

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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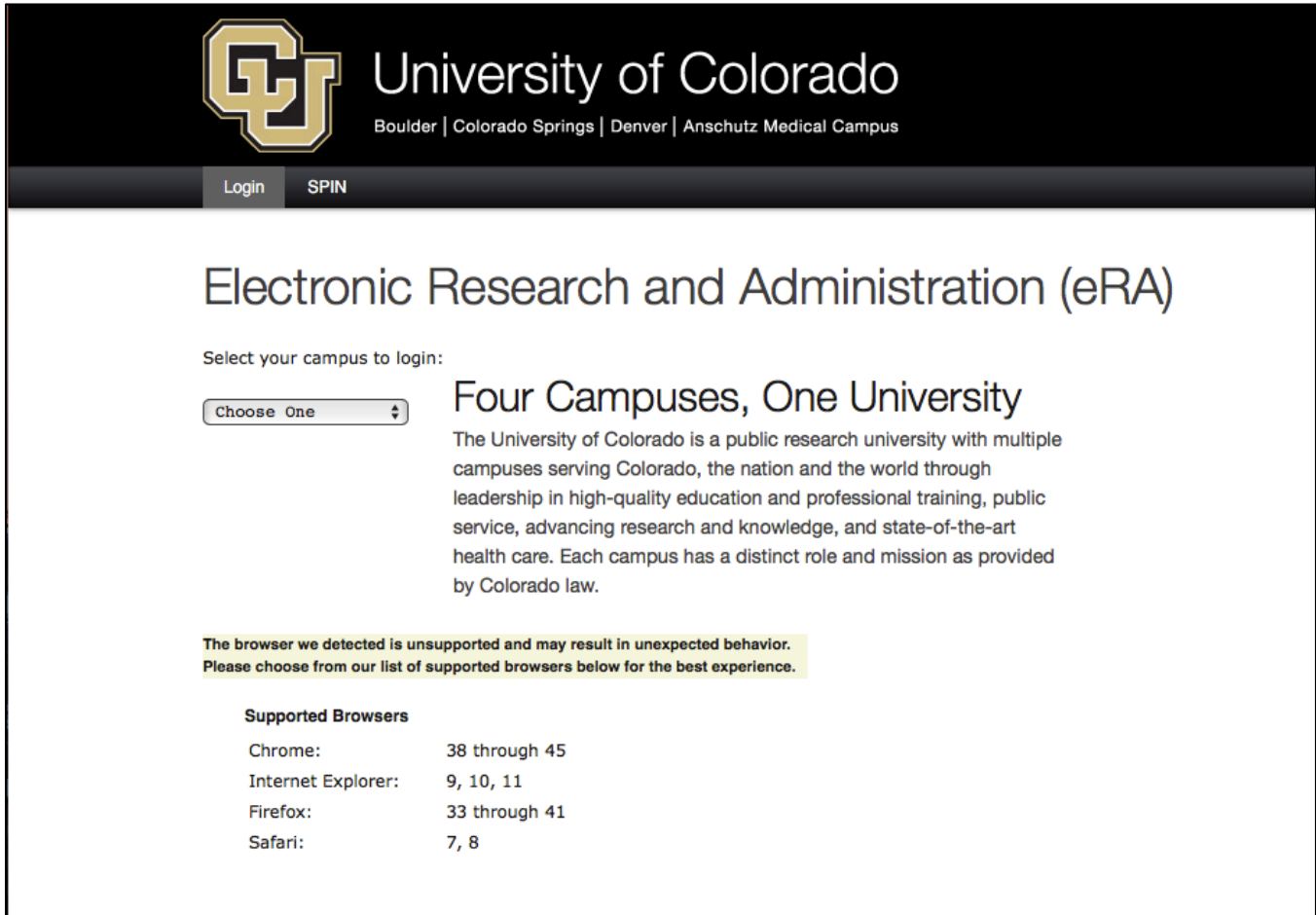
1. Login to eRA InfoEd

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.



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.

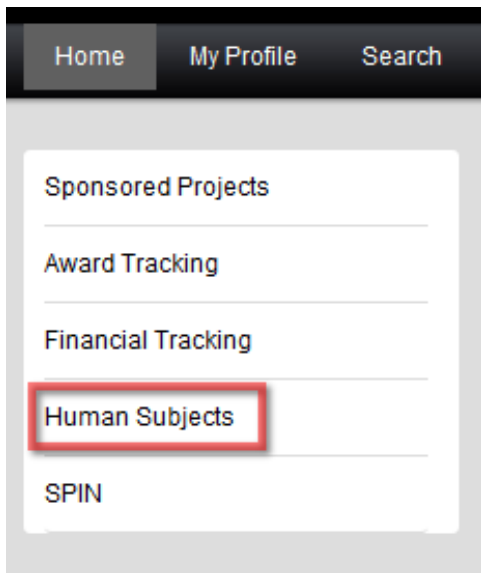
The browser we detected is unsupported and may result in unexpected behavior. Please choose from our list of supported browsers below for the best experience.

Supported Browsers

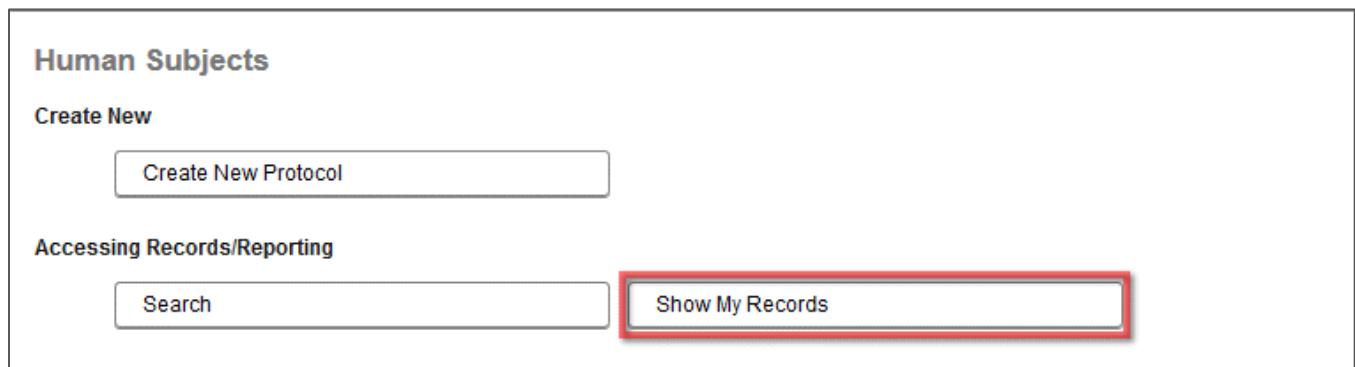
Chrome:	38 through 45
Internet Explorer:	9, 10, 11
Firefox:	33 through 41
Safari:	7, 8

2. Open the Protocol and Create a Submission

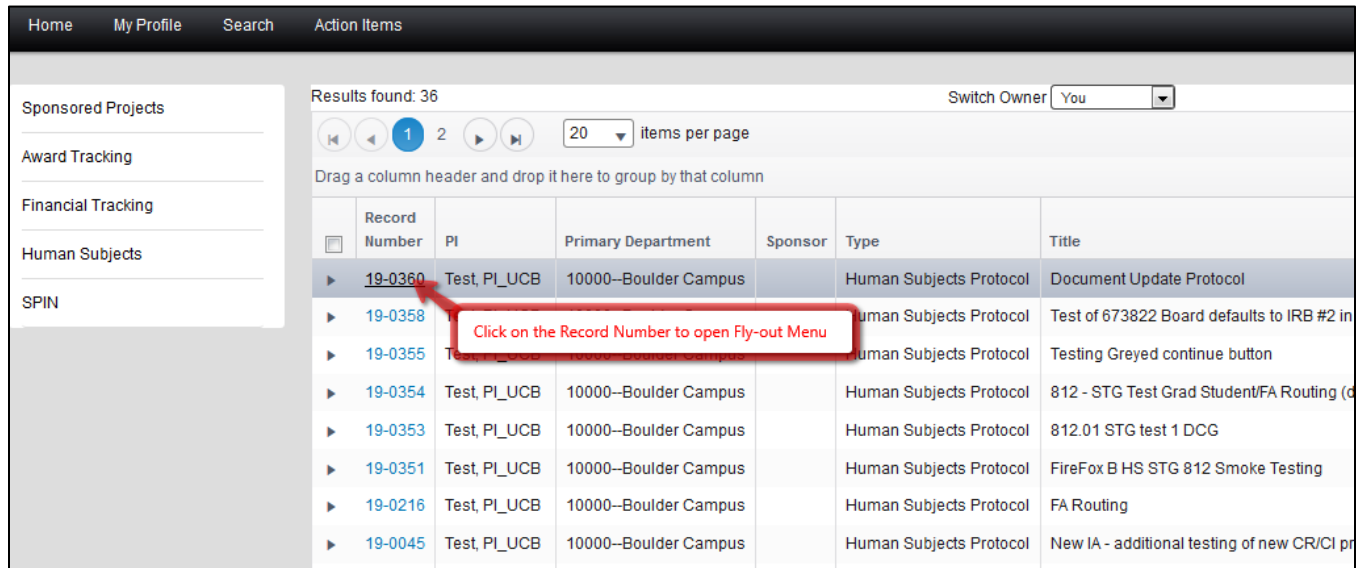
Step 1: On the *Home* screen, click **Human Subjects** in the menu on the left of the screen to access the Human Subjects menu.



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

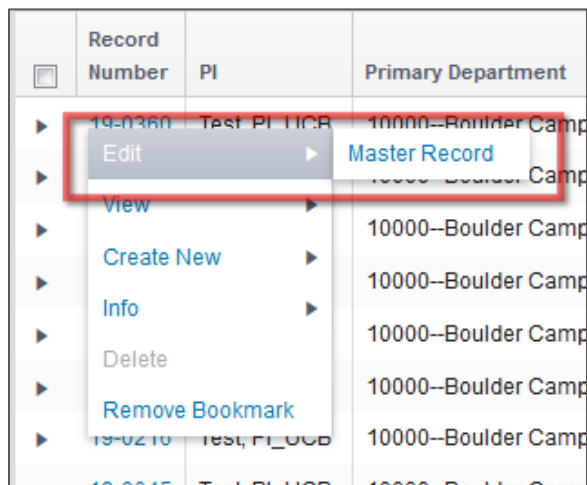
1 2 20 items per page

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, **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.



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

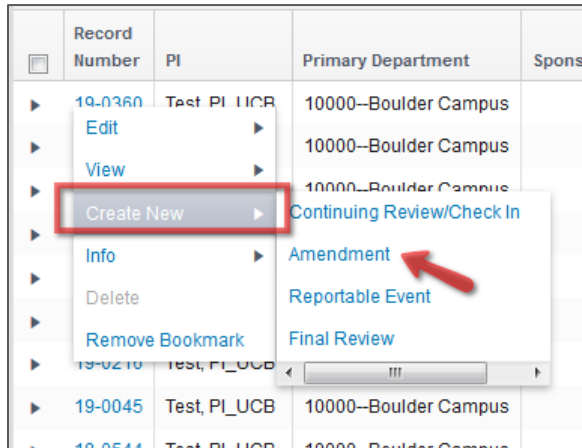
Info

Delete

Remove Bookmark

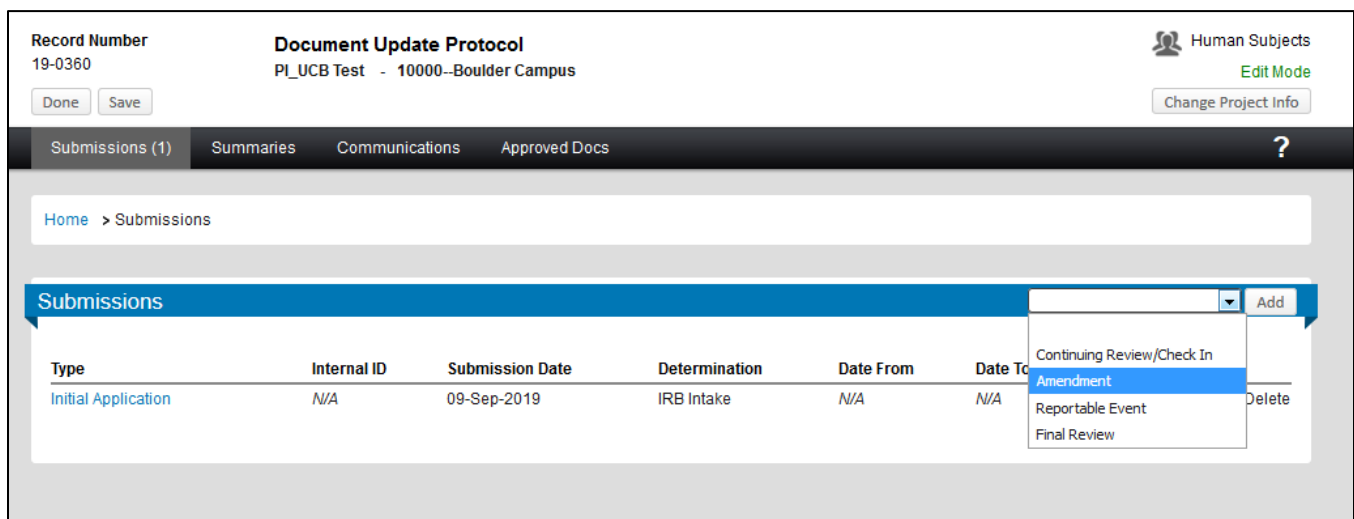
To create a new submission from this fly-out menu, **Hover** over Create New, and **Click** on the type of submission you wish to create - in this case, an Amendment. The Protocol will open and the **Amendment** screen will be displayed. Skip Step 4 if using this option.

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.

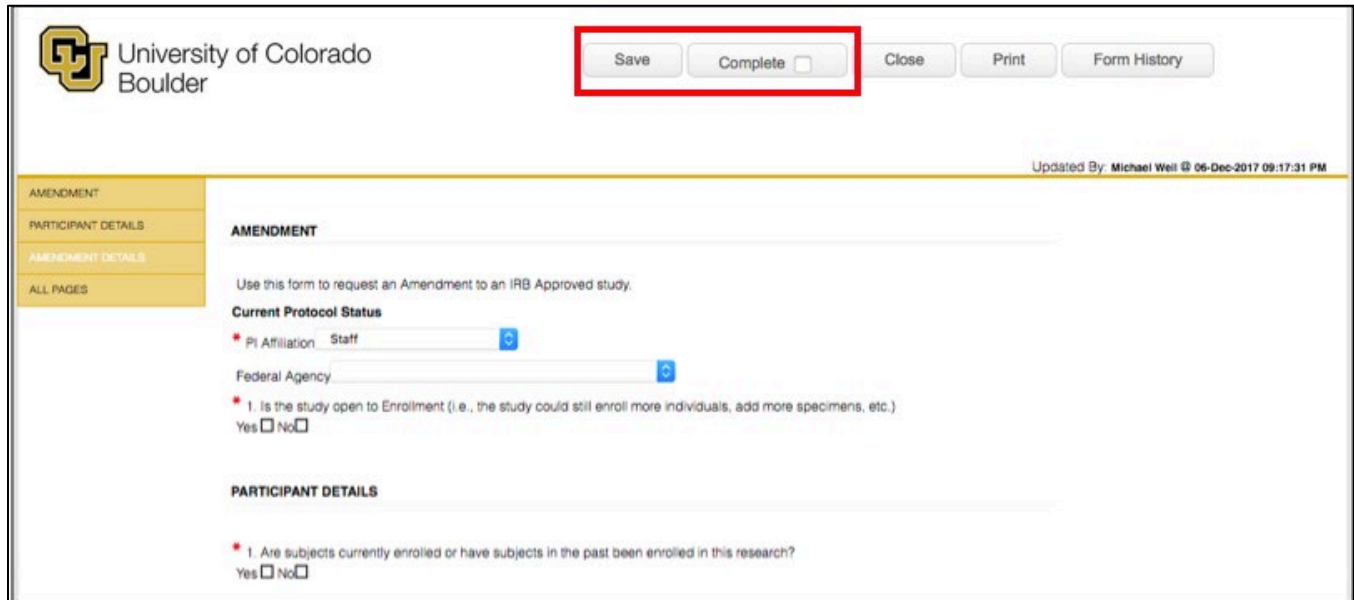


3. Complete the HRP-213 Amendment Form

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.

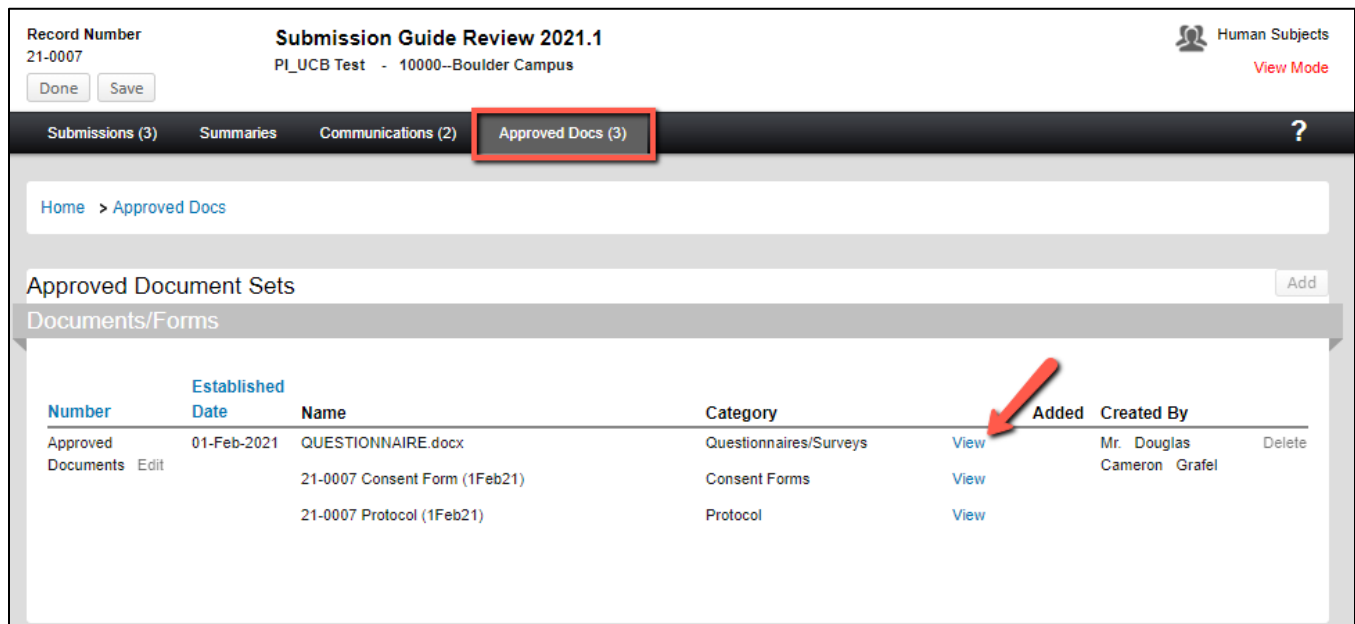
Step 5: Close the eForm.

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:



Record Number: 21-0007
Submission Guide Review 2021.1
PI_UCB Test - 10000--Boulder Campus

Human Subjects
View Mode

Submissions (3) | Summaries | Communications (2) | **Approved Docs (3)**

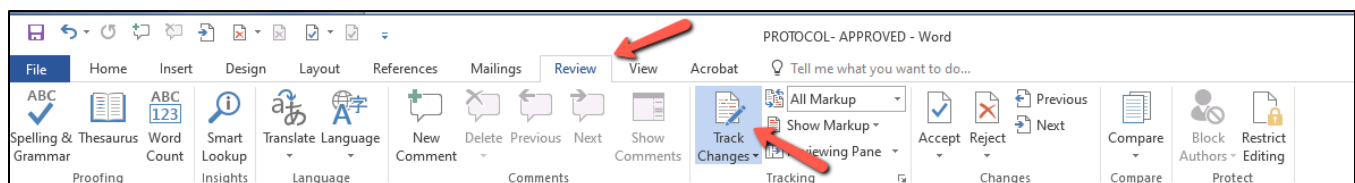
Home > Approved Docs

Approved Document Sets Add

Documents/Forms

Number	Established Date	Name	Category	Added	Created By	
Approved Documents	01-Feb-2021	QUESTIONNAIRE.docx	Questionnaires/Surveys	View	Mr. Douglas Cameron Grafel	Delete
		21-0007 Consent Form (1Feb21)	Consent Forms	View		
		21-0007 Protocol (1Feb21)	Protocol	View		

- 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:



File | Home | Insert | Design | Layout | References | Mailings | **Review** | View | Acrobat | Tell me what you want to do...

Spelling & Grammar | Word Count | Smart Lookup | Translate Language | New Comment | Delete | Previous | Next | Show Comments | **Track Changes** | All Markup | Show Markup | Accept | Reject | Previous | Next | Compare | Block Authors | Restrict Editing | Protect

STATUS BAR: TRACK CHANGES

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



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.

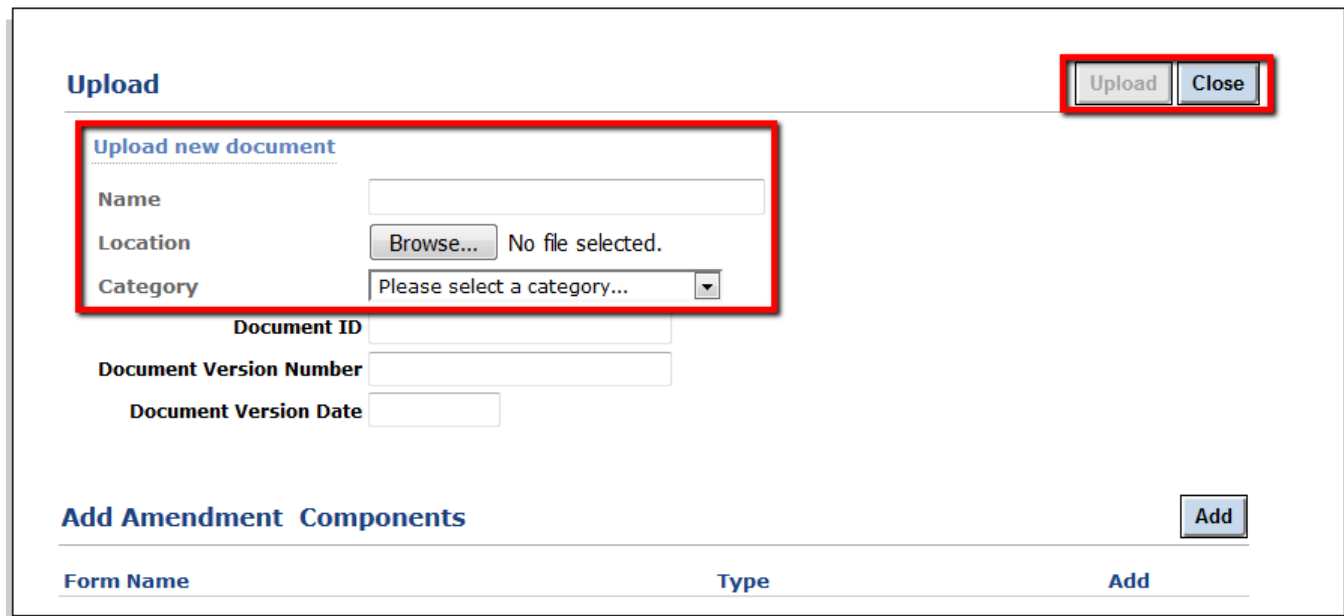
The screenshot shows the IRB eRA Amendment screen. At the top, there is a header bar with the record number '17-0483', the title 'TEST for V15', and the user 'Michael Weil - 10948--OIT-Administration'. There are buttons for 'Done', 'Save', 'Human Subjects', 'Edit Mode', and 'Change Project Info'. Below the header is a navigation bar with tabs for 'Submissions (2)', 'Summaries', 'Communications', and 'Approved Docs'. A breadcrumb trail shows 'Home > Submissions > Amendment > Submission'. On the left, there is a 'Submission' button. The main content area is titled 'Amendment' and shows a table with columns: 'Document/Form', 'Type', 'Status', and 'Submit'. The 'Add' link is highlighted in a red box next to the 'Document/Form' column header. The table contains one row with the following data: 'HRP-213 Amendment', 'Application Form', 'Completed', and 'PDF (Mandatory Form)'. The 'Status' column also shows 'Created on: 06-Dec-2017' and 'Status: In Development'.

Step 3: 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 4: Click the **Upload** button. The screen will refresh. Click the **Close** button.



Upload

[Upload](#) [Close](#)

Upload new document

Name

Location No file selected.

Category

Document ID

Document Version Number

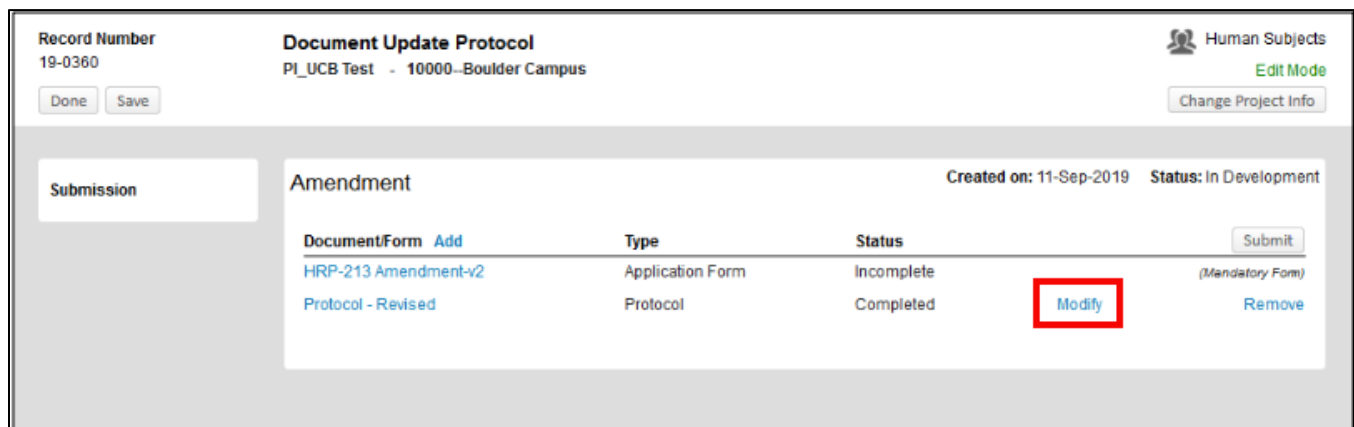
Document Version Date

Add Amendment Components

Form Name	Type	Add
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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.



Record Number: 19-0360

Document Update Protocol: PI_UCB Test - 10000-Boulder Campus

Human Subjects: [Edit Mode](#) [Change Project Info](#)

Submission

Amendment Created on: 11-Sep-2019 Status: In Development

Document/Form	Type	Status	
HRP-213 Amendment-v2	Application Form	Incomplete	Submit
Protocol - Revised	Protocol	Completed	Modify Remove

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

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

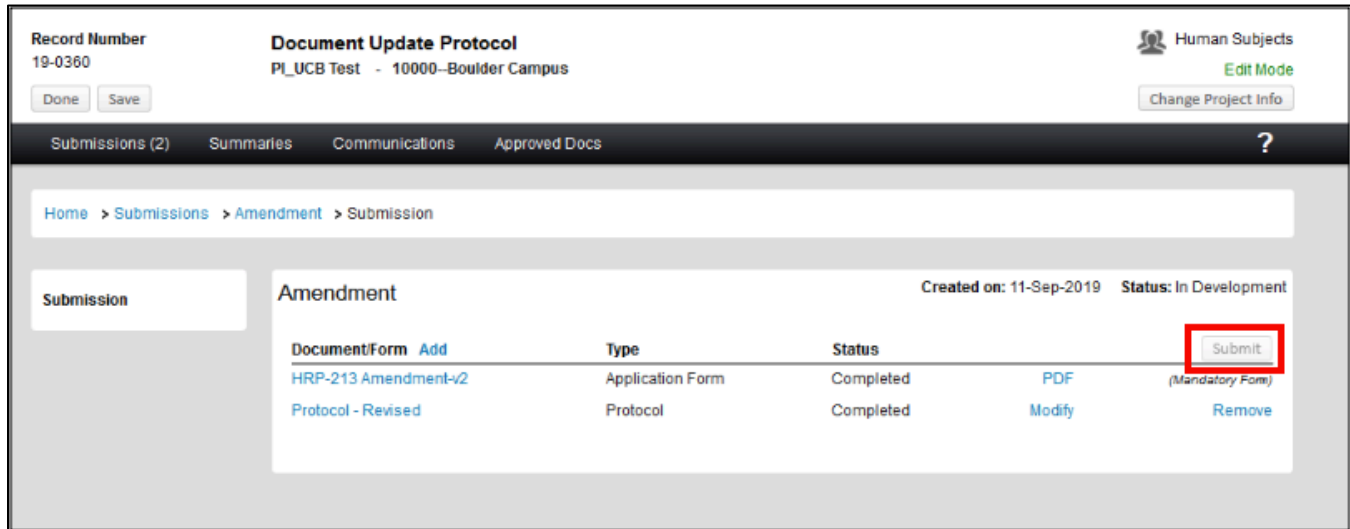
Document Version Number

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.



Record Number: 19-0360 | Document Update Protocol: PI_UCB Test - 10000-Boulder Campus | Human Subjects | Edit Mode | Change Project Info

Submissions (2) | Summaries | Communications | Approved Docs

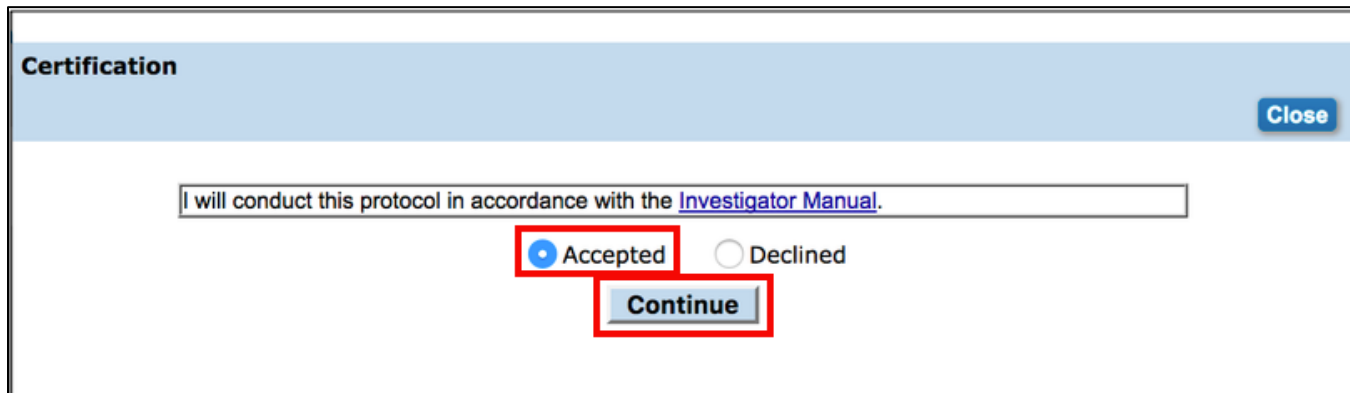
Home > Submissions > Amendment > Submission

Submission

Amendment | Created on: 11-Sep-2019 | Status: In Development

Document/Form	Type	Status		
HRP-213 Amendment-v2	Application Form	Completed	PDF	Submit (Mandatory Form)
Protocol - Revised	Protocol	Completed	Modify	Remove

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.



Certification | Close

I will conduct this protocol in accordance with the [Investigator Manual](#).

☒ Accepted
 ☐ Declined

Continue

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**.



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 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.



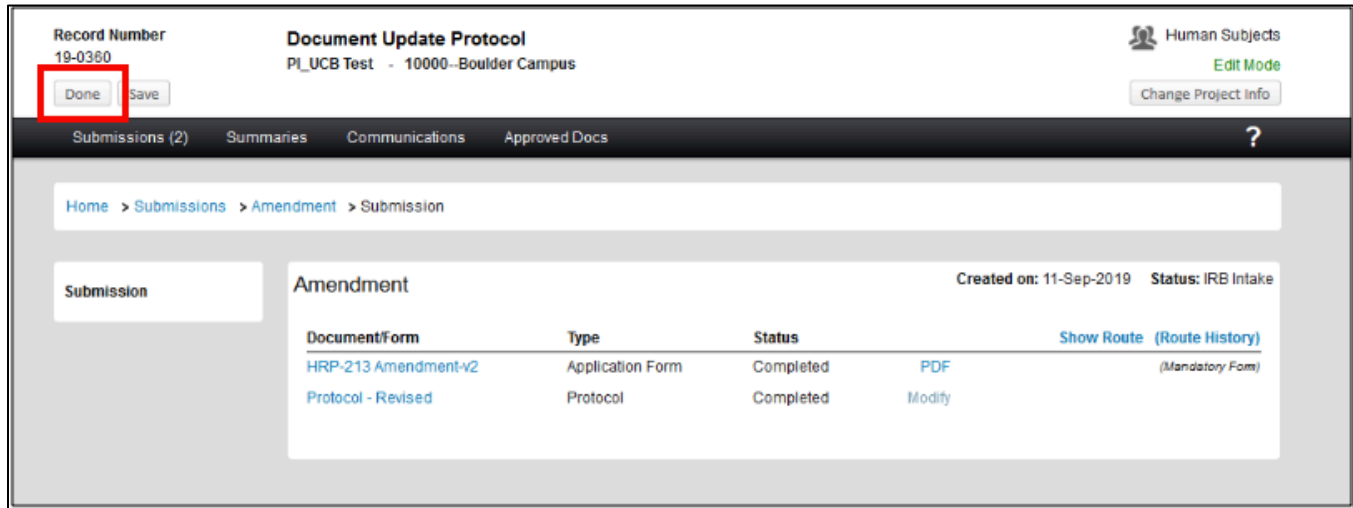
Protocol **17-0483 - Michael Weil "TEST for V15"** (In Development)

[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.



The screenshot shows the eRA system interface. At the top, there is a header bar with the following information:

- Record Number:** 19-0360
- Document Update Protocol:** PI_UCB Test - 10000-Boulder Campus
- Human Subjects:** Edit Mode
- Buttons:** Done (highlighted with a red box), Save, Change Project Info

Below the header bar is a navigation menu with the following items:

- Submissions (2)
- Summaries
- Communications
- Approved Docs
- ?

The main content area shows a breadcrumb trail: Home > Submissions > Amendment > Submission. Below this, there is a section titled "Amendment" with the following information:

- Created on:** 11-Sep-2019
- Status:** IRB Intake

Below this information is a table with the following columns: Document/Form, Type, Status, and Show Route (Route History). The table contains two rows of data:

Document/Form	Type	Status	Show Route (Route History)
HRP-213 Amendment-v2	Application Form	Completed	PDF (Mandatory Form)
Protocol - Revised	Protocol	Completed	Modify

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