

Student IRB Quick Start

Your Role

In student research that is reviewed by the IRB, you are the principal investigator (PI). As the PI it is your responsibility to ensure you and anyone else who will be working with you on the study, including your faculty advisor, have completed CITI training. You must track the progress of the study and find the right channels to complete any necessary tasks such as securing a POI or recruiting a suitable foreign local reviewer if you are conducting international research. The IRB's primary function is to review your study to ensure the safety of the participants. The IRB offers guidance for preparing your study for review, but ultimately you and your faculty advisor are responsible for the management of the study.

Your Advisor

Because you are a student you must identify a CU faculty member as your faculty advisor. Ideally your advisor should be familiar with conducting research involving human subjects. When you have questions, your advisor should be the first person you contact. He or she should work closely with you to design, submit and conduct your research. Your advisor must complete CITI training. This advisor is also responsible for electronically reviewing each submission that you submit to the office. This includes any Response submissions that are a result of the review process. Any submission that is submitted to the office without the electronic review of your faculty advisor will be returned to you without IRB review and will drop to the end of the review queue.

Checklist

- Read the Investigator Manual** (<http://www.colorado.edu/vcr/node/214/attachment/newest>). The manual outlines the entire IRB process from cradle to grave. It includes practical advice such as how to write a protocol and consent form, and provides explanatory information about various IRB topics such as the different classifications of research, IRB decisions, and overall study management.
- Identify the faculty advisor** who will work with you on this project. He or she should be a CU affiliate and must complete CITI training. If he or she has not completed the training when you submit your study for review, the review will be stalled until your advisor completes the appropriate course or you choose another advisor. Your advisor must review every submission you create in eRA including any Response submissions (e.g. Response to Incomplete or Response to Modifications) that arise from the review process. You will obtain this review electronically by routing every submission to your advisor through eRA (Tutorial: <http://www.colorado.edu/vcr/node/246/attachment/newest>)
- Contact your department's Personnel Payroll Liaison (PPL) and **request a Person of Interest Number (POI#)**. Be sure to request a POI# that specifically has the "Electronic Research Admin" type/privilege and [DEPA](#) access (POI Type "00007 - External Trainee" **or** POI Type "00015 - Security Access") or you will not be able to access the Electronic Research Administration Portal (eRA) or the DEPA reporting form and will need to contact the PPL again. The POI# will take 1-3 days

to become active once it is given the correct privileges. The IRB does not have a list of PPLs. Contact your department's front desk to find your PPL. Specific instructions to share with your PPL or faculty advisor about the student POI requirement is available here:

<http://www.colorado.edu/vcr/ori-compliance/human-research-irb/common-questions/student-pois>

- When you are given a POI#, **test your access to eRA** (<https://era.cu.edu>). Your POI# will be associated with your identikey; it is **not** your eRA username. **Your eRA login information is:**
 - Your CU Identkey
 - Your CU Password
 - Select **Boulder** as your campus

If you receive an login error message, review the "I can't login to eRA. What do I do?" Common Question before contacting the IRB. This FAQ is located on the website at:

<http://www.colorado.edu/vcr/human-research-irb/common-questions-irb#item-1>

- Register with the Collaborative Institutional Training Initiative (CITI) and **complete the training** (<http://www.citiprogram.org/>). You will need your POI# to complete registration. When you have registered, complete the **Social Behavioral Research Investigators and Key Personnel** course or the **Biomedical Research Investigators and Key Personnel** course – whichever is appropriate for your study. NONE of the Responsible Conduct of Research (RCR) courses satisfy the IRB training requirement. If you only complete the RCR course, your study will be returned to you without review and will drop to the end of the review queue.
- In MS Word, **draft the documents for your submission packet**. Use the guidance and template from the website (Guidance: <http://www.colorado.edu/vcr/node/1027> Templates: <http://www.colorado.edu/vcr/node/72>) At minimum, your submission packet should include:
 - a protocol document
 - consent forms
 - supporting documents such as interview questions, survey questions, recruitment emails/letters, advertisement flyers/radio ads/CU Buff Bulletins, etc.
- When your packet is complete, **login to eRA and create an Initial Application submission**. Use the tutorial: <http://www.colorado.edu/vcr/node/252/attachment/newest>. Be sure to route the submission to your advisor. Each time your advisor is not included on the submission, it will be returned to you without review and will drop to the end of the review queue.
 - An Initial Application submission usually undergoes at least one round of revisions. If you receive a Modifications Required letter, you will need to create a Response to Modifications submission to address the provisions from the letter. When creating this submission in eRA, use this tutorial: <http://www.colorado.edu/vcr/node/251/attachment/newest>. Remember to route this submission to your advisor.
- Submissions are reviewed on a **first come, first serve basis**. On average, IRB review can take up to 2 – 8 weeks depending on the complexity of the research and the type of review required. If the above items are not completed, the review will take longer. High volumes, which generally occur near the end of the semester, can also affect the timeline. **You may not engage in any form of research to include subject recruitment until you receive an approval letter.**