GUIDANCE: R2R Continuing Review-Final Report Submissions		
NUMBER	DATE	PAGE
HRP-917	04/14/2025 09/09/2024 08/01/2023 03/27/2023	1 of 6

GUIDANCE: R2R Continuing Review - Final Report Submissions

Continuing Reviews

Studies using an external IRB for review are required to submit a Continuing Review application in RUTH in order to document the terms of their ongoing approval and complete annual institutional requirements (i.e., COI, GCO, CITI). In addition to the continuing approval, this application captures any amendments from the previous approval period that did not require prompt submission in RUTH for PPHS and/or ancillary office review. Follow this guide to prepare your Continuing Review submission in RUTH.

DETERMINE WHICH TYPE OF RUTH SUBMISSION YOU WILL NEED

There are two types of submissions for a multi-site external IRB study (R2R). It is important to understand what you can submit with each submission type. For example, if you are submitting a Continuing Review approval letter and a new protocol, you will need to create both submissions.

1. **CREATE SITE MODIFICATION (sMOD)**
    - This submission should be used to register R2R continuing reviews and site closures, as well asR2R modifications that impact local context such as new/updated ICFs and local recruitment materials
    - This submission type will allow you to make changes to the following sections of the RUTH SmartForm:
        - Basic Site Information (Local PI, activities that site will perform)
        - Additional Local Funding Sources: There will rarely be a local funding source for a multi-site study under an external IRB.
        - Local Study Team Members
        - Local Research Locations
        - Local Site Documents: Sinai ICF(s), Sinai recruitment materials, external IRB *Continuing Review* approval letter, associated external IRB Modification approval letters (e.g. changes to site ICF)
        - Imaging

2. UPDATE STUDY DETAILS (USD):

- This submission should be used to register R2R modifications that do not impact local context (i.e., updating protocol, IB, etc.). This submission type should ONLY be used for documents that are used study-wide. While RUTH will allow for study closures to be submitted through this process, the PPHS asks that you not do so and, instead, submit study closures using the Site Modification submission type.
- This submission type will allow you to make changes to the following sections of the RUTH SmartForm:
    - Basic Study Information (title, protocol, identifiers)
    - External IRB
    - Study Funding Sources
    - Study Scope
    - Drugs
    - Devices
    - Study-Related Documents (e.g., IBs, package inserts, associated external IRB Modification approval letters (e.g., for Protocol or IB changes)).

STEP 1: 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 Triggering Event (TE) Form in eDMS. All staff listed on the TE need to complete their disclosure before FCOIR can begin their review process. *Note: Once FCOIR begins their review, they have 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 **CREATE SITE MODIFICATION**
    - Choose the modification type (you can select one or both options):
        - Select **STUDY TEAM AND RESEARCH LOCATION INFORMATION** if you need to make changes to either the study team or the location.

        - Select **OTHER PARTS OF THE STUDY** to upload the CR approval letter/documents
    - In the RUTH SmartForm,
        - Fill out 1-2
        - Fill out 3. Summarize the modifications, as indicated below:
            - Add “Continuing review approval submission”
            - Add new TE Form number
            - If making any modifications, list a summary of the modifications
        - Update applicable pages and fields, as summarized in the “Summarize the Modifications” field.
        - Local Study Team Members Page:
            - Update study personnel. All study personnel (other than Administrative Staff – Non-FCOI) must be listed on the TE Form.
            - Update roles for each member of the team listed as “In Limbo”
            - Update/confirm whether each individual is authorized to obtain consent.
            - Make sure the PI is not listed in the Local Study Team Members page.
        - Local Site Documents Page:
            - Consent Forms: Attach updated consent form(s), if applicable
            - Other Attachments: Attach external IRB continuing review approval letter (Category: Reliance – External IRB Document)
            - Attach other updated documents that have not been submitted since the previous PPHS review. If protocol or IB have been updated, create an **UPDATE STUDY DETAILS** submission to submit.
        - Click **FINISH.**
- Click **SUBMIT.** *Only the PI or PI Proxy will be able to complete this step.*
- Click **Manage Ancillary Reviews:** Assign FCOI (for all studies except those where BRANY negotiated the contract). *Only the PI or PI Proxy will be able to complete this step.* All staff listed on the TE need to complete their disclosure before FCOIR can begin their review process. *Note: Once FCOIR begins their review, they have three weeks to complete their review.*
    - You can check the status of the FCOIR review on the REVIEWS Tab in RUTH.
    - If the FCOIR issues a new or revised Management Plan (it will be an attachment in the REVIEWS Tab):
        - 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 for IRB review and approval.
- When external IRB approval documents are received, confirm the following prior to submission in RUTH (if applicable):
    - 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 external IRB has approved documents related to the COI (if applicable):
    - Click **EDIT MODIFICATION**
    - Click **MODIFICATION DETAILS**
    - Click **LOCAL SITE DOCUMENTS**
    - Attach the following in the RUTH SmartForm:
        - Continuation for a study enrolling subjects with a new COI Management Plan:
            - **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
    - Click **SUBMIT RESPONSE.**

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 **CREATE SITE MODIFICATION**
    - Choose the modification type (you can select one or both options):

- Select **STUDY TEAM AND RESEARCH LOCATION INFORMATION** if you need to make changes to either the study team or the location.
- Select **OTHER PARTS OF THE STUDY** to upload the CR approval letter/documents

- In the RUTH SmartForm,
  - Fill out 1-2
  - Fill out 3. Summarize the modifications, as indicated below:
    - Add “Continuing review approval submission”
    - Add “BRANY study where BRANY negotiated the contract”
    - If making any modifications, list a summary of the modifications
  - Update applicable pages and fields, as summarized in the “Summarize the Modifications” field.
  - Local Study Team Members Page:
    - Update study personnel.
    - Update roles for each member of the team listed as “In Limbo”
    - Update/confirm whether each individual is authorized to obtain consent.
    - Make sure the PI is not listed in the Local Study Team Members page.
  - 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. If protocol or IB has been updated, create an **UPDATE STUDY DETAILS** submission.
- Click **FINISH.**

- **NOTE:** 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.
- Click **SUBMIT.** *Only the PI or PI Proxy will be able to complete this step.*

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 in RUTH.

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.
- An acknowledgement letter will **not** be sent upon completion of CR submissions.

Final Reports

- Navigate to the 'Follow-on Submissions' tab of the study in RUTH and check to see if there are any active submissions opened. Make sure that all active submissions are either completed or discarded before proceeding with study closeout.
- Click **CREATE SITE MODIFICATION**, and select the modification type: **OTHER PARTS OF THE STUDY**.
    - *Do not use an **UPDATE STUDY DETAILS** submission to submit the study closure.
- Click **EDIT MODIFICATION**.
    - Modification Summary page: specify that this is a study closure under Modification Information- 3. Summarize the modifications.
    - Local Site Documents page: Attach the IRB approval letter for the study closure to Local Site Documents- 3. Other attachments.
- Click **SUBMIT RESPONSE**.