

Working with a Migrated Study

- Study team members are responsible for updating all additional information, including uploading important study documents (protocol, consent forms, etc.) at the time of the first modification or continuing review.
- This process is completed by submitting a modification, and updating all of the appropriate SmartForm questions.
- Studies pre-populated from HIRBERT will contain limited information.
 - HIRBERT Number
 - Study Title
 - PI with Department
 - Additional Person to Notify
 - Initial Approval Date
 - Review Type
 - Current Approval and Expiration date
 - Funding (ONLY if GMAS number was provided)
 - First Designated Institution
 - FDA, if triggered

Steps to “populate a migrated study”

1. Go to irb.harvard.edu
2. Navigate to the migrated study workspace
3. Click the “Create Modification” button.
4. Select “Modification”
5. Select BOTH types of modification on the first page of the SmartForm.
6. Clarify the rationale for the modification.
If the request includes ONLY updating information in ESTR, clearly indicate that you are ONLY “populating a migrated study”.
7. Select “continue” to page through the SmartForm and make edits.
8. Make all changes directly into the SmartForm (for example, if you are making changes to the approved protocol document, navigate to the “Study Scope” page and “Update” the protocol document with the newest version).
9. When all the changes are complete, select ‘finish’.
10. You will be directed to the submission workspace.
11. Contact the study PI to complete the ‘submit’ activity on the submission workspace.

