

Amendment Applications

IRBOnline Electronic Submission Systems

Introduction

- The Amendment Application is used to make any necessary changes to a study.
- What changes require an amendment depend on the original study determination:
 - Non-exempt (Minimal Risk or Greater Than Minimal Risk) – all changes to the protocol (application) and documents are required to be approved via amendment before implementing the change
 - Exempt – only some changes are required to be submitted via amendment
 - Facilitated Review – only some changes are required to be submitted via amendment
 - Non-Human Subject Research – no amendments can be submitted, if a new NHSR determination is needed, you must submit a new application

Key Points for Amendments

- Two Aspects to making changes
 1. Amendment Application – which explains the changes
 2. Updating the Study Application – actually making the changes in the form
- Inconsistencies between the Amendment Application and the updates to the Study Application is the #1 cause of revision requests
- Only one amendment can be open at any given time
- The PI or Research Team Contact can create the amendment
- Only the PI can submit an amendment as PI is responsible for approving any changes being made to study

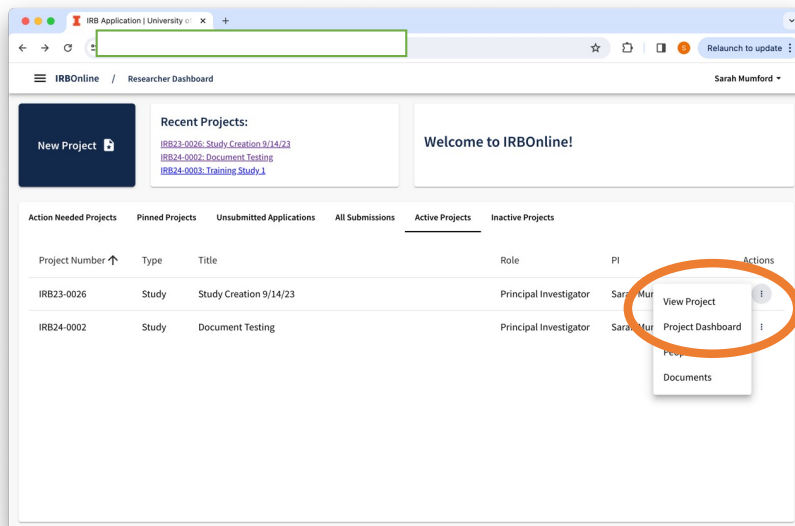
Researcher Dashboard – Active Projects

The screenshot shows the IRBOnline Researcher Dashboard for Sarah Mumford. The dashboard includes a 'New Project' button, a 'Recent Projects' section with links to IRB23-0026, IRB24-0002, and IRB24-0003, and a 'Welcome to IRBOnline!' message. The 'Active Projects' tab is highlighted with an orange circle. Below the tabs is a table of active projects.

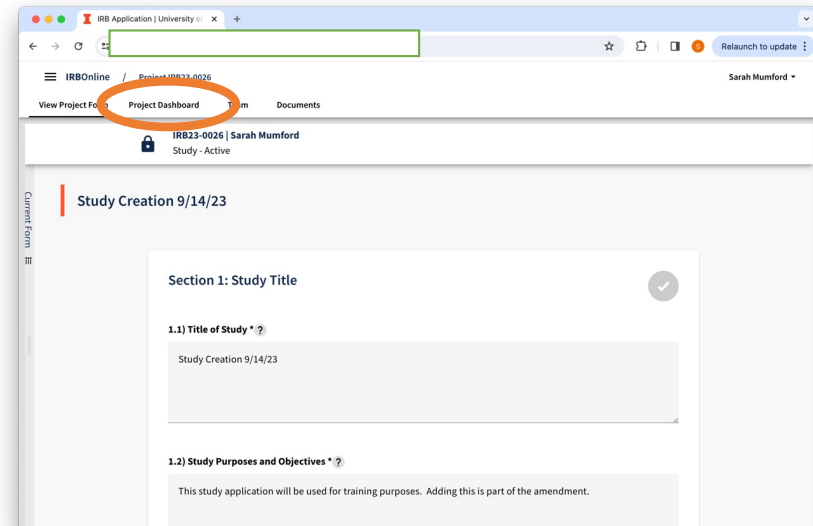
Project Number ↑	Type	Title	Role	PI	Actions
IRB23-0026	Study	Study Creation 9/14/23	Principal Investigator	Sarah Mumford	👁️ ⚙️ ⋮
IRB24-0002	Study	Document Testing	Principal Investigator	Sarah Mumford	👁️ ⚙️ ⋮

Accessing Project Dashboard

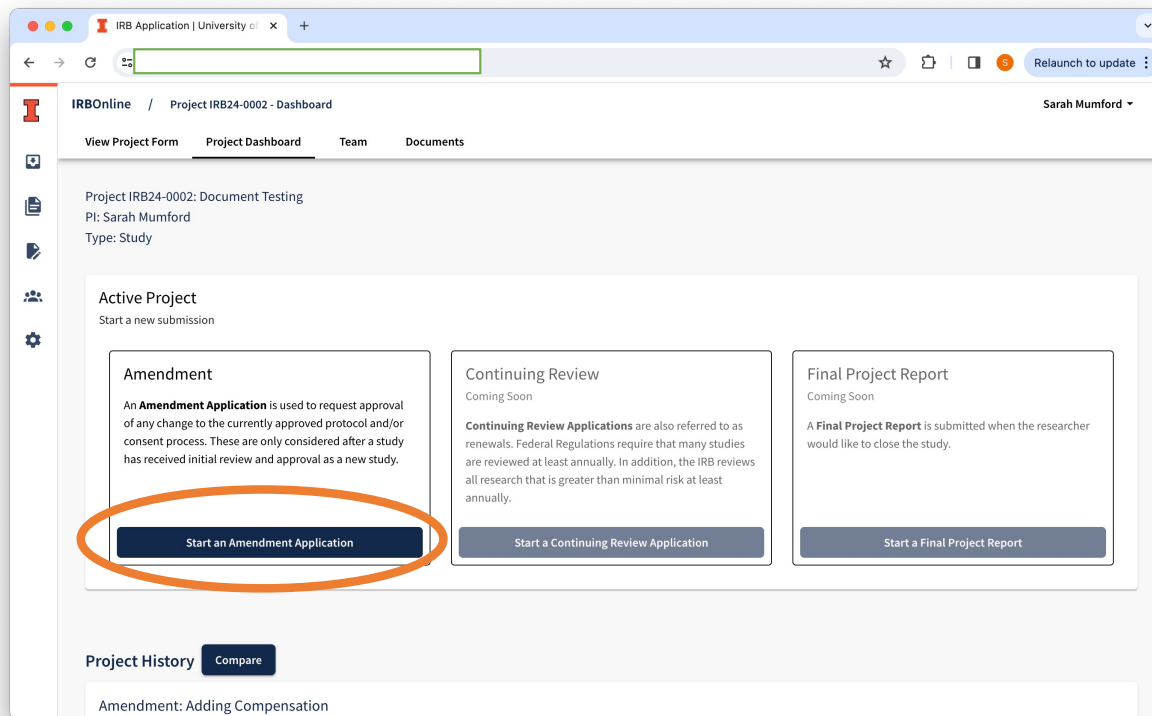
Option 1 – Select More Actions from Dashboard



Option 2 – View Project then use tabs



Creating the Amendment Application



Naming the Amendment –

1. Select a name that best describes the Amendment's purpose
2. Use a short, brief description that will be helpful for both you and the IRB reviewer to identify what is being changed
3. IRBOnline numbers the amendments as part of the documentation
4. Examples: "Adding Compensation", "Removing Questionnaire"

Opening Amendment Application

Left Pane:

1. Amendment Application
2. Describe the changes

The screenshot displays the IRBOnline web application interface. The browser address bar shows 'IRB Application | University of ...'. The page header includes 'IRBOnline / Project IRB23-0026' and a user profile 'Sarah Mumford'. Navigation tabs include 'View Project Form', 'Project Dashboard', 'Team', and 'Documents'. A 'Submission' button is visible. The main content area is titled 'IRB23-0026 | Sarah Mumford' and 'Study - Ongoing Submission [Amendment | Unsubmitted]'. It features two side-by-side panes. The left pane, titled 'Amendment: Increase enrollment', contains 'Section 1: Amendment Type' with a subsection '1.1) Type of Amendment (check all that apply) *'. It lists 'Administrative Changes' and 'Changes to study design elements', both with checkboxes. The right pane, titled 'Study Creation 9/14/23', contains 'Section 1: Study Title' with a subsection '1.1) Title of Study * ?' and a text input field containing 'Study Creation 9/14/23'. A green checkmark is visible next to the title section. Two orange circles highlight the 'Amendment Application' and 'Current Form' tabs in the left sidebar.

Right Pane:

1. Currently Approved Study Application
2. Edit this version to actually make the changes described in the amendment application
3. Once approval processed, this will become your new approved protocol application

Updating Documents

- If you are making changes to approved documents – you must attach a Tracked Change version of the approved document AND a Clean Version of the document with your changes – include “tracked” and “clean” in the file names
- The “clean” version will be the processed version once approved, but IRB reviewers use the tracked version to focus only on what changes rather than re-reviewing every document
- A tracked change version and a clean version of each document is also required during the review process if revisions are requested to the document

New Questions in Study Application

- Two new questions were added to the New Study Application and will require completion if you have an older project that did not already include these questions:
 - 1.4 – Was this project previously approved by the University of Illinois Urbana-Champaign IRB as part of an earlier application?
 - 2.2 – Select the Position of the Principal Investigator
- Section 21 Devices: Includes one new question if this section is applicable.

Amendment and IRBOnline Guidance

- [Research Topic – Amendments](#)
- [Copy of Amendment Application with commentary](#)
- [Research Topic – Submitting Documents for IRB Review](#)
- [Amendment Application Tutorial Video](#)
- [Should I submit an Amendment or a New Study?](#)
- [Researcher Dashboard Update – New Tabs](#)
- [Why won't my application submit?](#)