MODIFICATION SUBMISSIONS-POST MIGRATION

For ALL MIGRATED STUDIES, you will need to submit a modification to add the HRP-503 Application Form and, if necessary, the Research Protocol. The Research Personnel Roles must be updated from the "in limbo" state and you need to indicate who will be involved in obtaining consent.

Below are the instructions on how to submit this first modification along with a quick guide of the sections that require your review and clarification prior to submission to the IRB. You can submit both a continuation and modification at the same time.

1. Open the IRB workspace by selecting the **IRB** tab**,** then select the **ACTIVE** tab**.** Search for your project. Once you locate your project, click on the study to open the workspace.
2. From the parent study workspace, select **CREATE MODIFICATION/CR** on the left-hand side of your screen**.** Select **BOTH** "Other Parts of the study" **AND** "study team member information" as the modification type. This allows you to revise all sections of the study. See the modification guidance checklist below that outlines the required revisions needed before submitting to the IRB.

MODIFICATION GUIDANCE CHECKLIST:

RUTH Submission Tab	Required Revisions/Clarification
Basic Study Information	**Review questions 1-11 to make sure all project information was migrated correctly.** • #2 SHORT TITLE: Include an abbreviated title if you need one. • #7. Attach the protocol. Teams cannot use the PDF of their IDEATE application or their previously approved HRP 503 Template as the project's protocol. It is recommended that you use the NIH Guidance Template found here or create your own protocol for your submission. Check the NIH wizard for an example. • #8 and #9. Fill in the HIPAA identifiers and the related Health information that will be collected, if any. • #10. Clarify whether this research was initiated by the sponsor or faculty. • #11. Add the PI's department.
Study Funding Sources	Ensure the IF Number and funding source listed are correct and up to date.
Local Study Team Members	Update the roles of all Research Personnel, which will be listed as **"In limbo"** and indicate whether they will be involved in Obtaining Consent.
Study Scope	• Provide **Y/N** responses to each of the questions regarding Drugs, Devices, Specimen Banking, and Radiation Safety. • Complete the related tabs for those answered **YES**. • Confirm all relevant supplemental documentation is uploaded.
Local Research Locations	Review this section to make sure all sites are listed.

Local Site Documents	**Review the migrated documentation to ensure accuracy, completeness, and that the files are renamed if required (e.g. Consent form, Flyer, Social media text, etc).**
	
	For PAPER SUBMISSIONS:
	• The **Consent Form and Supplemental documents** were **NOT** migrated and will not be stamped/approved upon approval of your continuation submission. Therefore, you must upload all relevant documents into this modification for approval.
	  o Upload **CLEAN unstamped** version(s) of the consent form(s) and supplemental documents such as any advertisements or flyers **AND**
	  o Upload the previously approved **stamped version(s)** of the documents.
	• Upload your HRP-503 IRB Application
	• Attach a memo titled "PI Transition Memo" attesting to the modification's contents.

Select **FINISH** or **EXIT** upon completion of the above**.** From the Modification Submission Workspace ensure that the PI proxy is selected. When ready for submission, the PI or PI Proxy will select **SUBMIT** on the left-hand side of the modification workspace. The submission status will change from **PRESUBMISSION** to **PREREVIEW.**