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](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.
2) Create a New Protocol:
In eRA, “Protocol”\(^1\) 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.

![Human Subjects menu expansion](image)

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

![Create New Protocol](image)

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\(^1\) 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.

![Protocol Creation](image)

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.

![Select PI](image)

Step 5: The window will refresh to the **Initial Application** screen.
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 been in your Initial Application when it is created.

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.

![Image of eForm interface](image1)

**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.

![Image of eForm interface](image2)

**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.

![Image of eForm interface](image3)

**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.

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

**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.

*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.

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

a. **Name:** Enter a unique name (e.g. ConsentForm_010117).

b. **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.

c. **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.
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.

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

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.
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.

![Initial Application Screen](image)

**Step 2:** 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 3:** Click the **Upload** button. The screen will refresh. Click the **Close** button.
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.
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.

![Initial Application Screen](image)

**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 Window](image)

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.

![Routing Path](image)
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.