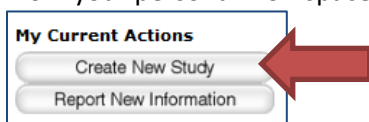




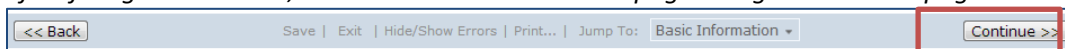
Creating a New Request for Ceded Review

Ceded review (also referred to as “External IRB”) is specific to when a Harvard-based Investigator is requesting that the Harvard IRB rely on the review of another institution. Follow these steps submit this kind of request for review. After submitting this information, the IRB may request additional information and may determine that Harvard IRB review is required.

1. Log in to irb.harvard.edu. You will be directed to your personal workspace.
2. From your personal workspace, Click on the “Create New Study” button



3. Navigate the SmartForm to fill in, at minimum, the following required items:
After filling in each item, click “Continue” to save the page and go to the next page.



SmartForm Page: Basic Information

Fill in all required fields, with the Harvard PI and Department indicated in appropriate spaces

SmartForm Page: Funding Sources

Indicate any funding sources managed through Harvard

SmartForm Page: Study Scope

- Items 1: Mark “yes”
- Items 2-3: Mark “no”
- Item 4: Attach a copy of one of the following:
 - The Catalyst Cede Review Request form (if there is one) OR
 - The form or protocol which was submitted to the external IRB

SmartForm Page: External Sites

Click “Add” and enter details about (at minimum) the external institution which may complete review.


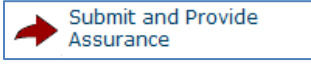
SmartForm Page: Consent, Assent and HIPAA Authorization Materials

This information is not required at initial submission, but may be requested during consideration and based on the nature of the project.

SmartForm Page: Supporting Documents

Attach all of the following that apply (*additional information may be requested by the IRB based on the nature of the project*)

- A completed IRB Authorization Agreement Request Form (only if the external IRB does not participate in Catalyst)
- Any Harvard- executed agreements (such as Data Use Agreements)

4. **Important!** Once the initial SmartForm is complete:
 - A study staff member must complete the “Submit” activity 
 - OR
 - The PI must complete the “Submit and Provide Assurance” activity 

5. Click the “My Inbox” link in the upper right corner to get back to your personal workspace.