

Protocol Migration Information and Steps

The Principal Investigator (PI)/study team will be responsible for creating and submitting a new modification with all of the below materials to populate each study's record. A modification to complete the population of the study record can be created at any time, but we strongly recommend submitting the Modification as soon as possible. The IRB cannot approve any new changes to the study or submit Reportable New Information (RNI) without completing this first modification to populate the study record. This means if an investigator would like to add new measures to their study or submit RNI, a modification to upload all study documents to the study's record must be submitted and approved prior to requesting new changes to the study or submitting RNI.

All active studies have a "shell" record migrated into RAMP IRB. The "shell" record contains the following: the protocol number, the study title, the PI name, and funding. The following materials need to be uploaded by the study team:

1. Either a copy of the currently approved IRBNet application and addenda (if applicable) or a new study protocol using the appropriate Toolkit template [link]

Note: The IRB will allow the continued use of the legacy IRBNet application in lieu of a study protocol **ONLY** for converted studies. All new study submissions must include the appropriate protocol template [link].

2. All currently approved consent documents in Word
3. All currently approved recruitment materials in Word
4. Individual copies of all data collection measures/materials (Word preferred)
5. Any additional materials that are included in the currently approved IRBNet record

A note re: Adding Study Team Members

In cases where a study team member other than the PI will be responsible for populating the study record in RAMP, the PI must first submit a modification to add that study team member as personnel. For more information on submitting modifications, please reference the training materials here: <https://ramp.gmu.edu/training-irb/>

Steps

Step 1: Pay special attention when selecting the Modification Scope in the e-form. If you are uploading study documents to populate your record AND adding study team members you will need to select both 'Study team member information' and 'Other parts of the study' for your Modification scope.

Step 2: Upload currently approved study documents into the record in RAMP

Step 3: If applicable: Add study team members to RAMP. Study team members can begin study activities as soon as possible as long as they have required CITI training (initial education requirements and/or additional initial education requirements) for conducting human subjects research. If any study team member, including the PI, has CITI training from an outside institution, the CITI certificate(s) will need to be manually uploaded into the record (see here for more information). This means that the study team members who are up to date on CITI do not have to wait until the Modification is approved to begin study activities.

Step 4: Make sure all study documents are in Word format.

Step 5: Click 'Finish' (clicking 'Finish' does not mean the submission is in our queue for review, it just means you have finished all required steps for creating a submission).

Step 6: Click 'Submit' under 'Next Steps' within the study record workspace (clicking 'Submit' will bring the submission to Pre-Review which means it is now in our queue for review).

Tips for Steps 5 & 6: When viewing the study workflow, Pre-Submission indicates the submission is not yet submitted for HRPP/IRB review (this means you can still edit and make changes if needed). Pre-Review indicates the submission is now with the HRPP/IRB office for review (this means that the submission is closed for editing unless it is 'Withdrawn' or 'Clarification Requested' by the IRB Coordinator assigned to review the submission. Withdrawing your submission to make additional edits will affect your spot in the queue.