CHECKLIST: RUTH Initial Submission

The purpose of this checklist is to provide support for research teams with preparing a new study 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 submission, please reach out to PPHS for submission instructions. For R2R submissions, please refer to the HRP-916-Guidance-R2R Initial Submissions 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.

Submissions that are in Clarifications Requested for four weeks will be withdrawn by PPHS due to lack of response.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

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.

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 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 personnel must have an appropriate role that best describes their activities on the study team. Only one role should be assigned to each personnel.

The Admin non-FCOI role is reserved for personnel only involved in administrative/ regulatory paperwork for the study. This role is not for personnel involved in the design, conduct, or reporting of the study. There may be no more than three (3) study team members with the Admin non-FCOI role.

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](mailto:GCO@mssm.edu) for further assistance on navigating the Infoed system.

For industry funded studies where the contract is manage by FACTS, if a GCO submission was not made before January 1 2024, then a GCO submission is not needed.

After completing the steps above, the following steps need to be completed in RUTH

☐ Every project requires an HRP-503 form with the application. Choose one of the three HRP-503 Application Forms to use for your application. These are found in the RUTH Library under Templates.

For record/specimen review only projects (e.g. retrospective chart reviews), use only the “HRP-503R – Record/Specimen Review Application”

For Exempt determination ([OHRP Exempt categories found here](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html)) applications, use only the “HRP-503E – Exempt Determination Application”

For all other applications, use the “HRP-503 – Full RUTH Application”

All projects require a protocol (with a few exceptions)

For studies using the HRP-503R or HRP-503E, these documents will stand as the protocol for the project. In the RUTH Smart form, upload the document on the Basic Study Information page under “Attach the Protocol”.  
 Regardless of the above, all multi-site/collaborative studies must submit a protocol.

For studies using the HRP-503 Full Application, a separate protocol must be submitted. A protocol can be an NIH grant, a sponsor protocol, or one created by the study team. A good example of a protocol can be found on the NIH website [here](https://grants.nih.gov/policy/clinical-trials/protocol-template.htm). If the NIH protocol example does not fit your project’s description, you can use the table of contents from NIH’s example for suggested headers.

Attach HRP-502 Consent forms, if applicable. All consent templates are found in the RUTH Library under Templates.

For the summary section of the consent form(s), include the Flesch-Kincaid Reading Ease Score and the Flesh-Kincaid Grade Level below. Note, all consent form summary sections included in your

application that present higher than 500 words, a Flesch-Kincaid Reading Ease grade of 70 or higher and a Flesh-Kincaid grade level of 9th or above will not be accepted and will be sent back to you for editing.

Flesch-Kincaid Reading Ease Score: \_\_\_\_\_\_

Flesh-Kincaid Grade Level: \_\_\_\_\_\_

For Exempt studies, a Research Information sheet may be needed (e.g., when interacting with people for surveys, interviews). This template (HRP-508) is found in the RUTH Library under Templates. Upload as Other Attachments > Doc Type “Research Info Sheet/Standalone HIPAA”.

Attach recruitment materials, if applicable. Ensure that there are approximately 2 inches of blank space at the bottom of each page of all the recruitment materials. This allows the RUTH approval stamp to be placed without any text being covered up.

Attach Drug/Device supporting documentation (e.g., Investigator Brochure, Package Insert, Instructions for Use)

Attach the Protocol Review and Monitoring Committee (PRMC) approval letter for all cancer-related studies.

Attach data collection sheets, if applicable

Attach Non-validated Survey/Questionnaire/ Interview instruments, if applicable

Attach any other supporting documents, if applicable

For projects where a consent form with HIPAA Authorization is not being used, complete the HIPAA Wizard found as a link in the RUTH Smart form under the Study Scope page. As directed by the HIPAA Wizard, the following forms may be needed, if applicable (all of these forms are found in the RUTH Library under Templates). Attach the completed HIPAA Wizard form along with any of the applicable forms mentioned below.

HIPAA Waiver or Alteration of Authorization form

HIPAA Request - Decedent Waiver form

HIPAA Request - De-identified Data form

HIPAA Request - Limited Data form

Limited Data form should be accompanied by the Data Use Agreement form on the PPHS website (under For Researchers --- Health Insurance Portability and Protection Act for Research (HIPAA) --- HIPAA Waivers and Data Use Agreement Template

Complete the Ancillary Review Form (found as a link in the RUTH Smart form under the Study Scope page)

While in RUTH, use the “Manage Ancillary Reviews” button on the submission workspace to assign any offices as specified on the last page of the completed ancillary review form.

Attach the completed ancillary review form to the local site documents page.

Fill in all fields of the RUTH Smart form. 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 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)

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 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).

The primary contact role can be assigned to any personnel with a Mount Sinai employee number, regardless of whether they are an approved study team member. The primary contact is required to follow the same guidelines as the Admin non-FCOI role. Only one primary contact is allowed per project.