Creating an Initial Application for a New Submission

This document will guide you in the process of submitting a new study for review to the IRB Office.

To review the submission requirements for an Initial Application submission please visit the IRB website.

STEP 1: Login to eRA

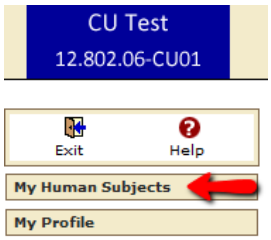
1. Navigate to https://era.cu.edu in Internet Explorer.
2. Click the **Login** tab on the left side of the screen and enter your CU Identikey username/password, and select "Boulder" as the Campus.
3. Click the **Login** button.
4. Upon successful login, the **My Open Action Items** screen will appear.

STEP 2: Create a New Protocol

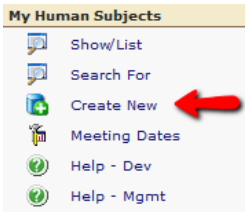
Create one protocol for a single study. All submissions for this study should be submitted through this protocol. Submission examples include but are not limited to: the Initial Application, any Response submissions, Continuing Reviews, and Study Closures. To create a protocol:

Already Created a Protocol?
Go to **My Human Subjects** > **Show/List** and click on the icon to access the appropriate protocol. Proceed to Step 3.

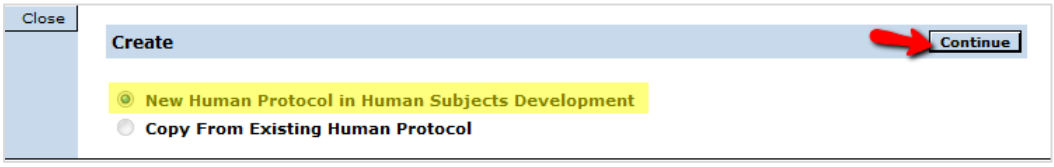
1. In the **My Open Action Items** screen, click the **My Human Subjects** tab in the menu on the left side of the screen.



2. Click the "**Create New**" link. A new window will open.

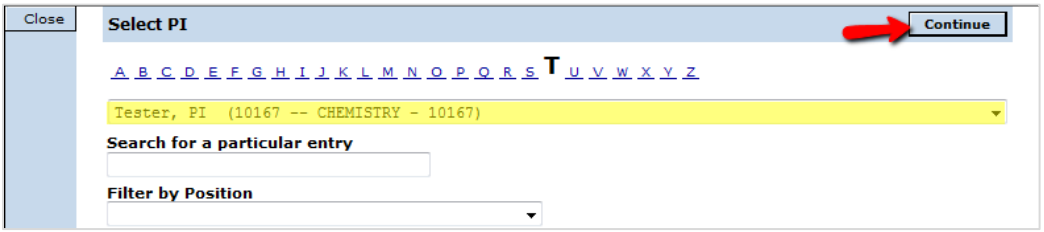


3. The "**New Human Protocol in Human Subjects Development**" option will already be selected. Click the **Continue** button.



4. Enter a title for the protocol you are creating then click the **Continue** button.

5. In the next screen you are assigning the Principal Investigator. Your name should populate in the dropdown box. If it does not, pick your name from the listed choices. The available choices are alphabetized by last name. When finished, click the **Continue** button.



6. The window will refresh to the **Components for Initial Application** screen.

STEP 3: Complete the Submission Components

1. The **Components for Initial Application** screen is the workspace for your submission components. Each study must include:
   (1) an Initial Application eForm
   (2) a protocol in MS Word document format (.doc)

   Many studies will also require a consent form in MS Word document format (.doc) or other supporting documents. For guided help on completing these items use the following links:
   - Edit the eForm
   - Download, Edit and Upload the Protocol
   - Download, Edit and Upload the Consent Form
   - Add and Attach Supporting Documents

Edit the eForm

To edit the eForm:

1. Click the icon to open the eForm in a new window.
2. In the new window, begin entering your information. Start by choosing your principal investigator affiliation (Faculty, Graduate Student, Staff, or Undergraduate Student). Because the eForm is a dynamic form, it will generate questions according to the answers you provide. Periodically save your work throughout your edits by clicking the Save button.
3. When finished, click the Save button. Then check the "**Complete**" box in the upper right corner. The eForm window will close and you will be returned to the **Components for Initial Application** screen.
4. Click the icon to view the eForm and verify all information.

Text Box Word Limit

Text boxes are limited to 500 words. If you must copy/paste text into the eForm from another document, be sure it is from a plain text source (e.g. Notepad).

Saving the eForm

If you cannot finish the eForm in one sitting, make sure you click the Save button before you close out of the eForm window. When you return, click the Check In/Out button to resume editing.

Download, Edit and Upload the Protocol

Because the protocol is a mandatory submission, it is already listed as an option under the **Components for Initial Application** screen. To create a protocol document from the template:

1. Download the protocol template by clicking on the icon.
2. A File Download dialog box will appear. Click the **Save** button to save the file to your computer's hard drive. Make sure you take note the folder name that you saved the protocol template under.
3. Navigate to the folder where you saved the document. Open the document in Microsoft Word and begin editing the document to fit your study.
4. Save the edited document.
5. Upload the protocol document by clicking the icon in the protocol listing. A new Document Upload window will open. Click the **Browse** button to open the dialog box that will allow you to find and choose the protocol document. Once you have selected the file and are back in the Document Upload window, click the **Upload** button to finalize your attachment. The Document Upload window will close and the **Components for Initial Application** screen will refresh.

Cam I Remove the Protocol?

The protocol is mandatory and cannot be removed.

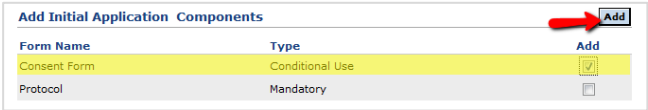
If you need to replace a protocol you have uploaded, click the upload icon (), and select the revised protocol document when picking your file.

Download, Edit and Upload a Consent Form

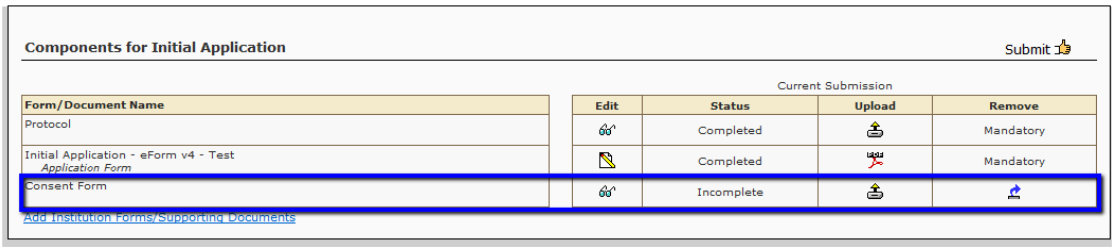
To add a consent form you must first add the Consent Form option to your attachment list. To do this:

1. Click the blue "**Add Institution Forms/Supporting Documents**" link on the **Components for Initial Application** screen.

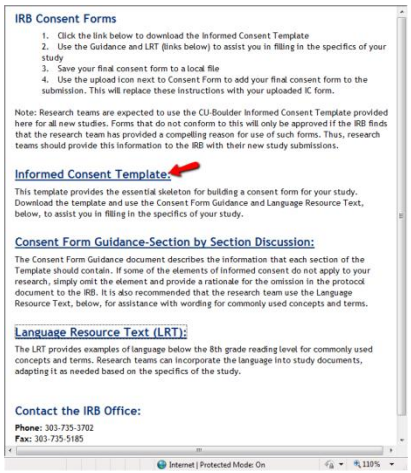
2. A new Add Components window will appear. At the bottom of this screen, under the **Add Initial Application Components** section, check the *Consent Form* **"Add"** box, then click the **Add** button.



3. The Add Components window will close, and the **Components for Initial Application** screen will refresh. A new listing for the Consent Form will appear in the table.



6. Click on the icon. A new Informed Consent Guided Help window will appear. Download the informed consent template by clicking on the "**Informed Consent Template**" link.
7. A File Download dialog box will appear. Click the **Save** button to save the file to your computer's hard drive. Make sure you take note the folder name that you saved the template under.
8. Navigate to the folder where you saved the document. Open the document in Microsoft Word and begin editing the document to fit your study. Use the Consent Form Guidance-Section by Section Discussion and the Language Resource Text (LRT) to help you complete the document. These forms are also available to download in the Informed Consent Guided Help window.
9. Save the edited document.



10. Close the Informed Consent Guided Help window. Back in the **Components for Initial Application** screen upload the consent form document by clicking the icon in the consent form listing. A new Document Upload window will open. Click the **Browse** button to open the dialog box that will allow you to find and choose the consent form document. Once you have selected the file you will return to the Document Upload window. You do not need to fill in the other fields. Click the **Upload** button to finalize your attachment, then click the **Close** button to close the window. You will return to the **Components for Initial Application** screen which will refresh.

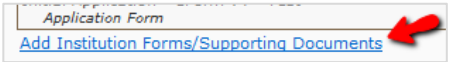
> **Need a New Consent Form Template?**
> The IRB Consent form help window with links to the guidance documents and the consent form template will be replaced when you upload your consent form. If you need to access to these items again, you may download them from the IRB website.

Add and Attach Supporting Documents

Supporting documents may be required for your study (e.g. ***additional consent forms, surveys, interview questions, recruitment materials, questionnaires etc.***). To see if you need to attach any supporting documents, review the submissions requirements on the IRB website.

> **Is It a Supporting Document?**
> ***CVs, Grants,*** and ***Conflict Management Plans*** are attached directly to the eForm. They **should not** be attached as supporting documents.

1. To add a new document, click the blue "**Add Institution Forms/Supporting Documents**" link on the **Components for Initial Application** screen.



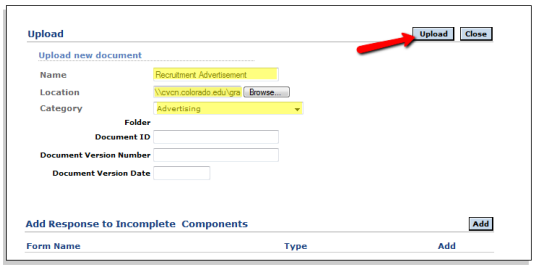
2. A new window will appear to allow you to upload your new document. Enter the following information:

   - **Name** - Give the new file a unique name (e.g. Consent Form – Student)
   - **Location** - Click the **Browse** button to select the file from your hard drive
   - **Category** - Pick an appropriate Category

   You do not need to fill in the other fields.

   When you have finished, click the **Upload** button to add the document. The Upload window will refresh. Repeat the upload process to add any other new documents. When finished, click the **Close** button to close the window and return to the **Components for Initial Application** screen.

Commonly Used Categories	
Advertising	Copies of recruitment flyers or advertisements
Response	Explanatory document that responds to provisions in an Incomplete or Modification letter
Misc. Documents	All other documents not explicitly stated in the list such as a non-CU-B CITI training certificate



3. Click the icon to view and verify that all documents are readable. If you need to completely remove an item from the submission, click the icon.

Step 4: Submit Your Initial Application

Before you send your submission to the IRB Office, make sure that you and all key personnel have current CITI training. Training is valid for a three-year period after course completion. The **principal investigator and all key personnel** must complete CITI training before research begins.

The two courses that qualify for the CITI training are:

(1) **Biomedical Research Investigators and Key Personnel**, and
(2) **Social Behavioral Research Investigators and Key Personnel**

You and your personnel should take the course that is appropriate to your type of research.

Other CITI Training Courses

The following courses **DO NOT** satisfy the CITI training requirement:

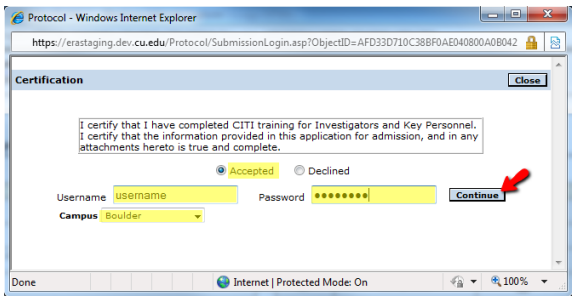
- Students in Research
- Reference Resource
- ANY Responsible Conduct of Research

*The discontinued *Coursework Projects* will be accepted; however, upon expiration the investigator should complete the Investigators and Key Personnel course.

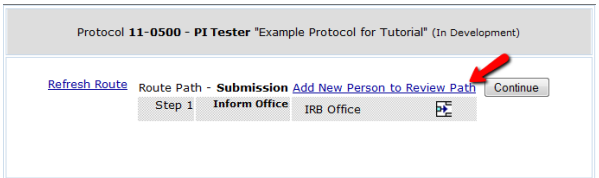
If you or your personnel's CITI training has expired, you or your personnel must pass the appropriate refresher course. **All submissions** with incomplete or expired CITI training will be returned **without** review. You may check your current CITI training status by visiting http://www.citiprogram.org.

1. If you are certain you and your personnel's CITI training is current, click the Submit icon in the upper right corner of the **Components for Initial Application** screen.

2. A new window will appear for you to verify that you have completed CITI training for Investigators and Key Personnel. Accept the terms and enter your (1) username, (2) password, (3) and select "Boulder" as your Campus. When you are finished, click the **Continue** button.

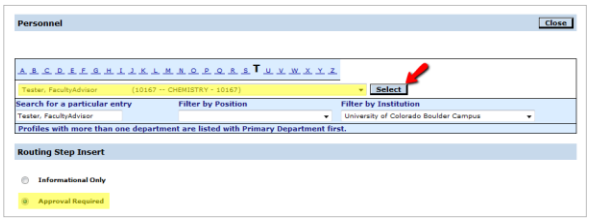


The next screen is the **Route Path** screen. If you are an **undergraduate** or **graduate student** you **MUST** route the submission to your faculty advisor **BEFORE** submitting it to the IRB Office. To route the submission:

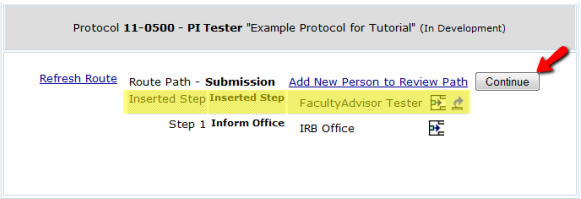


(1) Click the "**Add New Person to the Review Path**" link.

(2) A new window will open. Choose your faculty advisor's name from the dropdown list and make sure the **Approval Required** option is selected. Click the **Select** button.

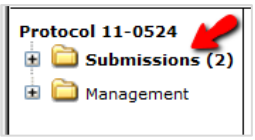


If successful, you will return to the **Route Path** window and your faculty advisor's name will appear at the top of the list as an **Inserted Step**. The listed step for your faculty advisor should *always* precede the Inform Office step.

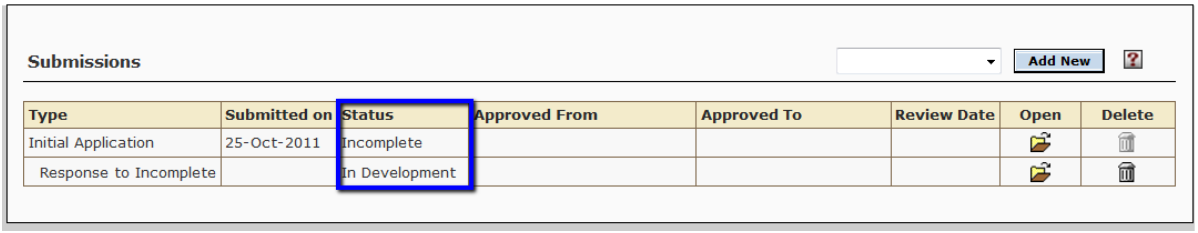


3. Confirm that the routing path is correct then click the **Submit** button.

4. You are finished with your submission. To verify that your submission was successful, click on the top-level **Submissions** folder located on the left side of the screen.



The window will refresh and the **Submissions** screen will be displayed. In the table, look for the Status column to view the status message of your submission.



5. The following table explains common status messages you may see:

Status Message	Description
In Development	You are working on a submission and it has not been sent to the IRB.
Awaiting Faculty Advisor Review	You are waiting for your faculty advisor to review and either approve or disapprove your submission.
IRB Intake	The submission has successfully been sent to the IRB.
Pending Review	The submission is with a Reviewer but a decision has not yet been made.
Scheduled for XXX Review	The submission has been scheduled for a specific type of review.
Completed	The submission has been reviewed and the principal investigator (PI) has been notified.
Approved	The submission has been approved by the IRB.
Modifications Required	The submission required modifications before review may continue.
Incomplete	The submission is incomplete.
Deferred	The submission requires further review at a later convened meeting.

6. When finished, click the Done icon in the upper left corner of the screen to close the study.
7. Back in the **My Open Action Items** screen, click the Exit icon in the upper left corner of the screen to completely exit out of eRA.

If you would like to provide feedback regarding the use of eRA please take a moment to complete this anonymous survey.