AMENDMENT REQUEST

Amendments can be submitted on “approved” studies only.
You can create only one Amendment at a time, but you can incorporate multiple changes in one Amendment request.

1. Click on the Applications tab

2. Find the approved study that you want to amend, and click on its name

3. Click the button

Home page

Study home page
4. Read the instructions, and click the [Continue ->] button

**Amendment Request Form**

To navigate within this form, use the Continue button.

5. **Page 1, Section 1.0:** Indicate the reason for your amendment request.

After you completed the entire first page of the Amendment Request Form, click the [Continue ->] button.

**Note:** Changes to documents such as protocol, measures, consent forms, and recruitment materials, can be made in this form only. Changes that are marked with a **double asterisk**, require an additional step: you will need to explain the change in this form, but also make this change in the Amended Application (see page 47 for instructions).
Completing the first page of the amendment will start the application **copying process**. This process can take anywhere from a few seconds to an hour depending on the size of the study.

- If the study has a large number of amendments and/or documents associated with it will take longer to process.

- If this is the case, at this point you can hit the **Finish** button while the process is taking place. The amendment will appear in your **Inbox** and the **State** will be **Copying**. Once the process is complete the state will change to **Pre-Submission**. At this point you will be able to continue work on the application.
6. Page 2 allows you to make **Consent form** updates
   ~ Section 1.0: upload an **unmarked** version of the consent form
   ~ Section 1.1: upload a **tracked changes** version of the consent form

7. Page 3 allows you to make **Recruitment materials** updates
   ~ Section 1.0: upload an **unmarked** version of the recruitment materials
   ~ Section 1.1: upload a **tracked changes** version of the recruitment materials

8. Page 4 allows you to add or replace your **Protocol** and **Measures**
   
   **Note:** If you are revising your Protocol, only upload the revised document with changes highlighted or tracked.

   **DO NOT delete any documents listed here! Use the Add or Replace buttons only.**
9. When the form is completed, click the Finish button

This action will take you to the Amendment home page.

**AMENDED APPLICATION**

If you are making a change to something other than a document, such as study title or study personnel:

10. Click the Amended Application button

* This is a copy of your approved application

11. Use the scroll-down menu to navigate to the section that needs to be revised, and make the appropriate change

12. Click Save and Exit
13. Click on **Submit Amendment**

14. Read the instructions and click the **OK** button

This action will send your Amendment Request to the RSRB Specialist.

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**AMENDMENT WITHDRAWAL**

You can withdraw the Amendment Request process at any time prior to the RSRB submission and review.

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1. Click on **Withdraw Amendment**

2. Provide a **reason** for withdrawal

3. Type in your **comments** (this is required)

4. Click the **OK** button