Institutional Review Board
Student Handbook Information
Cabrini University

Purpose of this document

This document provides an overview of common Institutional Review Board (IRB) policies and protocols. This document is not a full list of all policies and protocols pertaining to the IRB. For additional information, see the IRB website or contact the IRB chair.

Where to get information about Cabrini's IRB

Information about the IRB and its protocols and procedures can be found at www.cabrini.edu/irb. Additional information about IRB policies in general can be found at https://www.hhs.gov/ohrp/.

Purpose of the IRB

All faculty and students using active human subjects in scholarly research are required to seek approval from and to meet standards set forth by the University's Institutional Review Board (IRB) and the U.S. Department of Health and Human Services federal guidelines for the protection of human subjects. Specifically, the purpose of the IRB is to determine whether:

- procedures of proposed research will minimize risks to subjects;
- risks to subjects are reasonable in relation to expected benefits;
- selection of subjects is equitable;
- informed consent is obtained;
- the research plan makes adequate provision for monitoring data collected so as to ensure safety of subjects, protection of privacy, and the confidentiality of data;
- appropriate safeguards are included to protect the rights and welfare of subjects;
- confidentiality of subjects is maintained;
- research studies have safeguards to protect the safety of the campus community.

What needs IRB approval?

Research involving any process that exposes active human participants to psychological, physical, or any other kind of harm must be approved by the IRB.

Research that includes a systematic investigation—including research development, testing, and evaluation,—designed to develop or contribute to generalizable knowledge must be approved by the IRB.

Human subjects research includes processes that collect and/or use data from sources including, but not limited to:

- Survey research
- Collection of educational and classroom data
- Interviews

- Focus groups
- Educational, medical, human resource and other similar records
- Experimental data including, but not limited to, pre-post classroom assessments, pre-post examinations of the effect of social, physical, biological or other manipulation.

Determining what type of review your project needs

> **NOTE:** *Some populations are considered higher risk when recruited for research studies. In general this is due to their potential increased vulnerability in being recruited or the potential impact the research may have on them. Vulnerable populations that might be used by researchers at Cabrini include, but are not limited to, minors, pregnant women, individuals with cognitive disabilities, and prisoners.* ***When conducting research with a vulnerable population, or obtaining data regarding a vulnerable population, your protocol must have full review. If you need to have a full review, please see the IRB website, www.cabrini.edu/irb to see deadlines for submitting materials. Full reviews are only conducted during the academic year (Fall & Spring semesters) approximately two times per semester.***

Low risk research typically qualifies as an exempt review. This mean that one IRB member will review the protocol.

Research that has an elevated risk will qualify for an expedited review or a full review. An expedited protocol will have two IRB members review it. A full review will have the full IRB board review your protocol. You should consult with your faculty advisor regarding the level of review your protocol requires. The IRB website also provides details about determining what may qualify for expedited or full review.

Materials to submit to the IRB for a review

To have your research reviewed by the IRB, you must submit your protocol to irb@cabrini.edu. **The materials you submit to the IRB must be collated into ONE pdf document starting with the IRB protocol pdf form**. You will need to use **Adobe Acrobat** to fill out the IRB protocol pdf properly. IRB members will refer to the full document you submit for review as your "protocol." This will include the "protocol form" as well as the following items that must be included in the single pdf file:

- **The pfd version of the protocol form** found on the IRB website
- **A summary of the research project**
  This should not be a copied methods or procedures section of a research paper. The summary should provide clear description of the essential purpose of the research, the methods being used, and any additional detail not able to be provided on the IRB protocol form. Please be specific about the known characteristics of the participants you are recruiting, any permissions to access or process to ensure anonymity or confidentiality of the participants. The full process for obtaining consent should be described in this document as well as the materials you are using in the research. Any

process that may increase risk to the participants should be described in detail, and measures to minimize risk in these situations should also be thoroughly described.

- **Any relevant documentation** pertaining to research questions, interview scripts or other materials being used.
- **Consent forms.** Consent is required from active human subjects. Note that research with minors requires consent from the parents and assent from the child. Audio and video recording requires a separate consent form that is signed in person by each participant.
- **Permission to collect data (if applicable)**. If data are being collected from an outside institution, official permission must be submitted on letterhead with a signature. In most cases, data collection on campus, such as in a professor's class, should also be provided on letterhead. A copy of an email granting permission may be considered if the project is considered minimal in terms of risk; this is at the discretion of the IRB.
- **NIH Certificate.** ALL protocols must include a copy of NIH Training Certificates for all PIs, Co-PIs and other individuals involved in human subjects research. The NIH Training can be done online here: https://phrp.nihtraining.com/users/login.php. NIH Training must be updated every two years.
- **Submit your final IRB protocol in pdf format to irb@cabrini.edu**

What happens when you submit an IRB protocol?

Your protocol will be received by the IRB after you email your single pdf file to irb@cabrini.edu
Your protocol will be assigned to:

- One IRB member for review if your project qualifies for an exempt review
- Two IRB members for review if your project qualifies for an expedited review
- The IRB chair for review if your project qualifies for a full review

You will be notified via email that your protocol was received and who has been assigned to review your protocol. The IRB member(s) assigned to review your protocol will copied on that email.

- If your protocol is exempt or expedited: you will be contacted by the IRB members(s) assigned to review your protocol via email. They will indicated whether the protocol is approved or if additional information is needed. Communicate via email to provide this additional information. When approved, you will receive an email from the IRB member(s) indicating that the protocol is approved. **Do not start your research until this approval email has been received by you.**
- If your protocol qualifies for a FULL review, it will be forwarded to the IRB Chair. The Chair will contact you to confirm receipt of the protocol and indicate the date on which your protocol will be reviewed. You will receive a summary of the review within 7 days of the full review taking place. In that summary, you will be notified as to whether the protocol is approved as is or if additional information is needed. You must submit any requested information directly to the Chair of the IRB. If this information needs to be reviewed by the full IRB, this will happen at the next scheduled IRB full board meeting and the Chair will contact you within 7 days of that subsequent review. If the information does not need to be reviewed by the full IRB, the Chair will contact you regarding

approval after the appropriate information has been received. **Do not start your research until this approval email has been received by you.**

NOTE: *All persons listed on an IRB protocol should review the protocol prior to it being submitted to the IRB. If a protocol does not provide sufficient information or has numerous errors or omissions, it will be returned to you without review. You will be required to resubmit an updated protocol to irb@cabrini.edu.* ***In this situation, you should review your protocol with your faculty advisor before submitting the protocol.***

What if I collect data for more than one year?

You must submit a continuation form to keep your research active after 12 months from the approval date. For example, if your research was approved on December 1, 2018, your approval expires on December 1, 2019. To keep your project active, complete the continuation form on the IRB website and submit it to irb@cabrini.edu. If you are continuing to collect data after the one year mark, you must complete a continuation form.

What if I want to change my research project in some way?

Any changes in recruitment process, materials or procedures must be approved by the IRB prior to implementing these changes. Complete the IRB amendment form on the IRB website and submit it to irb@cabrini.edu.

Questions?

Problems during the review process:

- Contact the IRB member(s) assigned to review your protocol via email. If your protocol is under ***full*** review, contact the IRB chair. The IRB reviewer(s) or Chair names and emails are provided in the original email you received from the IRB (irb@cabrini.edu).
- If you have concerns about the process taking place between you and the IRB reviewer(s), contact the IRB Chair at irb@cabrini.edu.

See the IRB website for:

- The protocol form, continuation and amendment forms
- template consent forms
- definitions of IRB terminology
- dates for full board reviews
- decision trees to help determine whether your study qualifies for an exempt, expedited, or full review

More questions?

Contact the irb at irb@cabrini.edu