

CU Boulder – IRB eRA InfoEd

Final Review

Last Update: 23 October 2019

Preface:

This guide explains how to submit a final review to close a previously approved study. For more information about final reviews, visit the [Closing a Study 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>

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.

University of Colorado
Boulder | Colorado Springs | Denver | Anschutz Medical Campus

Login SPIN

Electronic Research and Administration (eRA)

Select your campus to login:

Choose One

Four Campuses, One University

The University of Colorado is a public research university with multiple campuses serving Colorado, the nation and the world through leadership in high-quality education and professional training, public service, advancing research and knowledge, and state-of-the-art health care. Each campus has a distinct role and mission as provided by Colorado law.

The browser we detected is unsupported and may result in unexpected behavior. Please choose from our list of supported browsers below for the best experience.

Supported Browsers	
Chrome:	38 through 45
Internet Explorer:	9, 10, 11
Firefox:	33 through 41
Safari:	7, 8

2. Open the Protocol and Create a Submission

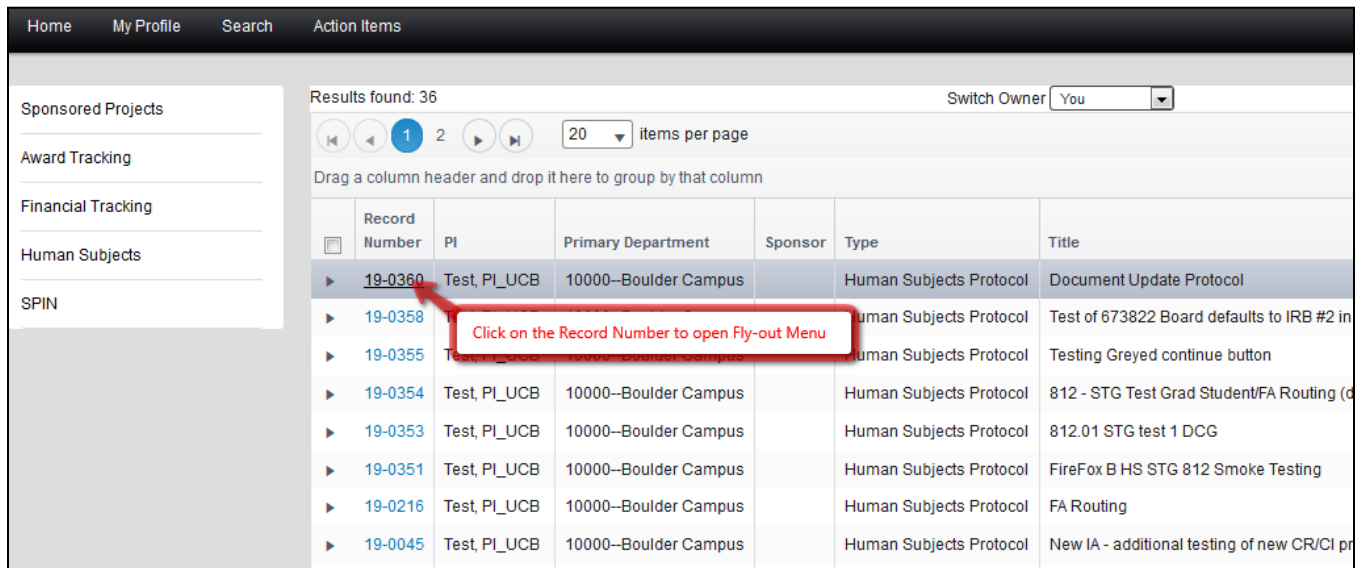
Step 1: On the *Home* screen, click **Human Subjects** in the menu on the left of the screen to access the Human Subjects menu.



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.



Home My Profile Search Action Items

Sponsored Projects

Award Tracking

Financial Tracking

Human Subjects

SPIN

Results found: 36 Switch Owner You

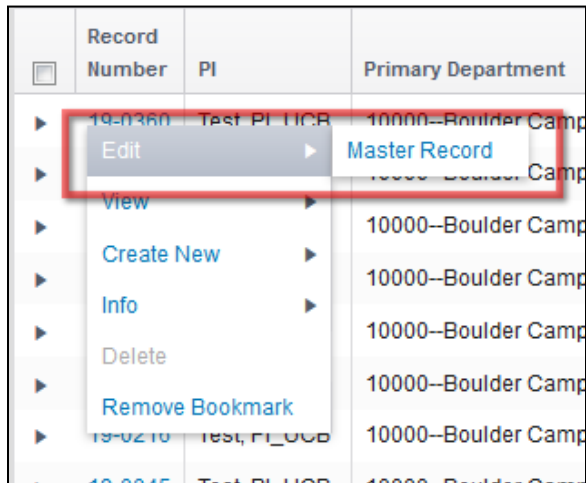
1 2 20 items per page

Drag a column header and drop it here to group by that column

Record Number	PI	Primary Department	Sponsor	Type	Title
19-0360	Test, PI_UCB	10000--Boulder Campus		Human Subjects Protocol	Document Update Protocol
19-0358	Test, PI_UCB	10000--Boulder Campus		Human Subjects Protocol	Test of 673822 Board defaults to IRB #2 in
19-0355	Test, PI_UCB	10000--Boulder Campus		Human Subjects Protocol	Testing Greyed continue button
19-0354	Test, PI_UCB	10000--Boulder Campus		Human Subjects Protocol	812 - STG Test Grad Student/FA Routing (d
19-0353	Test, PI_UCB	10000--Boulder Campus		Human Subjects Protocol	812.01 STG test 1 DCG
19-0351	Test, PI_UCB	10000--Boulder Campus		Human Subjects Protocol	FireFox B HS STG 812 Smoke Testing
19-0216	Test, PI_UCB	10000--Boulder Campus		Human Subjects Protocol	FA Routing
19-0045	Test, PI_UCB	10000--Boulder Campus		Human Subjects Protocol	New IA - additional testing of new CR/CI pr

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, **Hover** over 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.



Record Number	PI	Primary Department
19-0360	Test, PI_UCB	10000--Boulder Campus
19-0358	Test, PI_UCB	10000--Boulder Campus
19-0355	Test, PI_UCB	10000--Boulder Campus
19-0354	Test, PI_UCB	10000--Boulder Campus
19-0353	Test, PI_UCB	10000--Boulder Campus
19-0351	Test, PI_UCB	10000--Boulder Campus
19-0216	Test, PI_UCB	10000--Boulder Campus
19-0045	Test, PI_UCB	10000--Boulder Campus

Edit Master Record

View

Create New

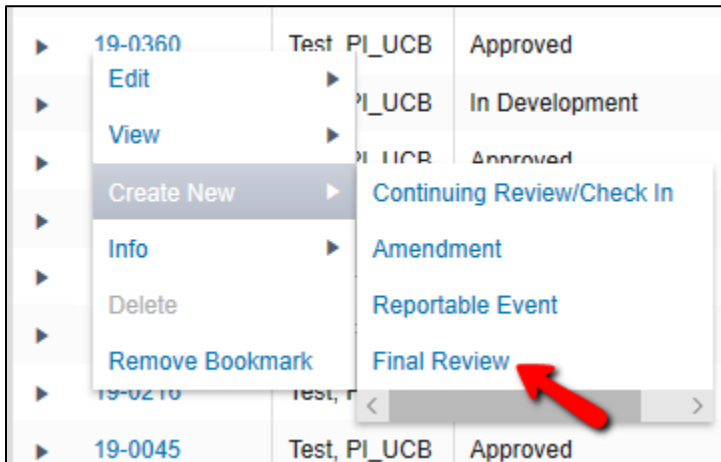
Info

Delete

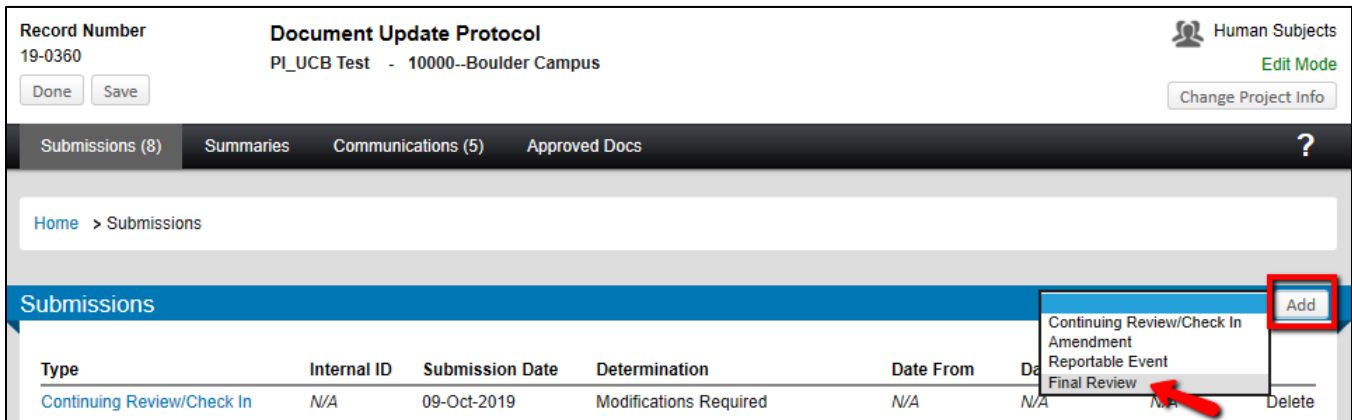
Remove Bookmark

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 Final Review. The Protocol will open and the **Final Review** 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.



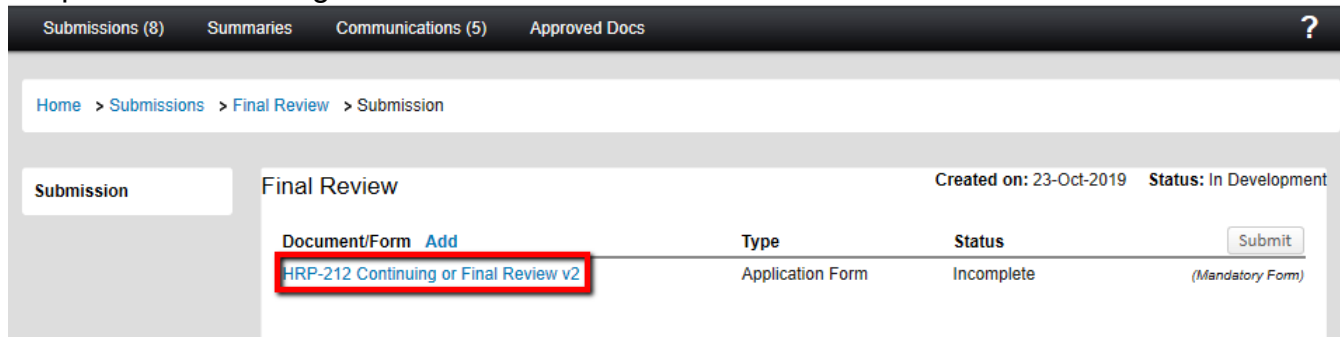
Step 4: If creating a new submission from the Submissions Page, in the top right corner of the Submissions table, select **Final Review** from the dropdown list, then click **Add**. – The screen will refresh to the **Final Review** screen.



3) Completing the Continuing Review or Final Review eForm:

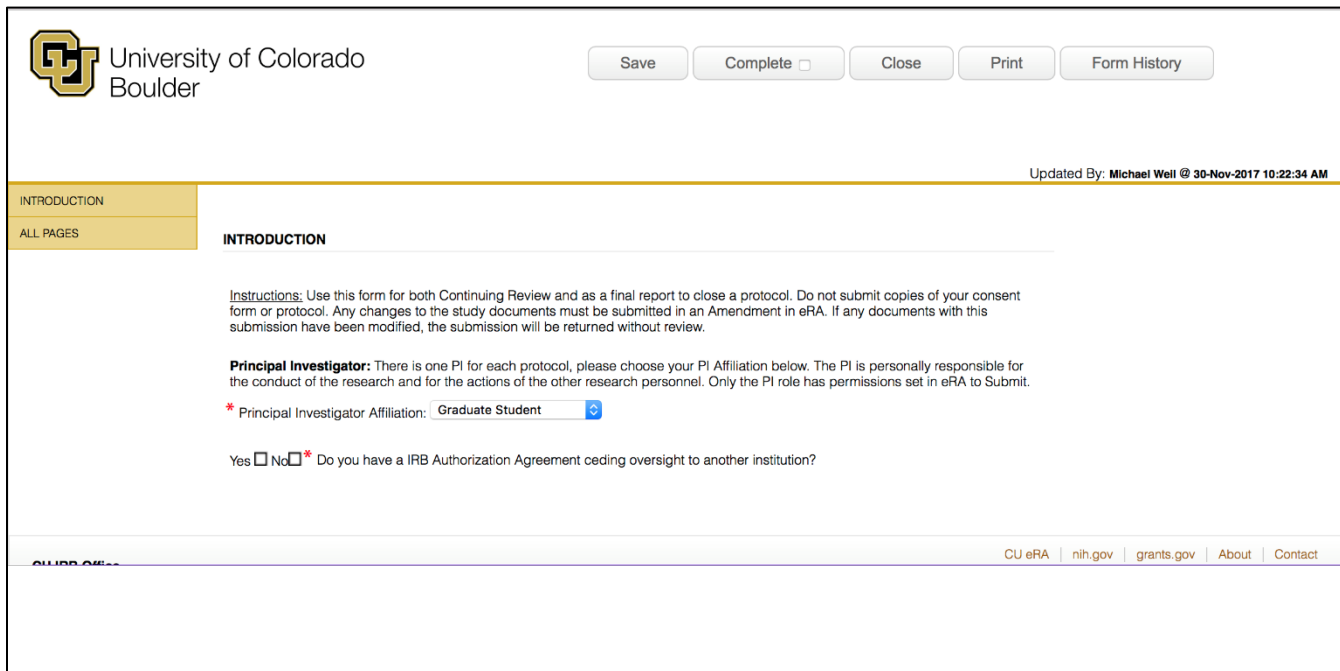
To complete the Continuing Review eForm, follow these 5 steps:

Step 1: Click on the **HRP-212 Continuing or Final Review** link under Document/Form. A new window will open with the Continuing/Final Review eForm. Click on the document link to open the Continuing Review Form.



Document/Form	Type	Status
HRP-212 Continuing or Final Review v2	Application Form	Incomplete

Step 2: Complete the form as guided.



University of Colorado Boulder
 Save Complete ☐ Close Print Form History

Updated By: Michael Well @ 30-Nov-2017 10:22:34 AM

INTRODUCTION

Instructions: Use this form for both Continuing Review and as a final report to close a protocol. Do not submit copies of your consent form or protocol. Any changes to the study documents must be submitted in an Amendment in eRA. If any documents with this submission have been modified, the submission will be returned without review.

Principal Investigator: There is one PI for each protocol, please choose your PI Affiliation below. The PI is personally responsible for the conduct of the research and for the actions of the other research personnel. Only the PI role has permissions set in eRA to Submit.

* Principal Investigator Affiliation: Graduate Student

Yes ☐ No ☐ * Do you have a IRB Authorization Agreement ceding oversight to another institution?

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IMPORTANT: The Continuing/Final Review E-Form will indicate if you have completed the form in a manner that indicates the study may be closed, based on your responses to the Current Protocol Status. If the message below is not displayed, either revise your responses as appropriate, or submit a Continuing Review for Approval.

Current Protocol Status

Answer each of the following questions:

Yes ☐ No ☒* Is the study Open to Enrollment (i.e., the study could still enroll more individuals, add more specimens, etc.)

Yes ☒ No ☐* Have all subjects completed all research-related interventions or interactions?

Yes ☐ No ☒* Will the research remain active only for long-term follow-up of subjects?

* Are the remaining research activities limited to analysis of identifiable data (i.e., you are only analyzing identifiable data and no other research activities are performed)?

Based on your answers, this study is ready to be permanently closed. This review will be the final report for the study.

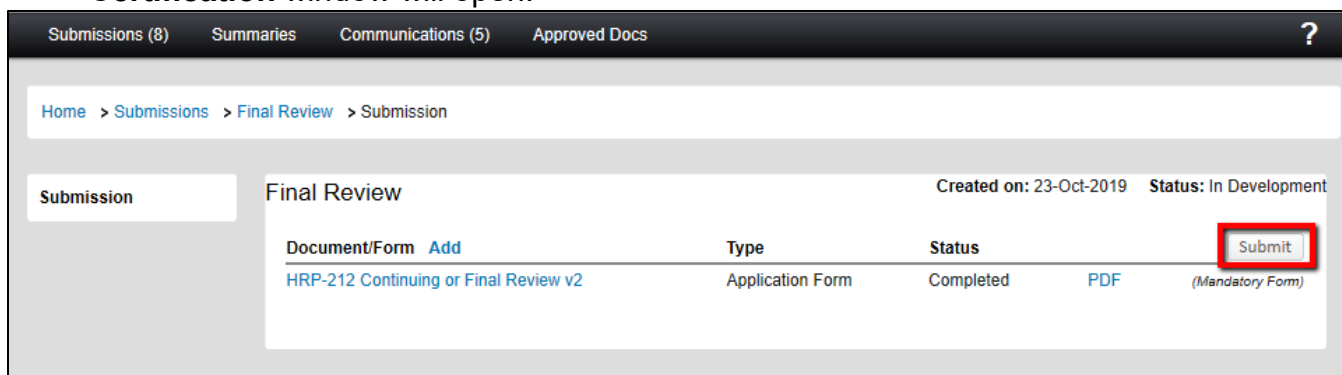
Step 3: If applicable, supporting documents can be uploaded as a part of the Continuing/Final Review eForm. Check the appropriate box or plus sign to upload annual reports for INDs and/or any publications that have resulted from the research. Click the Upload button and follow the prompts to upload the 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. The e-Form will automatically Close.

4) Submit Your Final Review:

Once the Continuing/Final Review eForm is completed and any necessary supporting documents are included, you can submit the Final Review Submission for review. Follow these 5 steps:

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



The screenshot shows the IRB eForm interface. At the top, there are tabs for Submissions (8), Summaries, Communications (5), and Approved Docs. Below the tabs is a breadcrumb trail: Home > Submissions > Final Review > Submission. The main content area is titled 'Final Review' and includes a 'Created on: 23-Oct-2019' and 'Status: In Development' label. A table lists the documents/forms submitted for review:

Document/Form	Type	Status
HRP-212 Continuing or Final Review v2	Application Form	Completed

At the bottom right of the table, there is a 'Submit' button, which is highlighted with a red box in the original image. Below the table, there is a note: '(Mandatory Form)'.



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.



Protocol **17-0483 - Michael Weil "TEST for V15"** (In Development)

[Refresh Route](#) Route Path - **Submission** [Add New Person to Review Path](#) **Continue**

Step 1 **Inform Office** IRB Office

No comments have been recorded yet

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

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