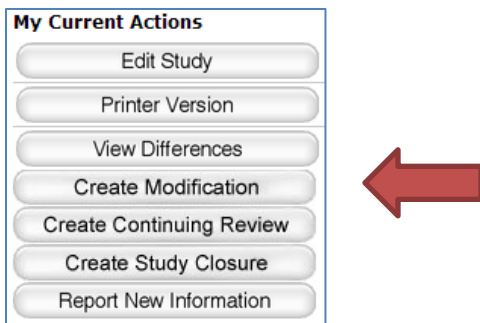




Modifying an Approved Study

Making any changes to the approved research will require a modification that will be reviewed and approved by the IRB before the changes go into effect.

1. Go to irb.harvard.edu
2. Navigate to an approved study workspace (see job aid: *How to Find a Study*)
 - 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 one or 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.

A screenshot of a SmartForm titled "Modification or Continuing Review / Study Closure". It includes a section for "What is the purpose of this submission?" with radio buttons for "Continuing Review" and "Modification" (selected), and a "Clear" link. Below is a "Modification Scope" section with checkboxes for "Study team member information" and "Other parts of the study" (checked). At the bottom, there are two status indicators: "Active modification for this study" and "Modification type(s)". Two red arrows point to the "Modification" radio button and the "Other parts of the study" checkbox.

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. 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).

Important! Only the Principal Investigator can **submit** a Modification (*activity marked with a red arrow*). Any other members of the study team who prepare the application must notify the PI when the application is ready to submit.

