CHECKLIST: RUTH Continuing Review-Final Reports

The purpose of this checklist is to provide support for research teams with preparing a continuing review or final report 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). For R2S submissions, please reach out to PPHS for submission instructions (irb@mssm.edu). For R2R submissions, please refer to the HRP-917-Guidance-R2R Continuing Reviews in RUTH or HRP-919-Guidance-R2R Closeout Submissions in RUTH both available in the RUTH Library > General tab.

Before you proceed with this checklist, it may be helpful to 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.

Submissions that are in Clarifications Requested for four weeks will be withdrawn by PPHS due to lack of response.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 “Modification/CR”, then “Continuing Review”.**

[ ] All personnel on the project must upload their CV/resume/biosketch to their profile. 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.

[ ]  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.

[ ]  All externally funded projects 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 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 a brief narrative summary of the research progress. Refer to the HRP-935-Guidance-Continuing Review Progress Report Instructions (found in the RUTH Library under General).

[ ]  Attach NIH/FDA progress reports, if applicable.

[ ]  Attach DSMB Reports, if applicable.

[ ]  Attach Adverse Event logs, if applicable.

[ ]  Complete and attach the HRP-212B, if study involves specimen/data banking (found in the RUTH Library under General).

[ ]  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.

FINAL REPORT

**To close out a study 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 “Modification/CR”, then “Continuing Review”.**

[ ]  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.

 [ ]  In Question #4, in order to close the study, the first four boxes must be answered/selected

[ ]  Attach a final report document providing a progress report of the last year of the study, providing information on why the research is being closed and what the plans are for the data and/or samples collected in the study, whether the data are being archived, destroyed or sent off site, etc. Please be sure to review the ISMMS Faculty Handbook for your responsibilities/requirements on data management/storage, etc.

[ ]  Attach NIH/FDA progress reports, if applicable.

[ ]  Attach DSMB Reports, if applicable.

[ ]  Attach Adverse Event logs, if applicable.

[ ]  Complete and attach the HRP-212B, if study involves specimen/data banking (found in the RUTH Library under General).

 [ ]  If the study is banking specimen/ data, then the study cannot be closed. See your consent form for more information. If you have future use/banking questions its unlikely your project can be closed. Contact the IRB@mssm.edu email box for help.

[ ]  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.