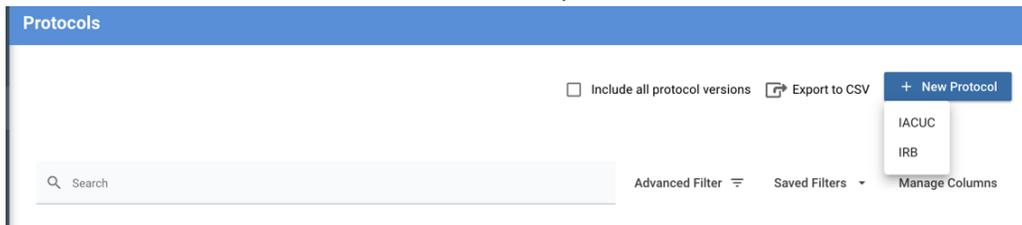


# How to create a new IRB Protocol

1. To access Kualu for IRB protocols go to <https://colostate.kuali.co/protocols> (or access via the IRB webpage)
  - a. Choose the appropriate CSU campus
  - b. Sign in with your CSU eID name and password
  - c. After signing in, the Principal Investigator will be directed to the “Manage Protocols” screen where all protocols will be stored once submitted (for review or for amendments). The title, number given to the protocol, and the status of each protocol are shown (Hint: You can search and filter protocols).
  - d. Click **+ New Protocol** and choose the IRB drop-down



2. Select PI name and Department from drop-down menu

**\*\*\* Make sure you don't select a unit with a "PB" designation or you will access the Pueblo IRB form and your protocol will not be directed to the correct committee**

Click **NEXT** to continue

3. Select the appropriate application type for the project you are submitting. Note that your selection will change form questions

Application Type

NHSR

Exempt

Expedited

Full Board

Request for Reliance on an External IRB

118 Determination

Does this study include use of existing data or biospecimens?

Yes

No

Does this study include use of student educational records and data?

Yes

No

Does this study include the use of human blood, cells, tissues or body fluids?

Yes

No

Application Type

NHSR

Exempt

Expedited

Full Board

Request for Reliance on an External IRB

118 Determination

**118 Determination**

Lacking Definite Plans

Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds.

This Kuali application will result in an acknowledgement from the CSU IRB that you intend to submit a protocol for review and approval before engaging with human subjects for the purposes of research.

Date project activity involving human participants is anticipated to begin:

 \_\_\_\_\_

Click **NEXT** to enter your IRB Protocol page

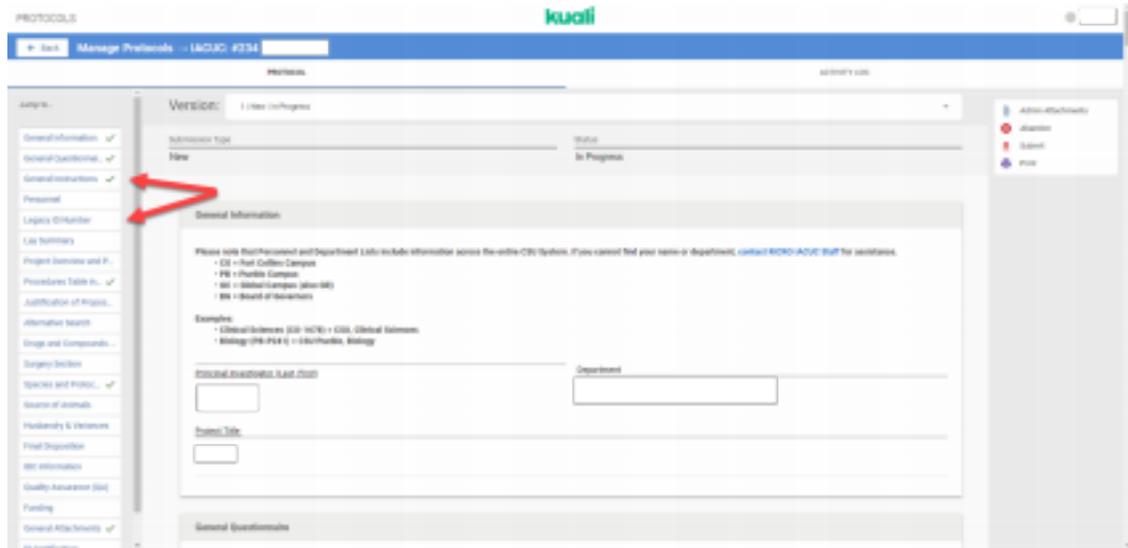
4. IRB Protocol page **GENERAL LAYOUT:**

- a. After entering the IRB Protocol page, clicking "**BACK**" will save your work and give the protocol an "***In Progress***" status which can be accessed for further corrections by clicking on the name of the protocol via the "Manage Protocols" home screen
- b. The left sidebar menu allows for access to each section of the protocol. To jump around to

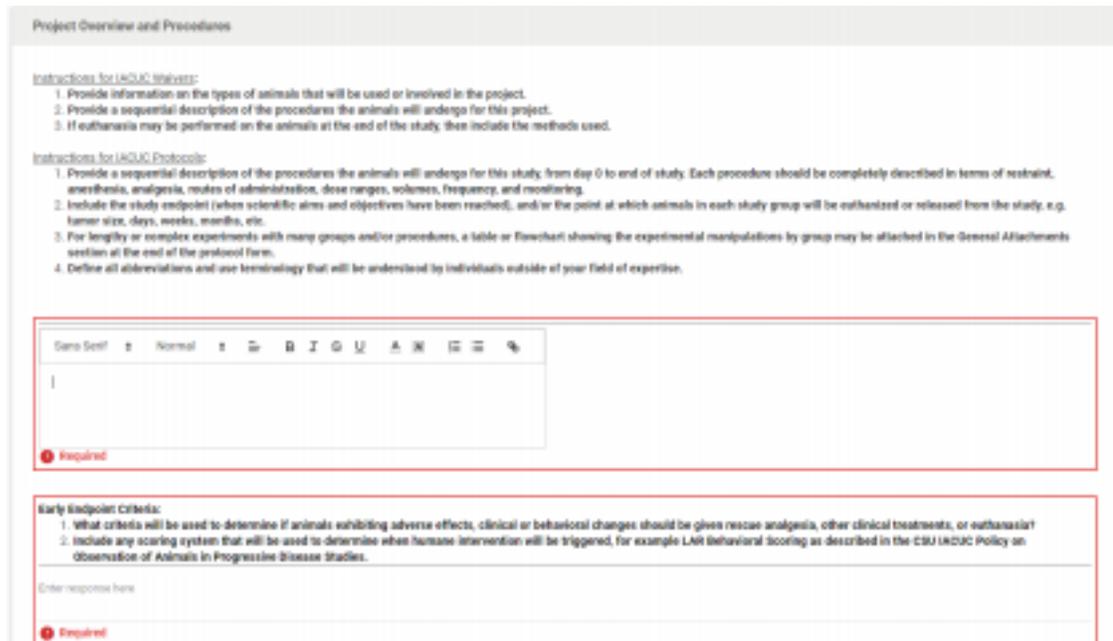
different sections, click on the corresponding section on the left sidebar menu.

c. Progressive logic is used throughout the form, so your answer ***may cause additional question fields to appear*** -- requiring you to enter additional information

d. Each section includes instructions pertinent to that section with hotlinks to their additional information



e. If a required section is not complete, a red box will appear



5. **General Attachments:** You will be prompted to attach relevant materials

Attachments

Attach all relevant documentation to your research in this section. Please label each item appropriately, so your IRB reviewers understand the purpose and population each document aims to address. Please delete the existing attachment and upload the Tracked Changes version and Clean revised document for review to update or revise any existing attachments.

Any documentation that a participant will see must be reviewed and approved by the IRB, including consent, recruitment, communications, tools, instruments, etc. Additional documents required for review include funding proposals, contracts, letters of agreement, methodology, related approvals, etc. For more information and guidance on what documentation to attach, please visit the IRB website.

Answers within your application indicate that the following documentation is required:

**Device Documentation:** device manufacturer's documentation, FDA determination, etc.

**Drug Documentation:** investigator's brochure or package insert, etc.

**Methodology Section:** drafted or final Thesis or Dissertation methodology

Columns Add Line

		ATTACHMENT TYPE	ATTACHMENT	NAME
		Debrief	<a href="#">KUALI IRB MODULE .PDF</a>	

6. **PI Certification:** checking this section ensures CSU IRB that all personnel are properly certified and trained, all procedures are conducted in accordance with IRB regulations

ACTIVITY LOG ANCILLARY REVIEW PERMISSIONS

Obligations

The Principal Investigator is ultimately responsible for the conduct of this project. Obligations of the Principal Investigator include the following:

- Receive IRB approval or determination prior to enrolling any subjects or collecting any data intended for research use.
- Manage and maintain all research records, including consent retention, for at least three (3) years after the close of the study, or longer per sponsor requirement.
- Ensure that personnel training status remains current.
- Provide all subjects a copy of the signed consent form, when applicable.
- Keep protocol up to date by submitting amendments for review and approval before instituting changes in any aspect of the study.
- Maintain current protocol approval by submitting renewals, as required.
- Promptly report any violations, deviations, unanticipated problems or adverse events to the IRB.
- Notify the IRB when the study is complete and take steps to close the protocol.

I understand that as the Principal Investigator I am fully responsible for the execution and management of this study and that I am responsible for the performance of any sub-investigators or key personnel including their adherence to all applicable policies and regulations. I understand and agree to the obligations listed above.

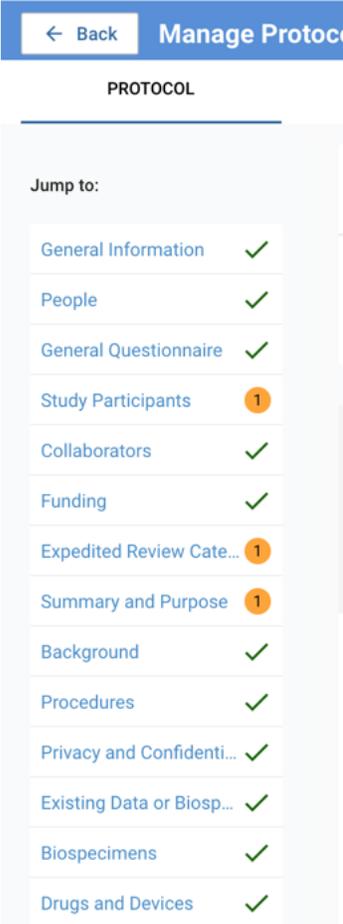
I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge.

Notify PI To Submit  
Admin Notes & Files  
Abandon  
Submit  
Print

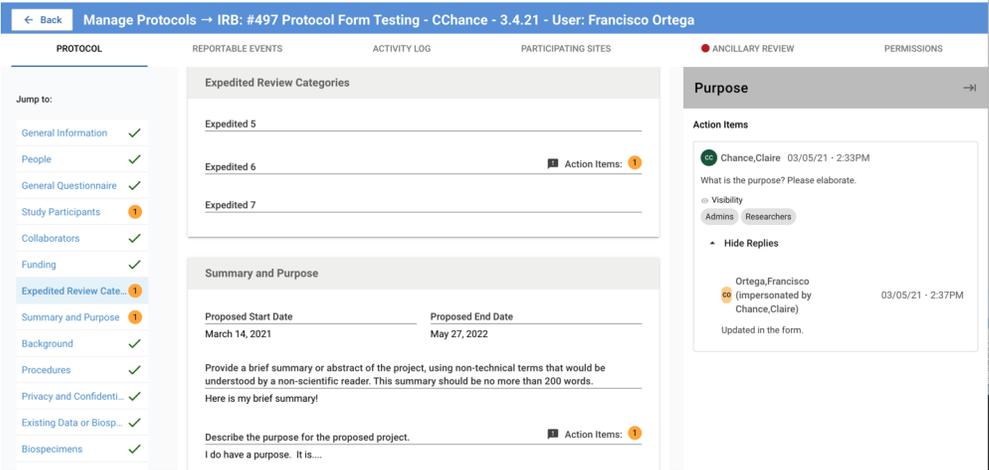
7. **Once all sections are completed, and accurate the best of the PI's knowledge, the protocol may be submitted for review**

- a. Submission does NOT mean the protocol is approved. The protocol must be reviewed by a designated member of the CSU IRB approval board.

8. After a designated member of the CSU IRB approval board has reviewed the protocol, the protocol may be returned for edits. Comments will appear throughout the protocol page as “**Action Items.**” The left sidebar menu will show which section has an action item (shown as an orange circle with a number for amount of comments in each section).



a. Click on the “**Action Item**” box to read comments/action items



9. At the top of the page, **each version of the protocol can be accessed via the drop-down menu** next to the **“Version” heading**. This includes the NEW version of the protocol with any revisions required after submission and any amendments.

The screenshot shows the top navigation bar with tabs: PROTOCOL, REPORTABLE EVENTS, ACTIVITY LOG, PARTICIPATING SITES, and ANCILLARY REVIEW. The main header reads "IRB: #497 Protocol Form Testing - CChance - 3.4.21 - User: Francisco Ortega". On the left is a "Jump to:" sidebar with menu items: General Information (checked), People (checked), General Questionnaire (checked), Study Participants (1), Collaborators (checked), Funding (checked), Expedited Review Cate... (1), Summary and Purpose (1), Background (checked), and Procedures (checked). A dropdown menu is open, listing versions: 1 | New | Revisions Required, 7 | Amended | Superseded, 6 | Amendment | Merged Amendment, 5 | Amendment | Revisions Required, 4 | Amended | Superseded, 3 | Amendment | Merged Amendment, and 2 | Initial | Superseded. To the right, a status box shows "Status: Revisions Required" and "Time in Current Status: Since March 8 - 24 days".

a. By checking the **“Compare Versions” box**, you can compare versions and any edited text will show in green

This screenshot shows the same interface as above, but with the "Compare Versions" checkbox checked. Below the header, there are two dropdown menus: "Selected Version:" set to "7 | Amended | Superseded" and "Compare a Version:" set to "4 | Amended | Superseded". Below these is a section titled "Amendment Instructions" with a list of five steps: 1. Complete this one-page form. 2. Update the sections of your protocol that you are requesting to amend. 3. Upload any amended documentation (consent; assent; attachments) in Tracked Changes and Clean Versions and appropriately label the items. 4. Electronically "sign" your application by clicking the check box on the Obligations page. 5. Remember to click "Submit Form" so that the IRB administrators receive your request. At the bottom, there is a prompt to "Summarize the proposed changes to the protocol in lay terms." and an "Action Items: 1" indicator. A sample of edited text is shown: "cProvide a brief summary of abstract v4 Removing the other group. v7".

10. When edits are finished, resubmit edited protocol (top right of page) to be reviewed by the CSU IRB