

QUICK GUIDE FOR THE R2R PROCESS FOR MODIFICATION SUBMISSIONS IN RUTH

Note: Modifications under the purview of an external IRB do not need to be submitted to the ISMMS PPHS unless they also affect local requirements (e.g. change in PI, change in recruitment procedures, change in a conditional office review – RSC, IDS, FACTS, etc.). The most recent versions of all study materials should be included at the time of Continuation Review.

- Click on the active study from the External IRB Tab
- Click UPDATE STUDY DETAILS
- Fill in the summary of the updates. Click Continue.
- The full Smart Form opens up for modification.
 - Update the applicable fields that are affected by the modification.
 - Upload any new or updated documents.
 - Upload the completed HRP-388 and assign any Ancillary Reviews indicated for any modification that includes Other Parts of the Study. This document is not required if the only change is updating Study Team Members.
 - If no Ancillary Reviews are necessary AND the modification does not impact any Sinai-specific consent form language or any Sinai policies and/or practices, the modification does not need to be submitted at this time and should be discarded. It should be submitted at the time of Continuing Review.
 - If personnel changes are made, please update the IF, as needed. The IF does not need to be updated if the personnel is “Administrative Staff – Non FCOI Role”.
- Click **FINISH**. *There is no Submit Button.*
- IF personnel (other than Non COI Role) is added with the Modification:
 - Click **Manage Ancillary Reviews**: FCOI assigned (for all non-BRANY studies if BRANY negotiated the contract). *Only the PI or PI Proxy will be able to complete these steps.*
- When the Submission is ready for PPHS review.
 - Click **ADD COMMENT**.
 - Write **Modification Submission is ready for PPHS review**. Send comment to IRB Coordinator. This will start the reviewing process.
DO NOT click **Finalize Updates**. *If you do, you will not be able to edit study details and any modifications to this submission will require you to submit a new “Update Study Details” submission. Only the Reviewing Analyst should Finalize Updates.*

WHEN PPHS CR REVIEW AND GCO REVIEW ARE COMPLETE

- Approval dates will be updated in the Study Workspace
- No acknowledgement letters will be sent upon completion of CR submissions