Preface:

This guide explains how to submit an amendment to modify an approved study. If you already have an outstanding amendment pending review do not submit a new amendment until the outstanding submission has been approved. To change an already submitted amendment, contact the IRB Office and request that your pending submission be returned to you for changes. Ultimately, only one submission should be under review. To review the submission requirements for an Amendment, visit the Amendment page of the IRB website.

If you encounter problems in the eRA system, such as error messages or performance issues, please contact the eRA Helpdesk at erahelp@colorado.edu.

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1. Login to eRA InfoEd

Step 1: Go to [https://era.cu.edu/login.asp](https://era.cu.edu/login.asp)

Step 2: From the dropdown, select Boulder.

Step 3: Login with your Username and Password.

Upon successful login, the My Open Action Items screen will appear.
2. Open the Protocol and Create a Submission

Step 1: On the *Home* screen, click **Human Subjects** in the menu on the left of the screen to access the Human Subjects menu.

![Human Subjects menu](image)

**Step 2:** Click **Show My Records**. The screen will refresh and you will see a list of your protocols.

![Show My Records](image)
Step 3: Click the Record Number of the Protocol you want to open and a fly-out menu will appear.

The following options are available:

To create a new submission, continue work on or edit an existing submission, or to respond to a request for modifications or an incomplete submission, Click the Edit option, then Click on the Master Record link. This will take you to the Submissions page for the study, where you may create a new submission following Step 4 below.
To create a new submission from this fly-out menu, Hover over Create New, and Click on the type of submission you wish to create - in this case, an Amendment. The Protocol will open and the Amendment screen will be displayed. Skip Step 4 if using this option.

**IMPORTANT:** DO NOT use this option to Respond to an Incomplete or Modifications Required letter.

**Step 4:** If creating a new submission from the Submissions Page, in the top right corner of the Submissions table, select Amendment from the dropdown list, then click Add. – The screen will refresh to the Amendment screen.
3. Complete the HRP-213 Amendment Form

To complete the HRP-213 Amendment Form, follow these 5 steps:

**Step 1:** Click on the [HRP-213 Amendment](#) link under Document/Form. A new window will open with the Amendment eForm.

**Step 2:** Complete the form as guided. The Amendment eForm is dynamic and will generate questions according to your answers. Periodically save your work by clicking the **Save** button.

**Step 3:** If applicable, supporting documents can be uploaded as a part of the Amendment eForm. Check the appropriate box or plus sign to upload annual reports for INDs and/or any publications that have resulted from the research. Click the Upload button and follow the prompts to upload the document. Click the glasses icon to preview the document.

**Step 4:** When all information has been entered, click **Save** at the top of the window, then click the **Complete** checkbox.

**Step 5:** Close the eForm.
4. Attach Any Necessary Supporting Documents:

Attach any supporting documents that may change as a result of the amendment. For example, if you are adding new personnel, you should attach a tracked changes version of the protocol document. To add Supporting Documents, follow these 4 steps:

Step 1: To add a new document, click the Add link at the top of the table on the Amendment screen. The link is located next to the Form/Document column header.

Step 2: A new Upload window will open. Complete the following:
- Name: Enter a unique name (e.g. Survey_010117).
- Location: Click the Browse button. A dialog box will open. Locate and select the document on your computer, then click the Open/Choose button in the dialog box to attach it.
- Category: Select an appropriate category from the list.

Note: Depending on your browser, the Location buttons may say “Choose File” rather than “Browse”.

Step 3: Click the **Upload** button. The screen will refresh. Click the **Close** button.

![Upload and Close buttons]

Step 4: On the **Amendment** screen, you will see the new supporting document attachment. Click on the name of the document to preview it.

If you would like to modify a document previously uploaded, click **Modify** to open the **Select a function** window. Choose the appropriate function.

![Modify button]
Upload a New Version allows you to upload a new version of the existing document, but does not change the Name or Category.

Modify the Attributes of the Document allows you to change the Name or Category of an existing document, but not to upload a new version of it.

Upload a New Version and Modify the Attributes of the Document allows you to both upload a new version of the document and to change the Name and Attributes. The change will take effect when you click the Upload button.
5. Submit Your Amendment

Once all of your attachments are uploaded, you can submit your Amendment for IRB review. To submit your Amendment, follow these 5 steps:

Step 1: On the Amendment screen, click the Submit button. A new Certification window will open.

Step 2: Accept the terms and click the Continue button. This page certifies that you have read and will conduct the research study described in the Protocol in compliance with the CU Boulder Investigator Manual. The screen will refresh.
If you are a student researcher, click the Add New Person to Review Path link at the top of the window. A new window will open. In the text field begin typing the last name of your advisor. A list of people will appear. Select your advisor from the list and confirm the Approval Required radio button is selected. Click the Add button. The new window will close. Confirm the routing path is correct. Your advisor’s name should be listed before Step 1 - Inform Office - IRB Office.

Step 3: Click the Continue button. The window will close and the status of the submission will be displayed in the top right corner of the Amendment screen.
Step 4: Click the Done button to close the window.

Step 5: Click the Logout link in the top right corner to exit eRA.