Office of Research Integrity
UNIVERSITY OF COLORADO **BOULDER**
INSTITUTIONAL REVIEW BOARD

CU Boulder – IRB eRA InfoEd

Amendments

Last Update: 1 February 2021

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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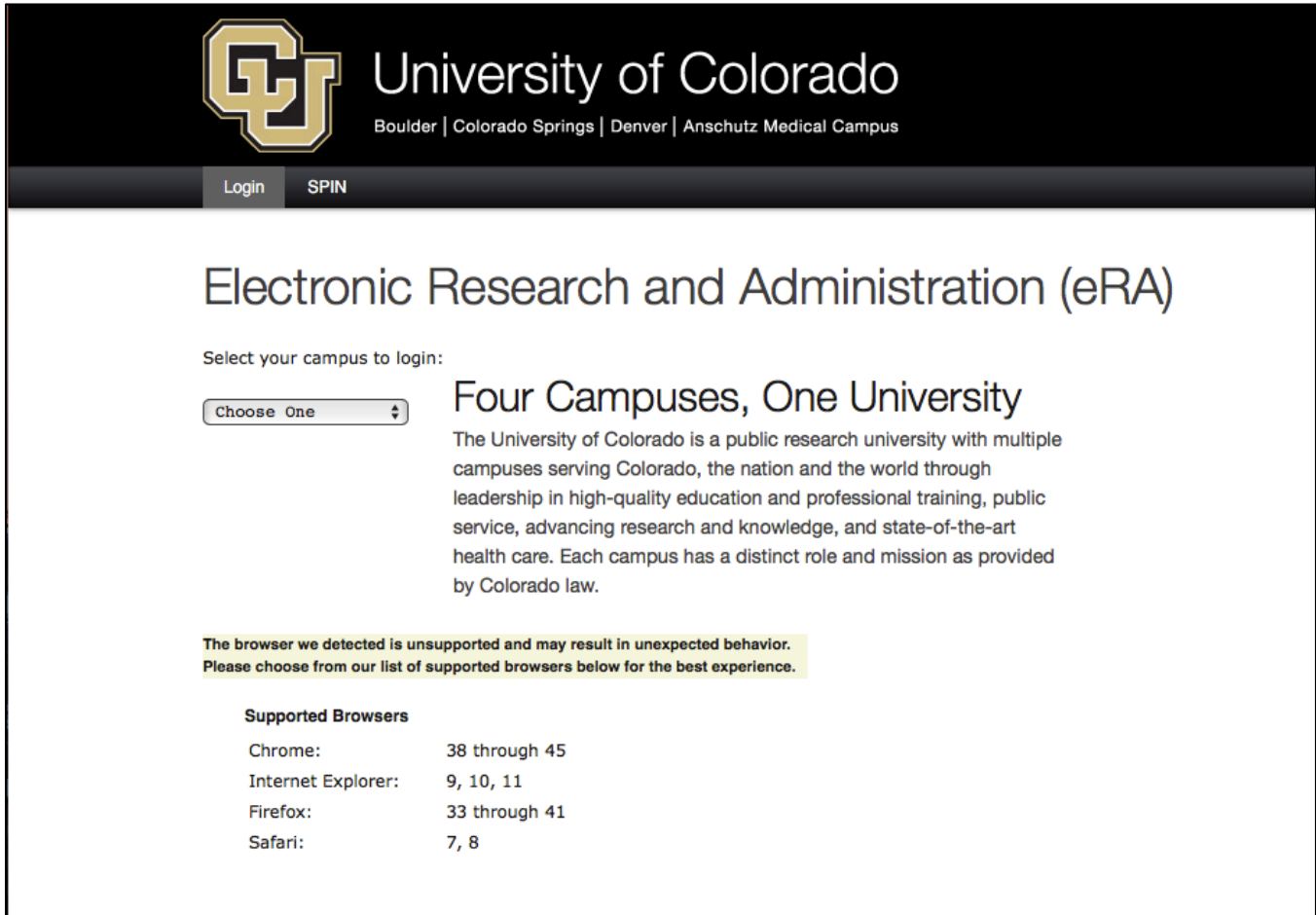
1. Login to eRA InfoEd

Step 1: Go to **https://era.cu.edu/login.asp**

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.

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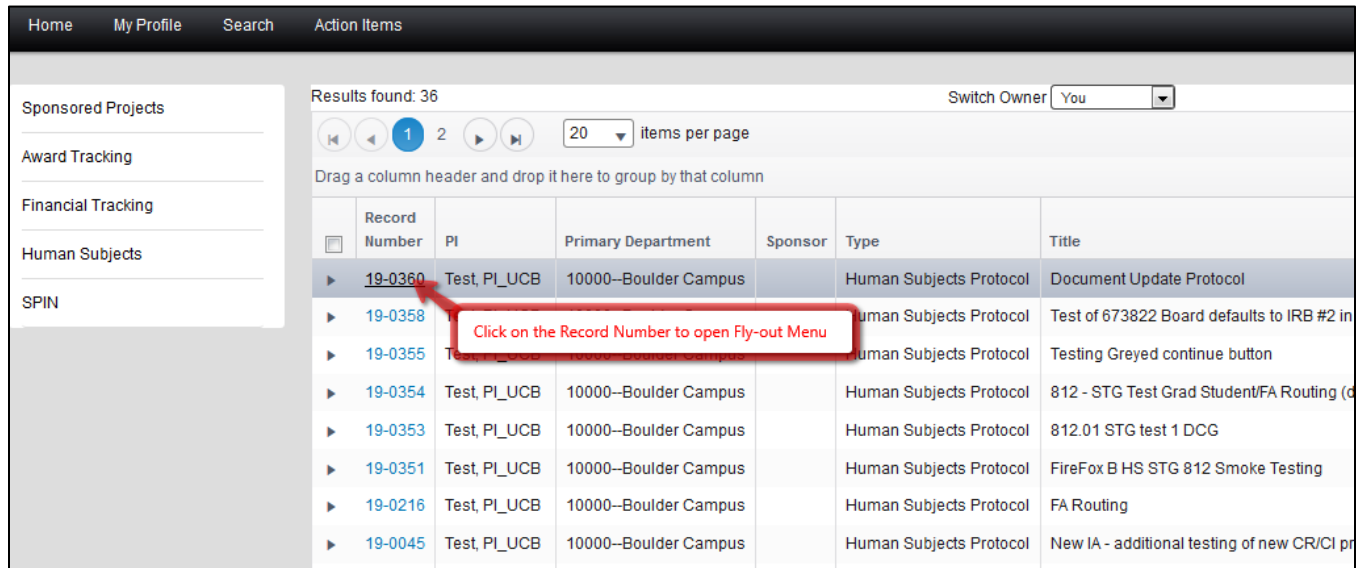# 2. Open the Protocol and Create a Submission

Step 1: On the *Home* screen, click **Human Subjects** in the menu on the left of the screen to access the Human Subjects menu.
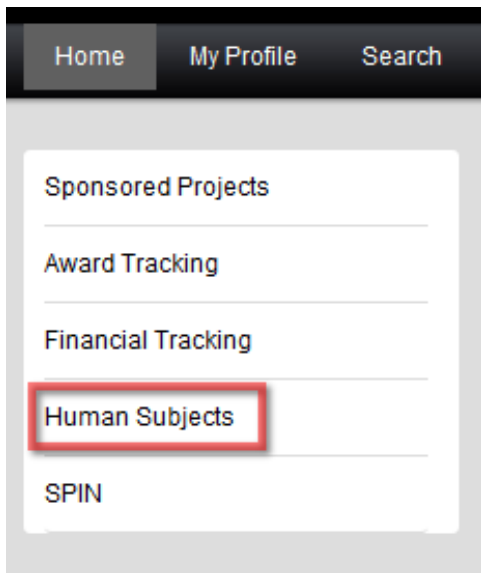
Step 2: Click **Show My Records**. The screen will refresh and you will see a list of your protocols.
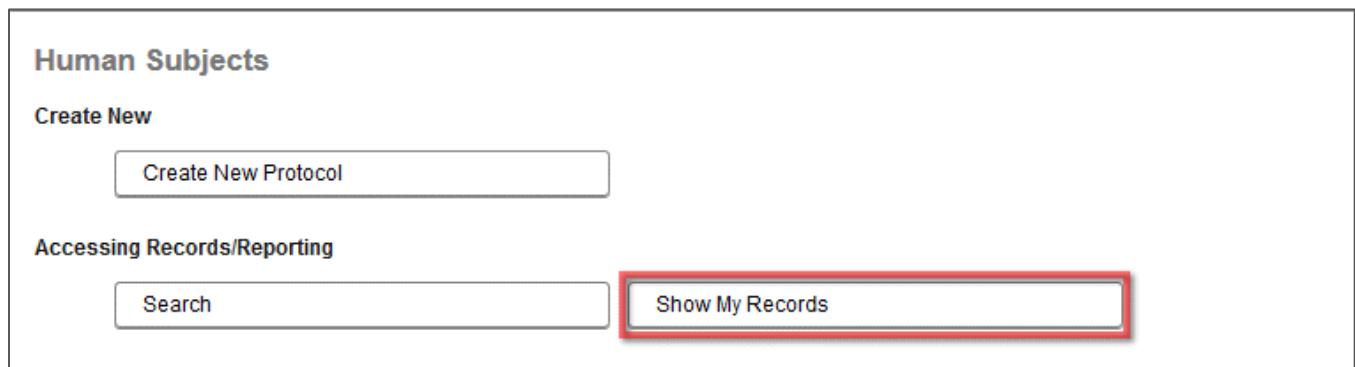
Step 3: Click the **Record Number of the Protocol** you want to open and a fly-out menu will appear.

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.
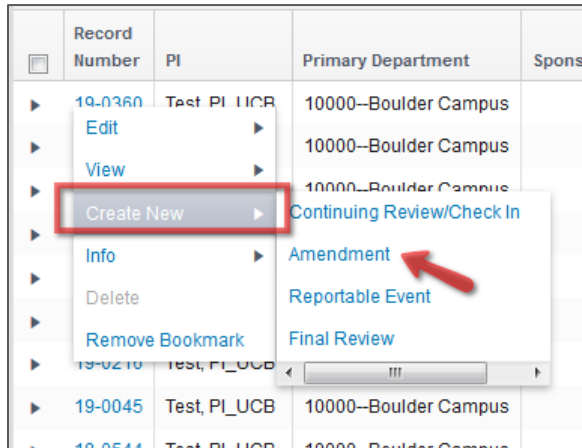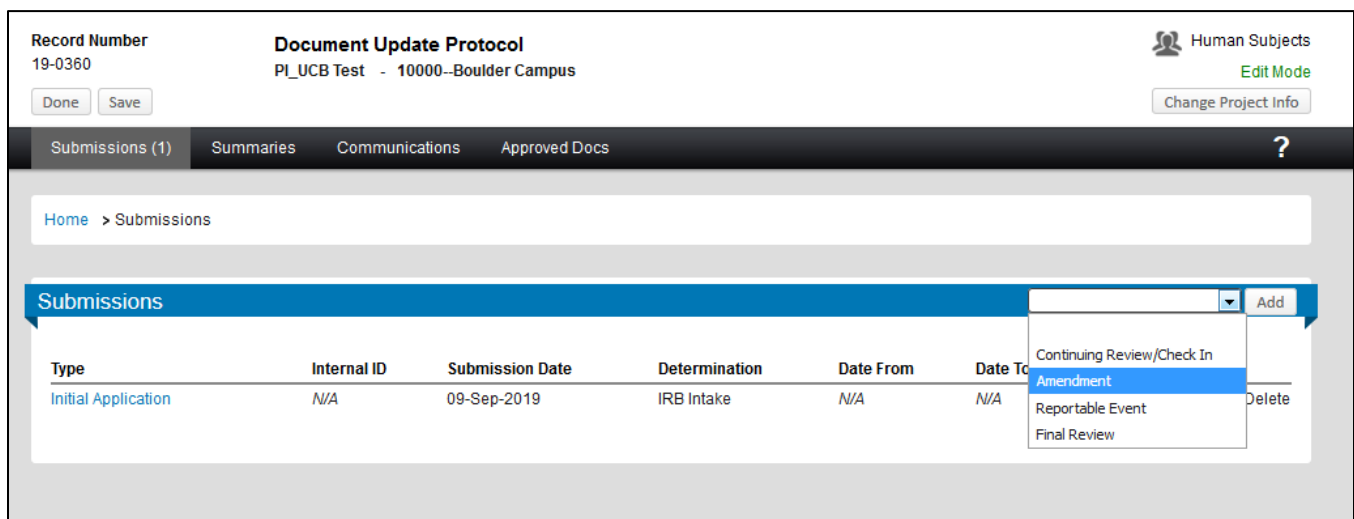
To create a new submission from this fly-out menu, **Hover** over Create New, and **Click** on the type of submission you wish to create - in this case, an Amendment. The Protocol will open and the **Amendment** screen will be displayed. Skip Step 4 if using this option.

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

NOTE: If an option is not available in the Create New flyout, it is because the same type of submission has already been created in this study. Only a single submission of any type can be In Development at once. Either complete the existing submission of this type, or access the Submissions Page as described above, delete the prior submission and create a new one following the steps below. If needed, contact IRBAdmin@colorado.edu for assistance with this issue.

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.
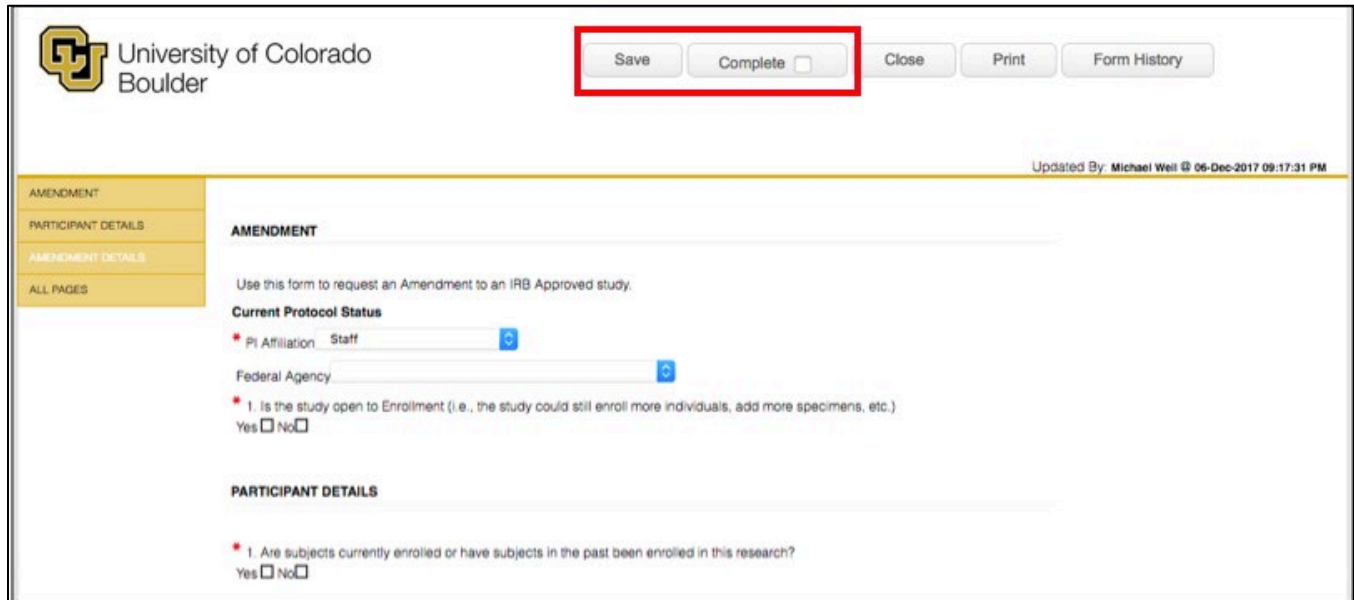
![CU Office of Research Integrity, University of Colorado Boulder, Institutional Review Board logo]

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.
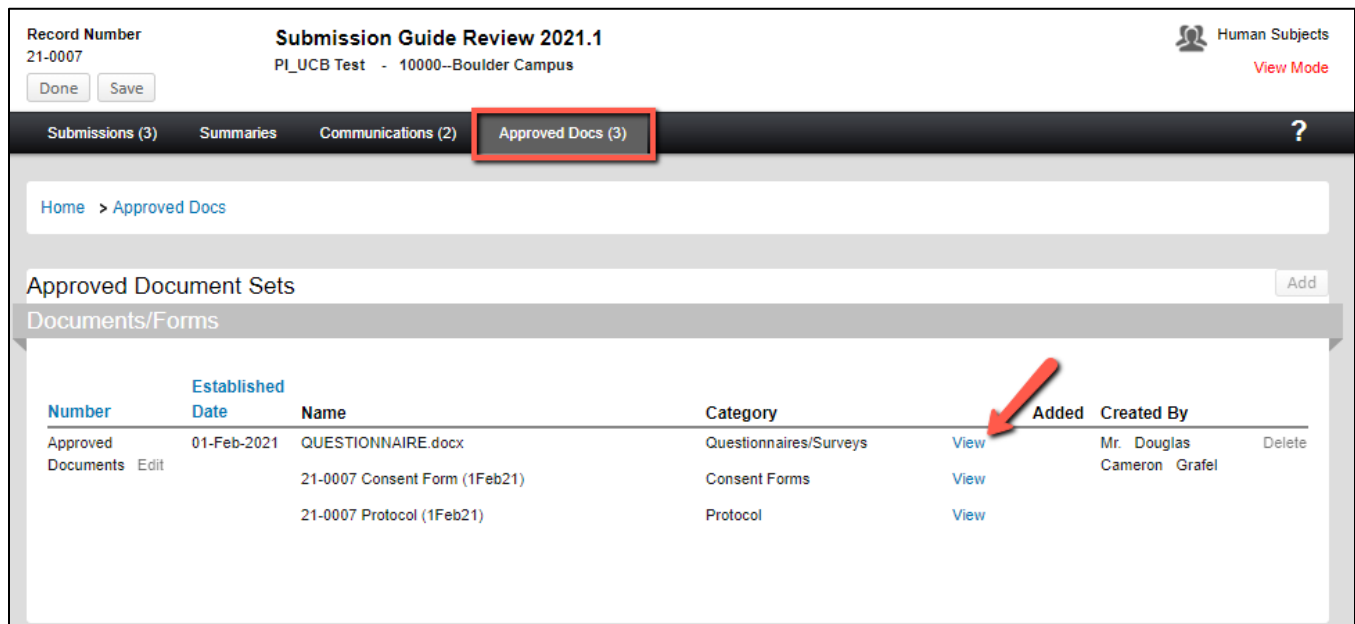
Step 5: Close the eForm.

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 5 steps:

Step 1: If you are updating a document that was previously reviewed and Approved by the IRB, access the Approved version of that document in eRA, make the necessary revisions and save that document to be uploaded. **If you do not use the correct, IRB-Approved version of an existing document, your submission may be returned un-reviewed to prevent the introduction of consistency or version-control errors.**

   i.   All Approved Documents for your study are found in the Approved Docs screen in eRA. Click Approved Docs in the black bar at the top of the study window:
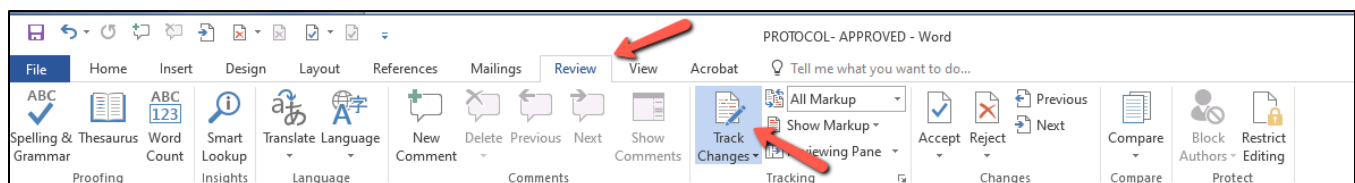
   ii.   Click the View link for the document that is being revised (see above).
   iii. When the document is opened for revision, ensure the Track Changes feature in MS Word is turned on:

   iv.   Save the revised document to your computer to be uploaded.

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Step 2: To add a new document to the submission, 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.
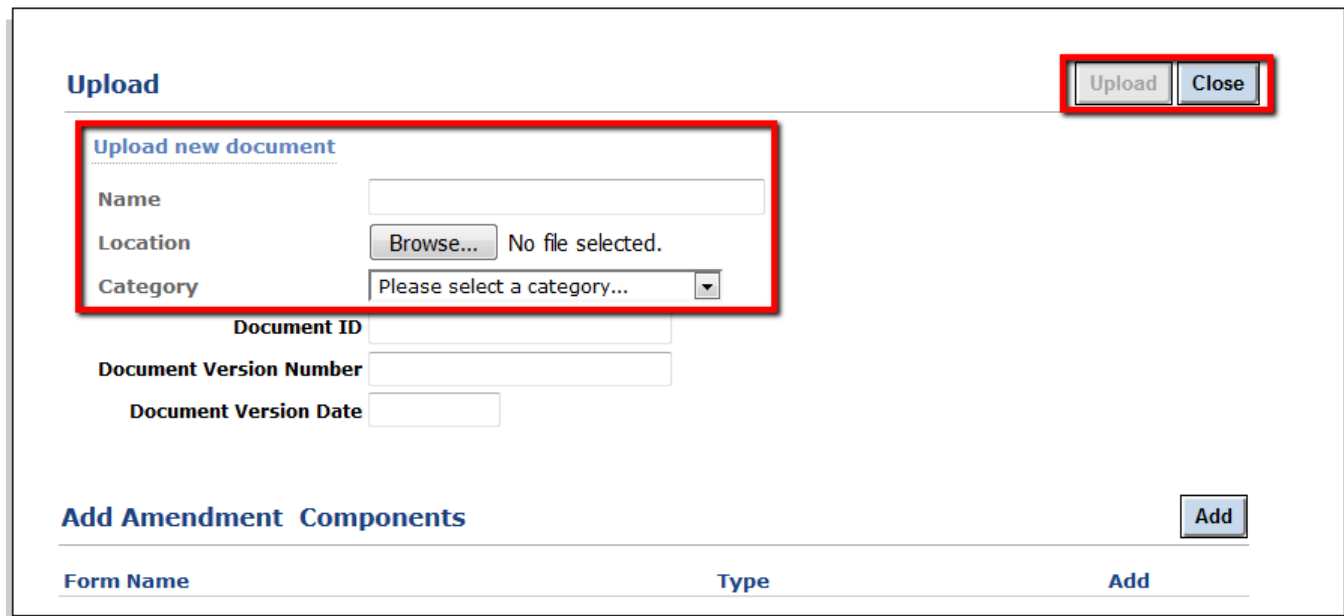

Step 3: A new **Upload** window will open. Complete the following:
  a. **Name:** Enter a unique name (e.g. Survey_010117).
  b. **Location:** Click the **Browse** button. A dialog box will open. Locate and select the document on your computer, then click the **Open/Choose** button in the dialog box to attach it.
  c. **Category:** Select an appropriate category from the list.

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

Step 4: Click the **Upload** button. The screen will refresh. Click the **Close** button.

Step 5: 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 in the submission, click **Modify** to open the **Select a function** window. Choose the appropriate function.

Select a function   Close

Upload a New Version

Modify the Attributes of this Document

Upload a New Version and Modify the Attributes of this Document

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

Upload   Upload Close

Upload new version of an existing document

Location Choose File no file selected
Document Version Number
Document Version Date

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.

Attributes   Save Close

Modify the attributes of the existing document

Name ConsentForm_010117
Category Consent Forms
Document ID
Document Version Number
Document Version Date

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.

Upload & Attributes   Upload Close

Upload a New Version and Modify the Attributes of this Document

Location Choose File no file selected
Name ConsentForm_010117
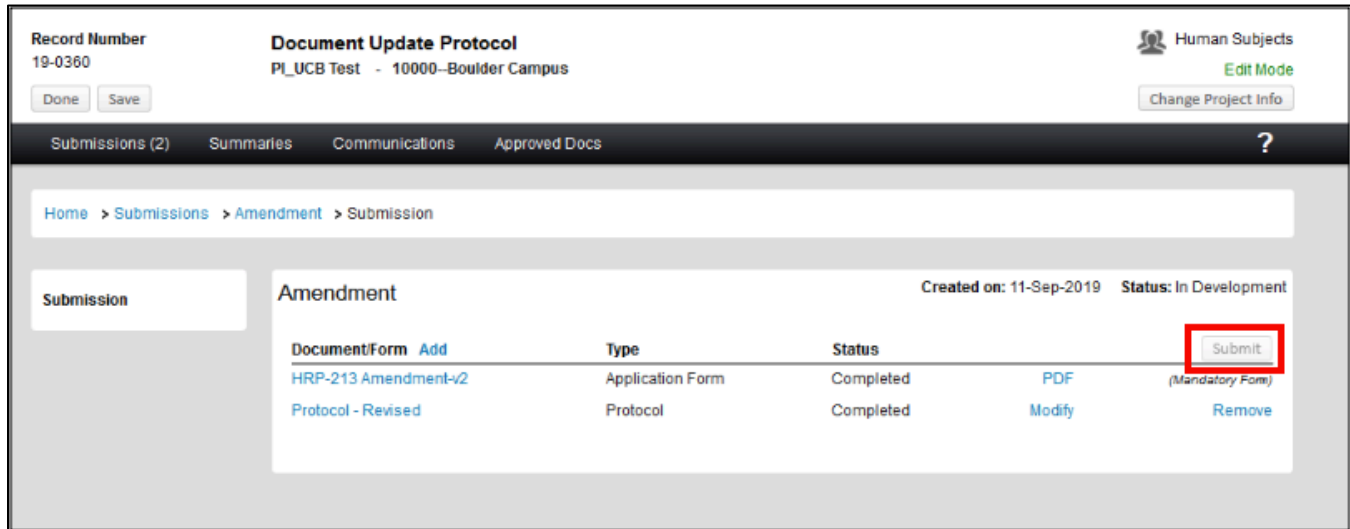Category Consent Forms
Document ID
Document Version Number
Document Version Date

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.
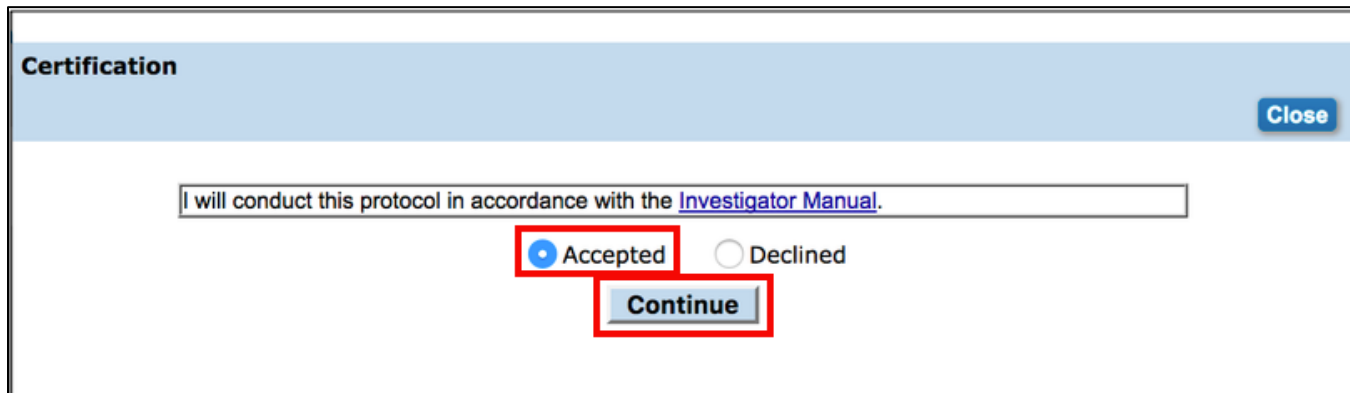
Step 2: **Accept** the terms and click the **Continue** button. This page certifies that you have read and will conduct the research study described in the Protocol in compliance with the CU Boulder [Investigator Manual.](#) The screen will refresh.

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.
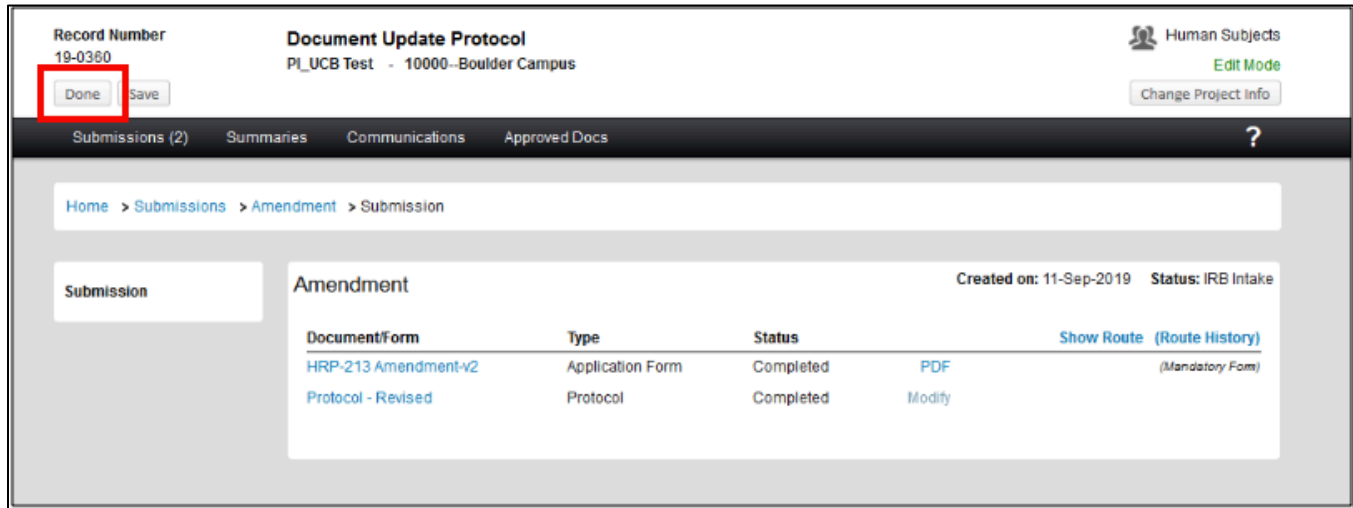
Step 4: Click the **Done** button to close the window.

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