CHECKLIST: RUTH Modifications

The purpose of this checklist is to provide support for research teams with preparing a modification submission in RUTH. All submissions to the IRB are made through RUTH. To access RUTH, visit [ruth.mssm.edu](http://www.ruth.mssm.edu) and log in with your Mount Sinai single sign-on credentials (email and network password). For R2S submissions, please reach out to PPHS for submission instructions. For R2R submissions, please refer to the HRP-918-Guidance-R2R Modifications in RUTH available in the RUTH Library > General tab.

Before you proceed with this checklist, become familiar with the IRB University 101, IRB University 201, and the RUTH training courses in PEAK if you have not done so. This checklist is not a substitute for those training courses.

Study team member updates must be submitted in real time. IRB/PPHS approval for study team member updates must be obtained prior to involvement in any human subject research-related activities.

Submissions that are in Clarifications Requested for four weeks will be withdrawn by PPHS due to lack of response.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.

STUDY TEAM MEMBER MODIFICATIONS ONLY

**To create a modification in RUTH to only add or remove study team members to the project, navigate to the parent study.**

* **On the left side of the screen choose “Modification/CR”, then “Modification”.**
* **Choose “Study Team Member Information” as the modification scope.**

**\*Tip: How to use the ‘compare’ tool to track personnel changes on a modification:\*** Navigate to 'Edit Modification' on the left side of the screen > Click 'compare' at the top left of the screen > Click the carrot under 'Compare current state of version', then click the *last* row under 'Version Description' > Navigate to the Local Study Team Members page to see list of all personnel modifications being done.

All personnel on the project must upload their CV/resume/biosketch to their profile. See [CV/PI Proxy/PC Quick Guide](https://icahn.mssm.edu/files/ISMMS/Assets/Research/PPHS/RUTH%20Quick%20Guide%20-%20CV-PI%20Proxy-Primary%20Contact.pdf). 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.

☐ Ensure there is only one CV uploaded per study team member

Ensure all added personnel involved in the design, conduct or reporting of the study have been added to the Triggering Event in eDMS and completed FCOI disclosures. All staff added to the TE need to complete their disclosure before FCOIR can begin their review process. Do not submit until all added personnel have completed the TE. Note: Once FCOIR begins their review, they have three weeks to complete their review.

All personnel must complete PPHS required education modules through [CITIProgram.org](https://www.citiprogram.org/). 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.

Ensure all added personnel’s completed CITI education is reflected on RUTH’s training tab. Once a CITI course is completed, it will be reflected in RUTH the following day.

State in “Summarize the Modification”, list the TE# (if personnel were added to the TE) and the names of the personnel being added and/or removed from the study team and include justification for the change. The PI does not have to be added to the study team member list since they are already listed on the study as PI.

Ensure that all added personnel are listed under one role. If their role is Administrative non-FCOI or Volunteer, they should not be involved in the consenting process.

Use the “Manage Ancillary Reviews” button to assign Financial Conflict of Interest (FCOI) – this is always required when you are adding new study team members unless adding Administrative non-FCOI personnel only (Note: FCOI review is not required for personnel *removal*).

All staff added to the TE need to complete their disclosure before FCOI can begin their review process. Do not submit until all added personnel have completed the TE process.

☐ 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

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. [See HRP-924 CV-PI Proxy-Primary Contacts](file:///C:\Users\ntowk01\Documents\Guidance%20Documents\HRP-924-Guidance-CV-PI%20Proxy-Primary%20Contacts%20(10.21.2020).pdf).

OTHER PARTS OF THE STUDY MODIFICATIONS

**To create a modification in RUTH for other parts of the study, navigate to the parent study.**

* **On the left side of the screen choose “Modification/CR”, then “Modification”.**
* **Choose “Other Parts of the Study” as the modification scope.**

Complete the Modification Summary field listing each change and provide the justification for each change listed. Include the TE# in the Modification Summary if modified (personnel addition) or created (new external funding).

If modifying the project to add external funding, externally funded projects are required to have an InfoEd submission. Contact the Grants & Contracts Office (GCO) at [GCO@mssm.edu](mailto:GCO@mssm.edu) for further assistance on navigating the Infoed system.

If modifying the project to add external funding:

Navigate to eDMS to complete a Triggering Event (TE) Form and obtain a TE#.

Once logged into eDMS, navigate to the COI link in the left side menu. If no COI link is available, contact the FCOI office at [Conflicts.of.Interest@mssm.edu](mailto:Conflicts.of.Interest@mssm.edu) for assistance with obtaining a COI link.

Click on the Triggering Event (TE) link underneath the COI link. Then click on the new Triggering Event Form to complete it.

Record the TE# that is listed next to ID on the form. You will be required to enter this TE# into your RUTH submission.

All personnel must complete their FCOI disclosures in the TE packet for the new external funding. Only the individual personnel can complete their FCOI disclosures. All staff added to the TE need to complete their disclosure before FCOIR can begin their review process. Do not submit until all added personnel have completed the TE. Note: Once FCOIR begins their review, they have three weeks to complete their review.

Attach a completed HRP-215 comparative review form. This form is found in the RUTH library under the General tab.

Update documents per the modification

To update existing documents throughout the RUTH smart form (preserve the document history), click on the Update button next to the existing files and then replace with the new document. ***Do not delete existing documents just to re-upload updated versions of that same document.***

Update any fields throughout the RUTH smart form affected by the modification.

You must use PPHS’s document naming convention when labelling documents. [Click here to download the HRP-903 PPHS Naming Convention.](file:///C:\Users\ntowk01\Documents\Guidance%20Documents\HRP-903-Guidance-PPHS%20File%20Naming%20Convention%20(02.01.2021).pdf)

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