How to create a new IRB Protocol

1. To access Kuali 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.

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

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 Tracking 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

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<thead>
<tr>
<th>ATTACHMENT TYPE</th>
<th>ATTACHMENT NAME</th>
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<tbody>
<tr>
<td>Debrief</td>
<td>KUALI IRB MODULE .PDF</td>
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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

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 a 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.

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

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