



IMPORTANT INFORMATION

1. **EXTERNAL IRB APPROVAL IS NOT ENOUGH!** The following criteria must be met before PPHS will grant permission to continue research activities:
 - a. External IRB approval letter must be received by PPHS
 - b. GCO submission must be started, *if the project involves external funding* or *“if required, per [GCO policy](#)”*
 - c. Annual IF must be completed
 - d. “Update Study Details” submission submitted to PPHS in RUTH
 - e. All study personnel have current CITI training
 - f. Manage Ancillary Reviews: FCOI assigned (for all non-BRANY studies if BRANY negotiated the contract)
 - g. When the above criteria are satisfied, PPHS will add a comment in RUTH, which will notify the PI, PI Proxy and Primary Contact that research-related activities may continue while the local continuing review process is completed.
2. It will be required at the time of continuing review to do the following for the study if it hasn't been done previously:
 - a. Training Tab: If any personnel are missing their training record, ask the individual to update their CITI profile with their institutional email address and life number so RUTH and CITI can properly link it.
 - b. Training Tab: Confirm that education is current for all personnel.
 - c. Local Study Team Members: Update study roles
 - d. Local Study Team Members: Update/confirm whether each individual is authorized to obtain consent.

CHANGES TO THE R2R CONTINUATION PROCESS WITH THE ROLLOUT OF RUTH

- Upon completion of the local review of the continuing review:
 - The approval dates will be updated in RUTH (new approval dates will only show in the Parent Study)
 - No acknowledgement letter will be sent. PPHS will add a comment in RUTH, which will be sent to the PI, PI Proxy and Primary Contact that states “Local CR is complete”.
 - GCO receives a daily report of approved submissions and study funds will be available.

FCOI REVIEW FOR ALL STUDIES EXCEPT IF BRANY NEGOTIATED THE CONTRACT

- FCOI Review is required for all R2R continuing review submissions EXCEPT if BRANY is the IRB of record AND negotiated the contract. If this applies, skip to BRANY section below.
- Six weeks prior to expiration, create the new Investigator Form (IF). *Note: FCOIR has three weeks to complete their review.*
- Log in to RUTH. *Only the PI or PI Proxy will be able to complete these steps.*
- Locate the study by clicking IRB >> External IRB Tab >> Locate the study in the list
- Click **Update Study Details**
 - Fill out 1. Summarize the updates
 - Add “Continuing review approval submission”

QUICK GUIDE FOR THE R2R PROCESS FOR CONTINUING REVIEW SUBMISSIONS IN RUTH



- Add new IF number
 - If making any modifications, list a summary of the modifications
 - Update applicable pages and fills, as summarized in the “Summarize the Updates” field.
 - Local Study Team Members Page:
 - Update study personnel. All study personnel (other than Administrative Staff – Non-FCOI) must be listed on the IF.
 - Update roles for each member of the team listed as “In Limbo”
 - Update/confirm whether each individual is authorized to obtain consent.
 - Local Site Documents Page:
 - Consent Forms: Attach updated consent form(s), if applicable
 - Other Attachments: Attach external IRB approval letter (Category: Reliance – External IRB Document)
 - Attach other updated documents that have not been submitted since the previous PPHS review.
- Click **FINISH**. *There is no Submit Button.*
- **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 **Continuation 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.*
- If the FCOIR issues a new or revised Management Plan:
 - Obtain all required researcher signatures;
 - Revise consent forms, as indicated in the COI Management Plan;
 - Submit the signed COI Management Plan and revised consent forms with to the external IRB.
- When external IRB approval documents are received, confirm the following prior to submission in RUTH:
 - Documented acknowledgement of the COI Management Plan on the approval letter
 - Approved consent forms contain COI language
 - If approval documents are incomplete, work with the external IRB to obtain revised documents prior to submission to PPHS.
- When COI Review is complete and external IRB has approved documents related to the COI:
 - Click **EDIT STUDY DETAILS**
 - Click **STUDY UPDATE DETAILS**
 - Click **LOCAL SITE DOCUMENTS**
 - Attach the following:
 - Continuation for a study enrolling subjects with a new COI Management Plan:

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- **Consent Forms:** Approved consent form(s) with applicable COI language
- **Other Attachments:** External IRB approval letter with documented approval of COI Management Plan and revised consent form(s)
- **Other Attachments:** Signed COI Management Plan
- Continuation for a study closed to enrollment with a new COI Management Plan:
 - **Other Attachments:** External IRB approval letter with documented approval of COI Management Plan
 - **Other Attachments:** Signed COI Management Plan

BRANY CONTINUING REVIEWS IF BRANY NEGOTIATED THE CONTRACT

If BRANY is the IRB of record AND negotiated the contract:

- Log in to RUTH. *Only the PI or PI Proxy will be able to complete these steps.*
- Locate the study by clicking IRB >> External IRB Tab >> Locate the study in the list
- Click **Update Study Details**
 - Fill out 1. Summarize the updates
 - Add “Continuing review approval submission”
 - Add “BRANY study where BRANY negotiated the contract”
 - If making any modifications, list a summary of the modifications.
 - 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.
 - Update applicable pages and fills, as summarized in the “Summarize the Updates” field.
 - Local Study Team Members Page:
 - Update study personnel. All study personnel (other than Administrative Staff – Non-FCOI) must be listed on the IF.
 - Update roles for each member of the team listed as “In Limbo”
 - Update/confirm whether each individual is authorized to obtain consent.
 - Local Site Documents Page:
 - Consent Forms: Attach updated consent form(s), if applicable
 - Other Attachments: Attach external IRB approval letter (Category: Reliance – External IRB Document)
 - Attach other updated documents that have not been submitted since the previous PPHS review.
- Click **FINISH**. *There is no Submit Button.*
- When the Submission is ready for IRB review.
 - Click **ADD COMMENT**.

QUICK GUIDE FOR THE R2R PROCESS FOR CONTINUING REVIEW SUBMISSIONS IN RUTH



- Write **Continuation Submission is ready for IRB 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 can Finalize Updates.*

PPHS REVIEW OF CONTINUING REVIEW DATA

- PPHS will review submitted information and documents
- PPHS will confirm completion of annual GCO submission in InfoEd
- Any issues with the submission will be communicated by PPHS adding a comment in RUTH, which is send an email to the PI, PI Proxy and the Primary Contact

WHEN PPHS CR REVIEW AND GCO REVIEW ARE COMPLETE

- Approval dates will be updated in the Study Workspace.
- Update Study details will be finalized.
- PPHS will write and send a comment to PI, PI Proxy and Primary Contact that the local CR review is complete.
- No acknowledgement letters will be sent upon completion of CR submissions.