



OFFICE OF
RESEARCH PROTECTIONS

Quick Start Guide for IRB Submission

1. (Recommended) Schedule a consultation with ORP to discuss your IRB submission. IRB staff can provide guidance on the anticipated level of risk to human subjects, required documentation, and other elements that contribute to IRB reviewer consideration.
 - a. Contact irb@villanova.edu to schedule a consultation. For international research, please arrange for a consultation 6-months ahead of your departure.
2. (Required) Complete IRB mandated CITI trainings (www.citiprogram.org) prior to submitting your application via Cayuse.
 - a. You can find a chart with the required trainings as well as a **CITI user guide** on the [Education and Training section](#) of the IRB website. Here are the basic requirements:
 - i. **Responsible Conduct of Research** (the exact title of this course will vary depending on your department. For example, it may be “Responsible Conduct of Research for Engineers” or “Social and Behavioral Responsible Conduct of Research”)
 - ii. **Basic Human Subjects** (Called “Biomedical Research -Basic/refresher” or “Social & Behavioral Research – basic/refresher”)
 - iii. **Conflicts of Interest** (be sure not to confuse with the “COI” module in other courses.)
 - iv. **Revised Common Rule** Only required for researchers who completed the *Basic Human Subjects* course prior to January 21, 2019. If you are starting the Basic course from scratch, you do not need to complete this course.
 - b. There is a user guide for CITI available on the [Education and Training section](#) of the IRB website.
3. (Required) Complete annual **Financial Conflict of Interest (FCOI) Disclosure** form
 - a. Request access to the “COI Risk Manager” by e-mailing COI@villanova.edu. The form is online and should take only a few minutes to complete. Provide your username and department.
 - b. This form is required for anyone listed on an exempt, expedited, or full board research protocol (do not complete if you are submitting a “help me determine if my project requires IRB review” application.)
4. (Required) Submit **Cayuse Request Form** to gain access to Cayuse IRB if you do not have an account.
 - a. This form is available in the [forms and templates section](#) of our website. Students must sign the FERPA waiver.
5. (Required) Complete IRB application on Cayuse IRB
 - a. In most cases, you will need an informed consent form for your participants to complete. You can find a template on irb.villanova.edu in the [forms and templates section](#).
 - b. You may also require data use or data share agreements, reliance agreements, or collaboration agreements depending on the scope of your project. Contact irb@villanova.edu or orp@villanova.edu to discuss the need.
 - c. There is a user guide for Cayuse IRB available on the [Education and Training section](#) of the IRB website.