assign all Ancillary Reviews indicated in the form by clicking the Manage Ancillary Reviews button prior to submission
- Assign Primary Contact for the study
- Assign PI Proxy(s) (This can only be done by the PI)
- Confirm that study team members have current CITI training via the TRAINING TAB

- Click SUBMIT to send to PPHS for initial review

INITIAL REVIEW

- If additional information is needed, the submission will be returned for CLARIFICATION REQUESTED. Address clarifications, then resubmit.
- When initial review is complete:
 - Study will move to Pending sIRB Review in Work Flow Map
 - Signed Reliance Documents are available by clicking the History Tab
 - Revised HRP-232 and comments from Ancillary Reviewers will be available in the History Tab.
 - Address the revisions prior to submitting to the external IRB

WHEN EXTERNAL IRB APPROVAL HAS BEEN OBTAINED

- Open study from EXTERNAL IRB TAB
- Click EDIT STUDY
- Click LOCAL SITE DOCUMENTS
- Add approved ICFs to CONSENT FORMS SECTION (Attach as Reliance – External IRB Document)
- Add Approval Letter to OTHER ATTACHMENTS (Reliance – External IRB Document)
- Click EXIT
- Click ADD COMMENT
 - #1 COMMENT: External IRB approval documents attached
 - #3 Who should receive an email notification? >> IRB Coordinator

WHEN ALL LOCAL OFFICES ARE COMPLETED AND CTA/AGREEMENTS HAS BEEN SIGNED

- The study will be moved to Review Complete.
- PI and Primary Contact will be notified
- Log into RUTH to access documents via the DOCUMENTS TAB.