# Guidelines for Student Researchers

Getting ready to conduct a research project for your Master’s thesis or doctoral dissertation? Have you been assigned to do research for a class and would like the option to publish the results for research purposes later? Will your research involve human subjects? If so, you may be required to submit a protocol to CSU’s Institutional Review Board (IRB). The IRB Coordinators in the Research Integrity & Compliance Review Office (RICRO) facilitate the review and approval of protocols that involve human subjects.

## Human Subjects Protocols – Tips from protocol creation to protocol closure:

* Work with your advisor to determine if your project meets the federal definition of [research](https://www.research.colostate.edu/ricro/irb/is-my-project-research/).
* Work with your adviser to determine if your project meets the federal definition of [research with human subjects](https://www.research.colostate.edu/ricro/irb/does-my-project-involve-human-subjects/).
* If your project is “research” with “human subjects,” your study does fall under the IRB’s purview, and will need to be reviewed and approved by the IRB prior to recruiting participants and collecting data.
* Human Subjects Protection Training is required prior to IRB approval of your protocol. Both your advisor (the Principal Investigator on the protocol) and you must have up-to-date training. To fulfill this requirement, researchers can take either the in-person or online human subjects protection training (preferably before working on your protocol). For more information on human subjects protection training, [visit the Researcher Training page](https://www.research.colostate.edu/ricro/irb/researcher-training/). Training must be renewed every three (3) years.
* Determine if your project meets the [Exempt](https://www.research.colostate.edu/ricro/irb/exempt-submissions/), [Expedite](https://www.research.colostate.edu/ricro/irb/expedite-review/), or [Full Review](https://www.research.colostate.edu/ricro/irb/full-board-review/) criteria. Exempt applications are submitted via email (Word document “Exempt Review Process and Form,” not via the eProtocol system). Protocols that fit the expedite or full criteria must be submitted via eProtocol: <https://csu.keyusa.net/>
* Work with your advisor to complete and submit the appropriate protocol form. Your advisor will be Principal Investigator (PI); you will be Co-Principal Investigator (Co-PI). Your advisor must complete the “Obligations” page and the “Conflict of Interest” page. Please do not click the “Submit Form” button (or in the case on an exempt application, email to the RICRO office) before you have confirmed with your advisor that your protocol is ready for submission. Please feel free to contact the IRB Coordinators if you need any assistance with the protocol form or review process.
* Submissions must include all documents in order for the reviewers to conduct their review (e.g., recruitment material, survey/questionnaire/interview questions, consent material, methodology chapter) . The methodology chapter is reviewed and compared with the IRB protocol/documents for congruency. Incomplete submissions will be returned prior to review with comments from the IRB coordinators that outline what additional material is required. Anything the participant will read, be given or be told, needs to be submitted for review.
* Once the review comments have been sent to you, please be sure to reply to the IRB as soon as you have had a chance to discuss the reviewer’s comments with your advisor and update your protocol.
* If you need to make any changes to your protocol once it has been approved, an Amendment is required, and needs to be reviewed and approved by the IRB.
* Protocols are approved for a period of no more than 365 days. If you will be continuing to recruit participants or analyze data with identifiers past the protocol’s expiration date, you will need to submit a continuing review form via eProtocol to renew your protocol. Please be sure to submit the continuing review form at least 30-45 days before your protocol will expire.
* Signed consent forms (if required for your project) from the participants must be kept with the PI on the project. The data that is collected, including survey results, interview transcripts, etc., must also be kept on campus with the PI in secure storage for a minimum of 3 years after the closure of your project. Discuss with your faculty advisor (PI) a secure retention plan for your data and consent forms.
* Protocols can be closed by submitting a Final Report Form via eProtocol at the data-analysis phase as long as your data no longer has identifiers.
* Once your project is complete (and **before** you leave CSU), please remember to submit a final report form via eProtocol to close your IRB protocol.

## Contact an IRB coordinator with any questions regarding your IRB protocol

## Resources:

[Regulations: U.S. Department of Health & Human Services](http://www.hhs.gov/ohrp/)
[Consent Form Readability Help: PRISM Readability Toolkit](http://prism.grouphealthresearch.org/resources/resources.htm)
[Field Training Guide: Johns Hopkins Bloomberg School of Public Health](https://www.jhsph.edu/offices-and-services/institutional-review-board/training/field-training-guides-for-data-collectors/)