CHECKLIST: RUTH Continuing Reviews-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 refer to the HRP-820 - FORM - R2S Overall Progress Report and HRP-812 - FORM - Site Continuing Review, available in the RUTH Library > General tab.

For R2R submissions, please refer to the HRP-454 – Checklist - RUTH R2R Continuing Reviews, available in the RUTH library > Checklist tab. You can also refer to the HRP-917-Guidance-R2R Continuing Reviews in RUTH, 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Submissions that are in Clarifications Requested for four weeks will be withdrawn by PPHS due to lack of response.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. The uploaded document must list Mount Sinai as the current employer, school, etc. To do this:

[ ]  The individual must log into RUTH using their Mount Sinai single sign-on credentials.

[ ] The individual must 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. Only the individual personnel can complete their FCOI disclosures. All disclosures must be completed 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.

[ ]  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. (\*\*\***Note -** If your study is industry funded, the contract is managed by FACTS, and your study did not make an initial GCO submission before Jan 1 2024 - no GCO submission is needed.) 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. The FCOI office should be added as both the “Organization” as well as the “Review Type” when assigning them. Question #3 “Is a response required?” should be answered YES.

[ ]  Enrollment questions – Questions #1 - #3: These questions should be answered accurately and should be consistent with:

[ ]  The enrollment numbers reported in the progress report document attached to question #6 of this submission (see below for additional details).

[ ]  The previous year’s continuing review submission. (e.g. Last year’s reported local enrollment total, when added to your response to question #2 “Specify enrollment totals at this investigator's sites since last approval” should equal your response to question #1 “Specify enrollment totals at this investigator's sites”).

[ ]  Under Question #6 “Attach Supporting Documents” The PPHS file naming convention must be followed for all attached documents. Please refer to the HRP-903 File Naming Convention document found under the “General” tab in the RUTH Library for guidance.

[ ]  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 the “General” tab).

* If this study involves a retrospective chart review component, indicate the date range, from the approved HRP-503, for which this study is approved to generate data and confirm that no data have been collected outside of this range.

[ ]  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. Click on the question mark icon to learn additional information regarding what details are expected for each field in the RUTH Smart form and ensure you provide complete and accurate information in all fields.

[ ]  After clicking the Finish button, you will be taken back to the continuing review submission’s main workspace page. 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. (**\*\*\*Note -** The PI proxy is a role that can only be assigned to a study team member by the project’s PI. There can be multiple PI proxies assigned to a project. See HRP-924-Guidance-CV-PI Proxy-Primary Contacts for additional information.

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.

[ ]  Enrollment questions – Questions #1 - #3: These questions should be answered accurately and should be consistent with:

[ ]  The enrollment numbers reported in the progress report document attached to question #6 of this submission (see below for additional details).

[ ]  The previous year’s continuing review submission. (e.g. Last year’s reported local enrollment total, when added to your response to question #2 “Specify enrollment totals at this investigator's sites since last approval” should equal your response to question #1 “Specify enrollment totals at this investigator's sites”).

[ ]  In Question #4, in order to close the study, the first four boxes (Research Milestones) must be selected.

[ ]  Under Question #6 “Attach Supporting Documents” The PPHS file naming convention must be followed for all attached documents. Please refer to the HRP-903 File Naming Convention document found under the “General” tab in the RUTH Library for guidance.

[ ]  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 the “General” tab).

* If this study involves a retrospective chart review component, indicate the date range, from the approved HRP-503, for which this study is approved to generate data and confirm that no data have been collected outside of this range.

[ ]  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 will be taken back to the continuing review submission’s main workspace page. 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. (**\*\*\*Note -** The PI proxy is a role that can only be assigned to a study team member by the project’s PI. There can be multiple PI proxies assigned to a project. See HRP-924-Guidance-CV-PI Proxy-Primary Contacts for additional information.