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GUIDANCE: R2R Initial Submissions in RUTH

Studies that plan to use an external IRB for review must be submitted in RUTH for local review by PPHS and any other relevant ancillary offices. The local pre-review must be completed prior to the external IRB review. Follow this guide to prepare your R2R study application in RUTH.

Only certain studies may be permitted to use an external IRB. Your study must meet at least one of the following criteria to use the R2R process:

- Research is an Industry-sponsored Multi-Center Clinical Trial where all must be true:
 - The Mount Sinai PI is not the overall PI of the Trial
 - The sponsor holds the IND/IDE
 - The study is not a first-in-human study
 - The study is not planned emergency research
 - The study does not involve the use of any [Schedule 1 drugs](#)
- Research is federally-funded and use of a single IRB is mandated as part of the grant
- Research is a Major Multi-Center Research Consortium Project
- Mount Sinai PI is a Collaborator on Human Research Primarily Conducted at Another Organization and PI's Role does not Include Interaction or Intervention with Subjects
- Mount Sinai is Engaged in the Human Research Solely Because it is Receiving Federal Funds

GCO SUBMISSION AND TRIGGERING EVENT FORM

As with any other study initial submission, you must also create a GCO submission for the project in InfoEd and create a Triggering Event (TE) Form to disclose study personnel financial interests in eDMS. These other submissions do not need to be approved before you begin your application in RUTH, but you must start them in order to receive tracking numbers from those other systems to cross-reference in your RUTH application. Links to those systems and more detailed directions for each may be found on the PPHS website:

<https://icahn.mssm.edu/research/pphs/researcher>

CREATE NEW SUBMISSION IN RUTH

Follow the directions below in the order of the screens that appear when creating a new submission in RUTH.

TRIGGERING EVENT (TE) FORM NUMBER

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

BASIC STUDY INFORMATION



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- #2 SHORT TITLE: Add a short title, as this will be the visible title in the dashboard spaces
- #3 BRIEF DESCRIPTION: Include a concise summary of the study, preferably one paragraph
- #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 eDMS via the TE Form listed. If BRANY is negotiating the contract, add the sponsor

LOCAL STUDY TEAM MEMBERS

- Confirm that study team members were pulled correctly from eDMS
- You can add additional Administrative staff that are not listed on the TE form 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. If BRANY is negotiating the contract, do not assign FCOI as an Ancillary Review, as FCOI will be managed by BRANY. Contact your BRANY representative for the proper steps for FCOI review.

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



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- 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. Resubmit when all requested changes are made and all ancillary offices complete their reviews.
- 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

WHEN ALL LOCAL OFFICE REVIEWS ARE COMPLETED



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- 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.