



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

# *BOULDER IRB eRA InfoEd Initial Application*

Last Update: 2 April 2018

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## Preface:

This guide provides an overview of how to submit an Initial Application for a new human subjects research study to the IRB Office for review. To review the submission requirements for an Initial Application submission, visit the [Submission Types page of the IRB website](#).



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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.**

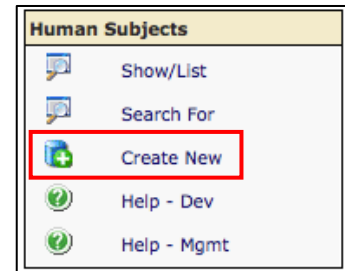
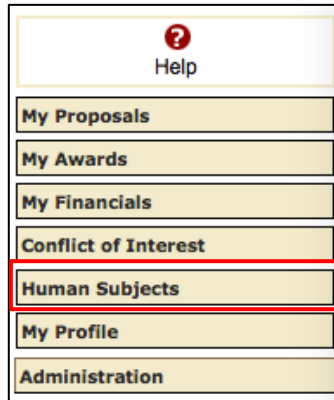
**Supported Browsers**

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

## 2) Create a New Protocol:

In eRA, “**Protocol**”<sup>1</sup> refers to a human subjects research study as a whole. Over the course of a research study, a Protocol in eRA can contain multiple submissions. The Initial Application is the first submission of a Protocol. All submissions for the study will be housed in this Protocol. To create a Protocol follow these 5 steps:

**Step 1:** On the **My Open Action Items** screen, click the **Human Subjects** menu on the left side of the window to expand the list, then click the **Create New** link. A new window will open.



**Step 2:** In the new window the **New Human Protocol in Human Subjects Development** option will already be selected. Click the **Continue** button.



<sup>1</sup> At CU Boulder, the term "Protocol" can refer to different elements of your study. As discussed above, "Protocol" can mean the overall study covering all aspects of the research, as well as the electronic record used to manage a particular study in eRA. It can also refer to the specific Protocol Document, which is the document describing the Objectives, Study Design, and Procedures reviewed by the IRB.



**Step 3:** Enter a title for the Protocol, then click the **Continue** button.

**Step 4:** In the next screen, your name will be listed by default under the **Member** field as the selected PI. Do not change this information. If another investigator is the Principal Investigator for the study, that person must create and submit the Initial Application. Click the **Continue** button.

**Step 5:** The window will refresh to the **Initial Application** screen.

| Document/Form                          | Add | Type             | Status     | Submit                  |
|--|-----|------------------|------------|-------------------------|
| HRP-211: FORM - Initial Application v7 |     | Application Form | Incomplete | (Mandatory Form)        |
| Protocol                               |     | Protocol         | Incomplete | Upload (Mandatory Form) |



### 3) Complete the Submission Attachments:

The **Initial Application** screen is where you will upload your submission documents. Each study must include:

- an Initial Application eForm (i.e. HRP-211: FORM – Initial Application)
- a Protocol Document **in MS Word format (.docx or .doc)**

Placeholders for these two documents will already be in your Initial Application when it is created.

The screenshot shows the IRB eRA Initial Application screen. At the top, it displays the Record Number (17-0483) and the study title (TEST for V15) by Michael Weil. There are buttons for 'Done', 'Save', 'Human Subjects', 'Edit Mode', and 'Change Project Info'. Below this is a navigation bar with 'Submissions (1)', 'Summaries', 'Communications', and 'Approved Docs'. A breadcrumb trail shows 'Home > Submissions > Initial Application > Submission'. The main content area is titled 'Initial Application' and shows 'Created on: 04-Dec-2017' and 'Status: In Development'. A table lists the attachments:

| Document/Form                          | Add | Type             | Status     | Submit                  |
|--|-----|------------------|------------|-------------------------|
| HRP-211: FORM - Initial Application v7 |     | Application Form | Incomplete | (Mandatory Form)        |
| Protocol                               |     | Protocol         | Incomplete | Upload (Mandatory Form) |

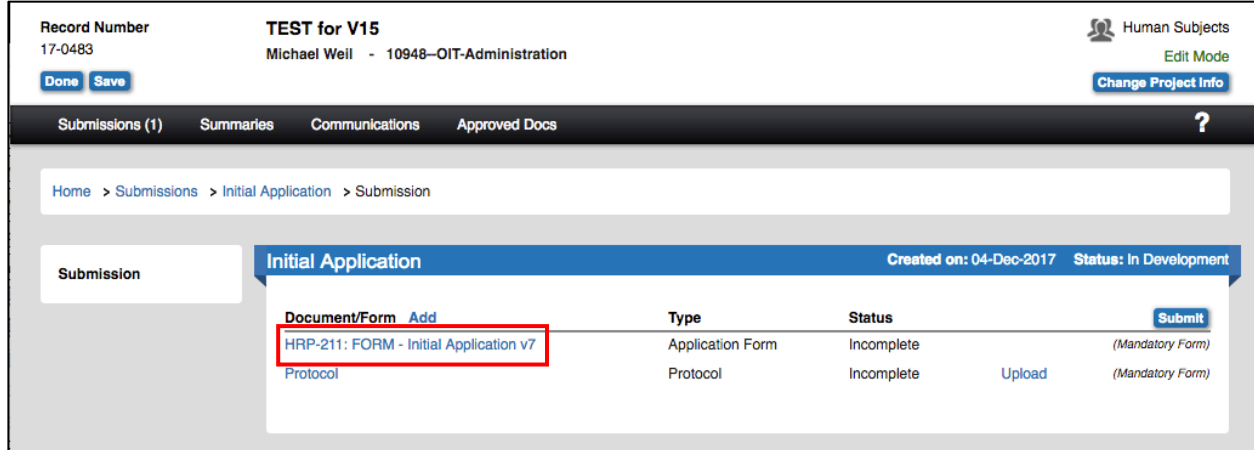
Many studies also require a Consent Form **in MS Word format (.doc or .docx)**, as well as other supporting documents. Use the following links for guidance on how to add or edit these attachments:

1. eForm
2. Protocol
3. Consent Form
4. Supporting Documents

## eForm

The **eForm** is an electronic dynamic form. To complete the eForm, follow these 4 steps:

**Step 1:** Click on the **HRP-211: Form – Initial Application** link. A new window will open.



Record Number: 17-0483 | TEST for V15 | Michael Weil - 10948-OIT-Administration | Human Subjects | Edit Mode | Change Project Info

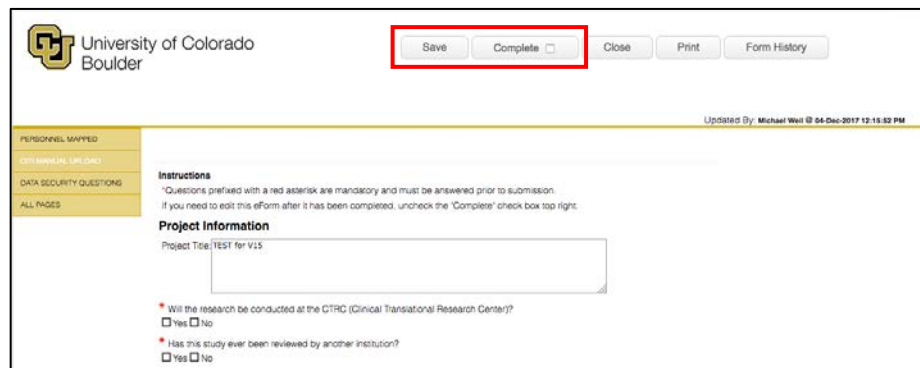
Submissions (1) | Summaries | Communications | Approved Docs

Home > Submissions > Initial Application > Submission

Submission: Initial Application | Created on: 04-Dec-2017 | Status: In Development

| Document/Form                          | Add | Type             | Status     | Submit                  |
|--|-----|------------------|------------|-------------------------|
| HRP-211: FORM - Initial Application v7 |     | Application Form | Incomplete | (Mandatory Form)        |
| Protocol                               |     | Protocol         | Incomplete | Upload (Mandatory Form) |

**Step 2:** Enter the required information in the eForm. It is dynamic and will generate questions according to your answers. Periodically save your work by clicking the **Save** button.



University of Colorado Boulder | Save | Complete  | Close | Print | Form History

Updated By: Michael Weil @ 04-Dec-2017 12:15:02 PM

PERSONNEL MAPPED | CONTINUING EDUCATION | DATA SECURITY QUESTIONS | ALL PAGES

**Instructions**  
 \*Questions prefixed with a red asterisk are mandatory and must be answered prior to submission. If you need to edit this eForm after it has been completed, uncheck the 'Complete' check box top right.

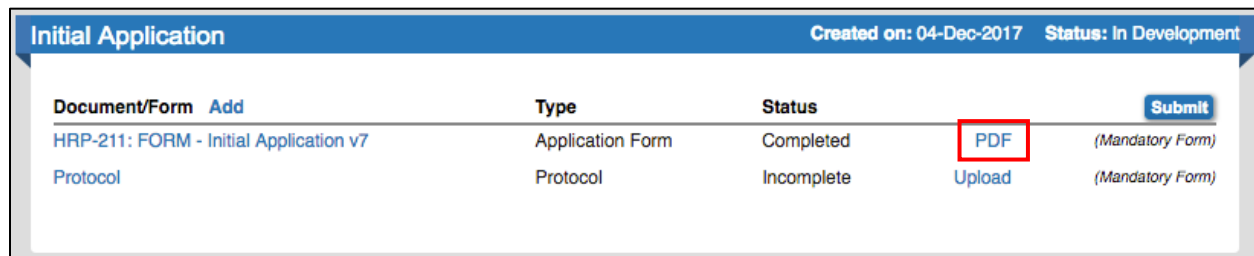
**Project Information**  
 Project Title: TEST for V15

\* Will the research be conducted at the CTIRC (Clinical Translational Research Center)?  
 Yes  No

\* Has this study ever been reviewed by another institution?  
 Yes  No

**Step 3:** When you have finished with the form, check the **Complete** box.

**Step 4:** Click the **PDF** link review the eForm and verify all information is correct.



Initial Application | Created on: 04-Dec-2017 | Status: In Development

| Document/Form                          | Add | Type             | Status     | Submit                  |
|--|-----|------------------|------------|-------------------------|
| HRP-211: FORM - Initial Application v7 |     | Application Form | Completed  | PDF (Mandatory Form)    |
| Protocol                               |     | Protocol         | Incomplete | Upload (Mandatory Form) |

### Tip: CITI Training Completion

All key personnel listed on a study must have current CITI training. The eForm will automatically import this information for investigators who have correctly set up their CITI profile. If the information is not present, a place to upload CITI certificates is also included. Reports for the principal investigator, co-investigators, faculty advisors and all other key personnel should be attached. For more information, [visit the CITI Training page of the IRB website.](#)

## Protocol

The **Protocol Document** is the document that explains the design and procedures of your study. Every study must have a complete Protocol Document. You can [download the Protocol Template from the IRB website](#) or from within eRA. To complete the Protocol Document, follow these 6 steps:

**Step 1:** Click on the **Protocol** link. A new window will open where you can download the template. This step and Step 2 may be skipped if you have downloaded and completed the Protocol Document from the IRB's website.

| Initial Application                    |     | Created on: 04-Dec-2017 |            | Status: In Development |                  |
|--|-----|-------------------------|------------|------------------------|------------------|
| Document/Form                          | Add | Type                    | Status     |                        | Submit           |
| HRP-211: FORM - Initial Application v7 |     | Application Form        | Completed  | PDF                    | (Mandatory Form) |
| <b>Protocol</b>                        |     | Protocol                | Incomplete | <b>Upload</b>          | (Mandatory Form) |

**Step 2:** Click on the corresponding link to download your preferred version (formatted or ADA compliant). Save the document to your computer, then close the window. Open the template in MS Word.

**HRP-503: TEMPLATE - Protocol**

**Download:**

- [Formatted version](#)
- [ADA compliant version](#)

Use this template to draft the protocol document for your study. This template includes essential topics of interest that the IRB looks for during review.

Remove all template guidance **before** you attach the file to the submission. The template guidance is only intended to help you draft the document and should not be retained in the final version.

**Contact the IRB Office:**

Phone: 303-735-3702  
 Email: [irbadmin@colorado.edu](mailto:irbadmin@colorado.edu)  
<https://www.colorado.edu/vcr/irb>

**Step 3:** Complete the form as guided, then click **File > Save As** to save the file to your computer with a unique name (e.g. Protocol\_010117).

**Step 4:** In your Internet browser, return to the Initial Application screen. Click the **Upload** link for Protocol Document. A new Upload window will open.

**Step 5:** Click the Location **Browse** button. A dialog box will open. Locate and select the completed Protocol Document on your computer, then click the **Open/Choose** button in the dialog box to attach it. Click the **Upload** button.

**Upload** Upload Close

Location **Browse...** No file selected.

Folder [ROOT] ▾

Document ID

Document Version Number

Document Version Date

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

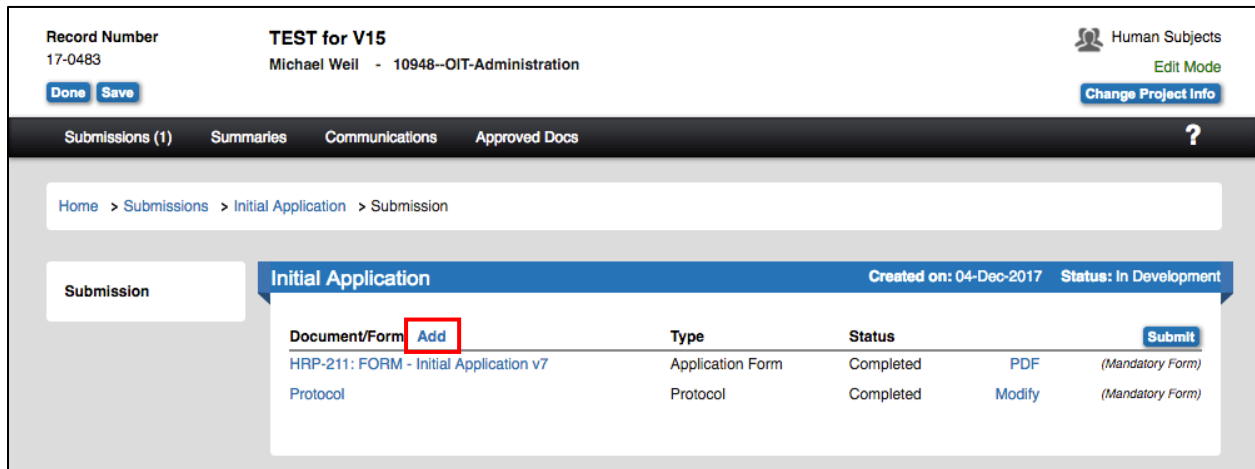
**Step 6:** Click the **Upload** button. The Upload window will close and the **Initial Application** screen will refresh. Click on the **Protocol** link to view the attachment.



## Consent Form

A **Consent Form** is a common attachment you may be required to include. You can [download the Consent Form template from the IRB website](#). To add the Consent Form, follow these 4 steps:

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



The screenshot shows the 'Initial Application' screen for record 'TEST for V15'. At the top, there are buttons for 'Done', 'Save', 'Change Project Info', and 'Edit Mode'. Below the navigation tabs, a table lists documents. The 'Add' link in the 'Document/Form' column header is highlighted with a red box.

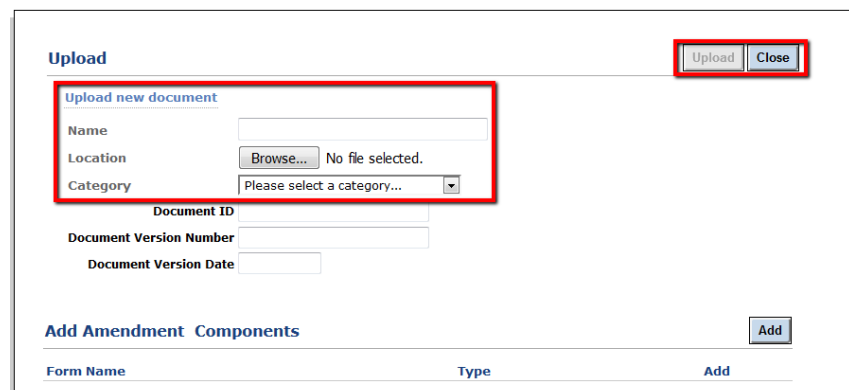
| Document/Form                          | Add | Type             | Status    | Submit                  |
|--|-----|------------------|-----------|-------------------------|
| HRP-211: FORM - Initial Application v7 |     | Application Form | Completed | PDF (Mandatory Form)    |
| Protocol                               |     | Protocol         | Completed | Modify (Mandatory Form) |

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

- Name:** Enter a unique name (e.g. ConsentForm\_010117).
- 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.
- Category:** Select **Consent Forms**.

**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.



The screenshot shows the 'Upload' window. The 'Upload' and 'Close' buttons at the top right are highlighted with red boxes. The form fields include 'Name', 'Location' (with a 'Browse...' button), 'Category' (a dropdown menu), 'Document ID', 'Document Version Number', and 'Document Version Date'. At the bottom, there is an 'Add Amendment Components' section with an 'Add' button.



**Step 4:** On the **Initial Application** screen, you will see the new Consent Form 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.

Record Number: 17-0483  
TEST for V15  
Michael Weil - 10948--OIT-Administration

Human Subjects  
Edit Mode  
Change Project Info

Done Save

Submissions (1) Summaries Communications Approved Docs

Home > Submissions > Initial Application > Submission

Submission

**Initial Application** Created on: 04-Dec-2017 Status: In Development

| Document/Form Add   | Type             | Status    |               | Submit           |
|---|------------------|-----------|---------------|------------------|
| HRP-211: FORM - Initial Application v7                    | Application Form | Completed | PDF           | (Mandatory Form) |
| Initial Application eRA Tutorial (dated 2014-10-29) .docx | Consent Forms    | Completed | <b>Modify</b> | Remove           |
| Protocol  | Protocol         | Completed | <b>Modify</b> | (Mandatory Form) |

**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** Upload Close

Upload new version of an existing document

Location Browse... No file selected.

Document Version Number

Document Version Date

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

**Attributes** Save Close

Modify the attributes of the existing document

Name Initial Application eRA Tutorial (dated 20

Category Consent Forms

Document ID

Document Version Number

Document Version Date

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

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.

**Upload & Attributes** Upload Close

Upload a New Version and Modify the Attributes of this Document

Location Browse... No file selected.

Name Initial Application eRA Tutorial (dated 20

Category Consent Forms

Document ID

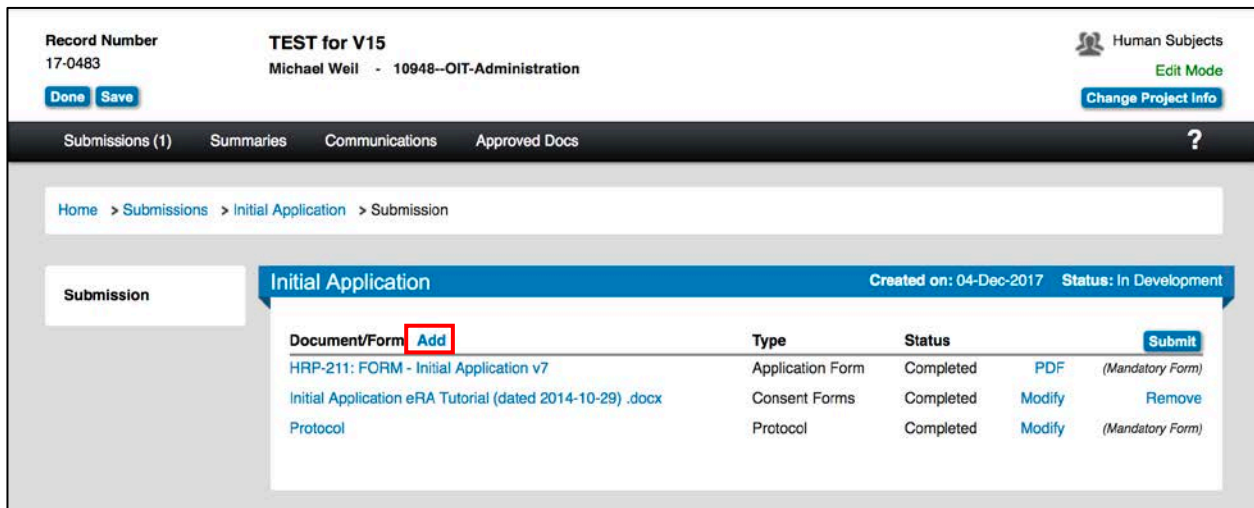
Document Version Number

Document Version Date

## Supporting Documents

**Supporting Documents** may be required for your study (e.g. *additional Consent Forms, surveys, interview questions, recruitment materials, questionnaires etc.*). Review the [submission type requirements on the IRB website](#) to determine which supporting documents are required for your study. 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 **Initial Application** screen. The link is located next to the **Form/Document** column header.



Record Number: 17-0483  
 TEST for V15  
 Michael Weil - 10948--OIT-Administration

Human Subjects  
 Edit Mode  
 Change Project Info

Submissions (1) | Summaries | Communications | Approved Docs

Home > Submissions > Initial Application > Submission

Submission: Initial Application  
 Created on: 04-Dec-2017 | Status: In Development

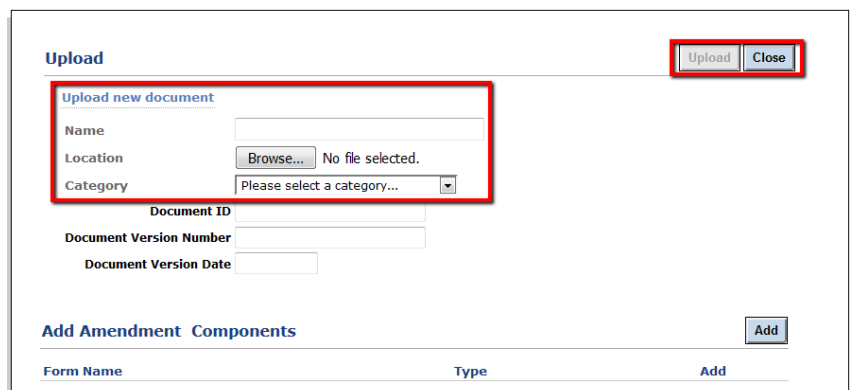
| Document/Form   | Type             | Status    |        | Submit           |
|---|------------------|-----------|--------|------------------|
| HRP-211: FORM - Initial Application v7                    | Application Form | Completed | PDF    | (Mandatory Form) |
| Initial Application eRA Tutorial (dated 2014-10-29) .docx | Consent Forms    | Completed | Modify | Remove           |
| Protocol  | Protocol         | Completed | Modify | (Mandatory Form) |

**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

Upload new document

Name:

Location:  No file selected.

Category:

Document ID:

Document Version Number:

Document Version Date:

Add Amendment Components

Form Name:  Type:  Add:



**Step 4:** On the **Initial Application** 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.

Record Number: 17-0483  
TEST for V15  
Michael Weil - 10948--OIT-Administration

Human Subjects  
Edit Mode  
Change Project Info

Done Save

Submissions (1) | Summaries | Communications | Approved Docs

Home > Submissions > Initial Application > Submission

Submission

Initial Application Created on: 04-Dec-2017 Status: In Development

| Document/Form Add   | Type             | Status    |        | Submit           |
|---|------------------|-----------|--------|------------------|
| HRP-211: FORM - Initial Application v7                    | Application Form | Completed | PDF    | (Mandatory Form) |
| Initial Application eRA Tutorial (dated 2014-10-29) .docx | Consent Forms    | Completed | Modify | Remove           |
| Protocol  | Protocol         | Completed | Modify | (Mandatory Form) |

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 Upload Close

Upload new version of an existing document

Location  no file selected

Document Version Number

Document Version Date

Attributes Save Close

Modify the attributes of the existing document

Name

Category

Document ID

Document Version Number

Document Version Date

Upload & Attributes Upload Close

Upload a New Version and Modify the Attributes of this Document

Location  no file selected

Name

Category

Document ID

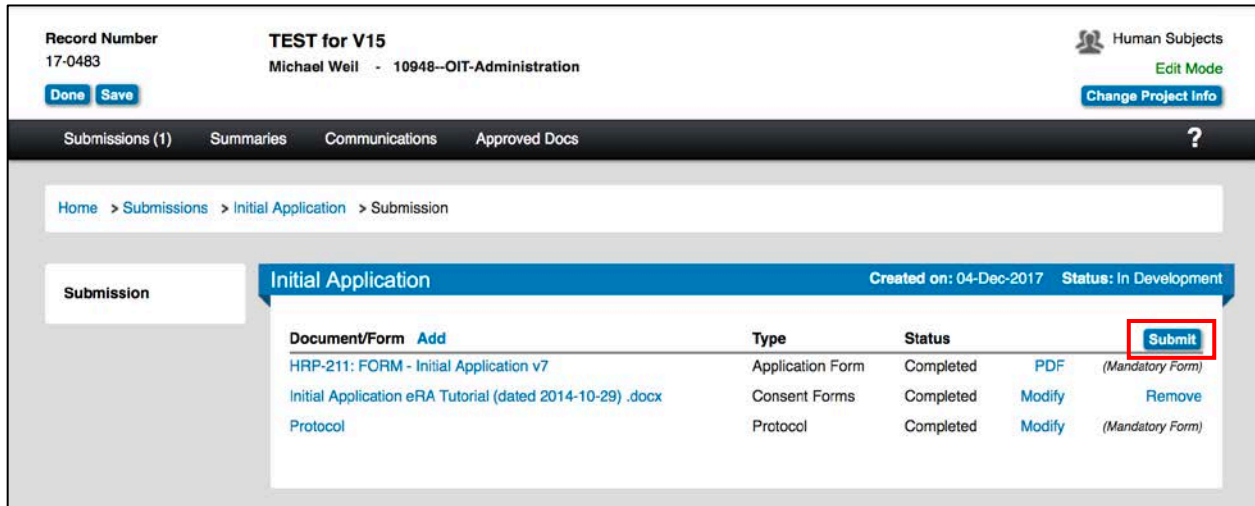
Document Version Number

Document Version Date

#### 4) Submit Your Initial Application

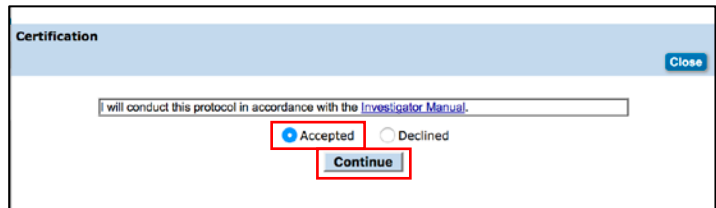
Once all of your attachments are uploaded, you can submit your Protocol for IRB review. To submit your Initial Application, follow these 5 steps:

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



| Document/Form   | Type             | Status    | Actions                 |
|---|------------------|-----------|-------------------------|
| HRP-211: FORM - Initial Application v7                    | Application Form | Completed | PDF (Mandatory Form)    |
| Initial Application eRA Tutorial (dated 2014-10-29) .docx | Consent Forms    | Completed | Modify Remove           |
| Protocol  | Protocol         | Completed | Modify (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**.



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

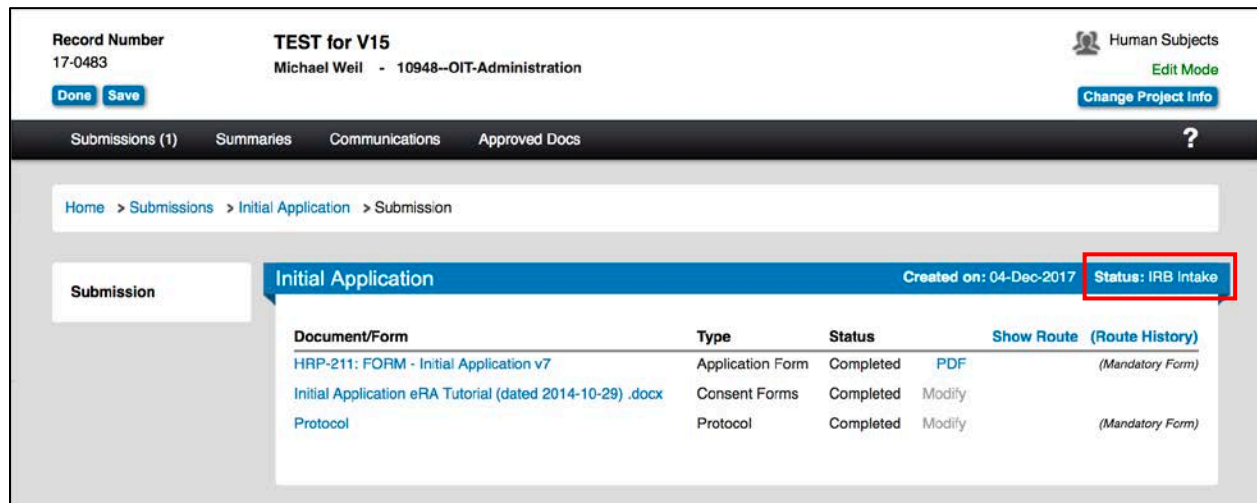
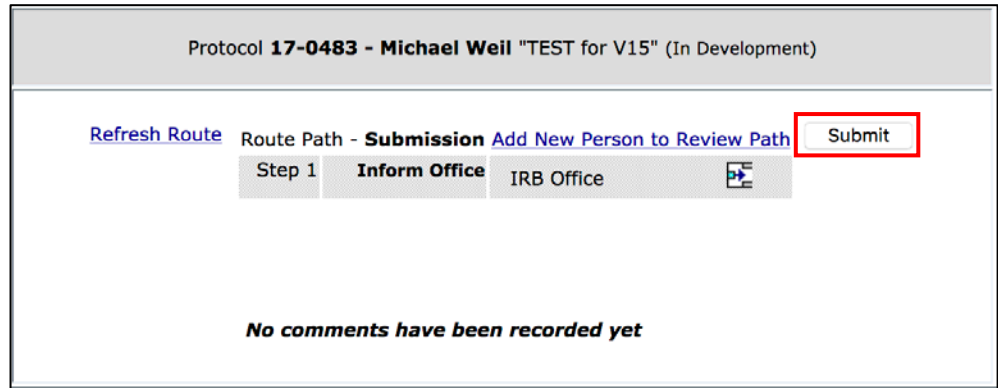
Route Path - Submission **Add New Person to Review Path** Submit

Step 1 Inform Office IRB Office

No comments have been recorded yet



**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 **Initial Application** 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.