Preface:

This guide explains how to create a response submission when you have received either an Incomplete, Modifications, or Deferral determination letter from the IRB Office. To review the submission requirements for a Response submission, visit the Response Submission page on 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:

**Step 1:** On the **My Open Action Items** screen, click the **Human Subjects** menu to expand the list, then click the **Show/List** link. A new window will open. – The screen will refresh and you will see a list of your protocols.

**Step 2:** Click the folder icon  to open the protocol that received the Incomplete, Modification, or Deferral determination. – A new window will open to the **Submissions** screen.

**Step 3:** Click on the **Respond** link that appears beside the submission that was returned. A new window will open.

**Step 4:** Select the appropriate submission type for the determination you received (i.e. Response to Modifications, Response to Deferral, Response to Incomplete) Click the **Save** button. The new window will close and the protocol window will refresh to the **Response to <Type>** screen.
3) Complete the Response Submission:
Complete the provisions outlined in the determination letter received from the IRB. To fulfill the requirements, you may have to **ADD** a new document, **MODIFY** and upload a new version of an existing document or **EDIT** an eForm.

To **ADD** a new document:

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

**Step 2:** A new **Upload** window will open. Complete the following:

- **a. Name:** Enter a unique name (e.g. ConsentForm_010117).
- **b. Location:** Click the **Browse** button. A dialog box will open. Locate and select the completed consent form on your computer, then click the **Open/Choose** button in the dialog box to attach it.
- **c. Category:** Select the appropriate category for the revised document.

**Step 3:** Click the **Upload** button. The screen will refresh. Click the **Close** button.
Step 4: On the Response to <Type> screen, you will see the new document listed. Click on the name of the document to preview it.

To MODIFY or upload a revised document:

Step 1: Open and revise the document. Click the name of the document needing revisions. Make any necessary changes as outlined in the letter from the IRB. Ensure tracked changes have been turned on for Word Documents. Then save the revised document to your computer.

Step 2: Click Modify for the document to be changed to open the Select a function window. Choose the appropriate function.

Upload allows you to upload a new version of the existing document, but does not change the Name or Category.

Upload and Attributes 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.
Step 3: A new Upload window will open. Complete the following:

a. **Location:** Click the **Browse** button. A dialog box will open. Locate and select the completed consent form on your computer, then click the Open/Choose button in the dialog box to attach it.

b. **Name:** (If needed) Enter a unique name (e.g. ConsentForm_010117).

c. **Category:** (If needed) Select the appropriate category for the revised document.

d. Click the **Upload** button in the Upload Window. The revised document will upload and the window will close.

To EDIT an eForm:

**Step 1:** To revise an eForm, click on the name of the form needing revision

**Step 2:** Uncheck the **Complete** checkbox at the top of the form.

**Step 3:** Make any needed changes. Click the **Save** button, and then re-check the **Complete** checkbox.

4) Submit Your Response Submission:
Once all of your attachments are uploaded, you can submit the submission for review. To submit your response submission, complete these 5 steps.
Step 1: On the Response to <Type> screen, click the Submit button. A new Certification window will open.

Step 2: Accept the terms and click the Continue button. This window 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 Submit button. The window will close and the status of the submission will be displayed in the top right corner of the Continuing Review 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.