



Managing and Updating a Migrated Study

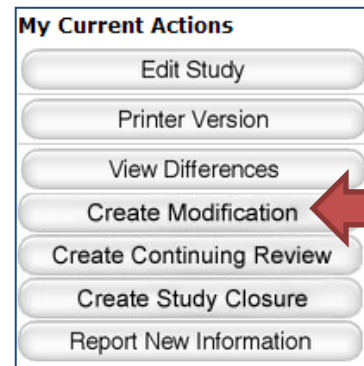
Basic information from studies that were submitted to and reviewed by the IRB prior to implementation of the ESTR-IRB System was ‘migrated’ from the old IRB database to ESTR. The ESTR-IRB team migrated a *skeleton record* from the legacy system, with only the following data points, when available:

- Study ID Number
- Principal Investigator Name
- Responsible Department
- Additional Contact Person
- Research Study Title
- Funding Source/GMAS ID
- Current Status (at the time of conversion)
- Initial Approval Date
- Current Expiration Date

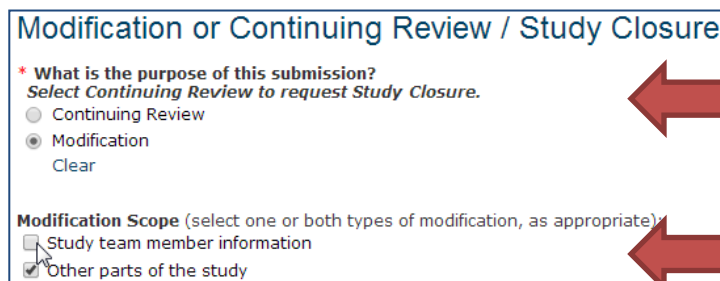
Study team members are responsible for updating all additional information, including uploading important study documents (protocol, consent forms, etc.) at the time of the first modification or continuing review. This process is completed by submitting a modification, and updating all of the appropriate SmartForm questions.

Creating a Modification to Update a Migrated Study

1. Go to irb.harvard.edu
2. Navigate to an approved study workspace
 - This is a submission numbered without letters or with the prefix “IRB”
 - The main study must not be in the middle of review
3. Click the “Create Modification” button.
4. Select “Modification”
5. Select BOTH types of modification on the first page of the SmartForm. **NOTE:** *The system will only allow one personnel change and one full modification to be open at a time.*



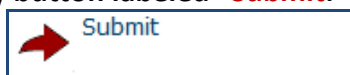
6. By selecting ‘continue’; the system will guide you through some questions about the requested change, and take you to a copy of the SmartForm.



7. 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”.
 - If the request includes changes, clearly indicate that you are updating ESTR AND including changes (provide details about those changes).



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. When a Continuing Review or Modification is in the Pre-Submission state:
 - **Only the PI will see an activity button labeled “Submit.”**



- Other study team members and the Primary Contact will not have access to an activity that will move the submission to the IRB.

Important! In order to send the Modification for IRB review, the study PI will need to click the “**Submit**” activity button (*activity marked with a red arrow in the submission workspace*).