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: Choose Multi-site.
- #7 ATTACH 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-232R 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) for “1. Select study team members to act as proxy” (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 CLARIFICATIONS 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-232R 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
- Attach approved ICFs to CONSENT FORMS SECTION (Use "Update" to replace draft copies without adding or deleting)
- Attach 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

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WHEN ALL LOCAL OFFICE REVIEWS ARE COMPLETED

- The study will be moved to Active.
- PI, PI Proxy(s) and Primary Contact will be notified
- Log into RUTH to access documents via the DOCUMENTS TAB.
- Note: The PPHS letter will be sent even if the FACTS CTA is pending. However, it is the responsibility of the study team to ensure that that CTA has been fully executed prior to beginning any research-related activities.