CHECKLIST: RUTH R2R Continuing Reviews

The purpose of this checklist is to provide support for research teams with preparing a continuing review submission in RUTH. All submissions to the IRB are made through RUTH. To access RUTH, visit [ruth.mssm.edu](http://ruth.mssm.edu/) and log in with your Mount Sinai single sign-on credentials (email and network password).

Submissions that are in Clarifications Requested for four weeks will be withdrawn by PPHS due to lack of response.  The submission may be resubmitted once the requested changes have been made at any time.

CONTINUING REVIEW

**To create a continuing review submission in RUTH, navigate to the parent study. The parent study is the approved study that is found on the Active tab of the IRB submissions page in RUTH. On the left side of the screen choose “Create Site Modification” then “Other parts of the site” for the Modification Scope; if the continuing review is coupled with personnel changes, also select “study team and research location information” for the scope.**

**All continuing review submissions shall be submitted to RUTH no later than 6 weeks prior to local expiration of the study.**

All personnel on the project must upload their current CV/resume/biosketch to their profile and remove any outdated CVs. Only the individual can upload their own CV/resume/Biosketch to their profile. Remember that the uploaded document must list Mount Sinai as the current employer, school, etc. To do this:

The individual can log into RUTH using their Mount Sinai single sign-on credentials.

The individual will click on their name in the top right corner of the RUTH screen and follow the prompts for a CV upload.

Navigate to eDMS ([edms.mssm.edu](https://edms.mssm.edu/COI/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5b0A7646F3B149874E902185897C144551%5d%5d)) to complete a Triggering Event (TE) Form and obtain a TE#. All projects must have a current TE Form completed in the eDMS system. A new TE Form is required every year.

All personnel must complete their FCOI disclosures in the TE Form for the new external funding. Only the individual personnel can complete their FCOI disclosures. All disclosure must be complete before FCOI can review the submission.

☐ To assign FCOI review, click “Manage Ancillary Reviews”, then click ‘Add.’ Then:

☐ For item 1: Select Financial Conflict of Interest (FCOI) for ‘Organization’ and leave ‘Person’ blank

☐ For item 2: Select FCOI

☐ For item 3: Select ‘Yes’

☐ Click ‘OK’ at the bottom of the page

☐ Note: Once FCOI review has been managed, **do not** click the “update” button

List the current TE number in the “Summarize the Modifications” field in RUTH

All personnel must complete PPHS required education modules through [CITIProgram.org](https://www.citiprogram.org/) unless BRANY is managing the contract. All training modules must be kept up-to-date. These courses are:

Basic course for investigators/ research staff (refresher needed every 3 years)

Data Security and HIPAA training

HIPAA for research update

Rigor, Reproducibility and Ethical Behavior in Biomedical Research (only for *faculty, students, residents, fellows*)

GCP for Clinical Trials with Investigational Drugs and Biologics (*if your project is FDA regulated or if required by external sponsor*). A refresher is not required by the PPHS but may be required by your study sponsor.

All externally funded projects, except for industry-funded studies initially submitted after Jan 1, 2024 (if your industry-funded study has a GCO number, InfoEd continuing review submissions are still required), must have an InfoEd submission for a Grants & Contracts Office (GCO) review. Externally funded means that the study is not School-sponsored and is not a cooperative group sponsored research. Contact GCO at [GCO@mssm.edu](mailto:GCO@mssm.edu) for further assistance on navigating the Infoed system.

Use the “Manage Ancillary Reviews” button to assign Financial Conflict Of Interest (FCOI) – this is required for all continuing review submissions.

Attach the external IRB’s continuing review approval letter or check-in letter in Local Site Documents under the “Other attachments” section

Fill in all RUTH smart form fields for continuing review. Use the question mark icon to understand what detail is expected for each field in the RUTH Smart form and ensure you provide complete and accurate information in all fields.

You must use the HRP-903-Guidance-PPHS File Naming Convention when labelling documents.

After clicking the Finish button, you’ll be taken back to the project workspace. Click SUBMIT on the left side of the screen. Only the PI and PI proxy are able to click SUBMIT. Without clicking SUBMIT, the submission has not been sent to the IRB for review and will remain with the study team until SUBMIT is clicked.

The PI proxy is a role assigned to a study team member by the PI. Only the PI can assign a PI proxy. There can be multiple PI proxies assigned to a project. See HRP-924-Guidance-CV-PI Proxy-Primary Contacts.