

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.
 - 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”.

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