

HOW TO SUBMIT REQUIRED MATERIALS TO THE IRB

Overview:

If you intend to submit a proposal for research that will involve human subjects, your plan for managing the human subjects' aspect of your project must be approved by the College's Institutional Review Board (IRB).

When applying for IRB review, please note that there are two separate “tracks” for applying for IRB approval and/or notify the IRB. The track you should apply for depending on whether your research fits the technical definition of research as spelled out in federal code [45CFR46](#). For the purposes of the Rocky Mountain College Institutional Review Board policies, and in accordance with the Code of Federal Regulations, Title 45, Part 46:

***Research** “means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities” (source: [The Code of Federal Regulations, Title 45, Part 46.102\(l\)](#)).*

To begin the IRB approval process, please decide which track best describes your research.

Track 1 (T1) is intended for projects that fit the above definition of research and that will be disseminated outside of the class setting (via a public talk, publication, etc.). There are three types of T1 review:

1. Exempt Review
2. Expedited Review
3. Full Review

Track 2 (T2) is for projects conducted in the context of a class that do not fit the above definition of research human subjects and the results will NOT be disseminated outside of the class setting. If there is even a remote possibility that class-based research may, at some point in the near or distant future be disseminated, researchers are encouraged to pursue the appropriate Track 1 review.

Track 1 - Exempt Review

Research that qualifies for exempt review is, like expedited review, exempt from review by the full committee and from continuing review, unless otherwise specified by the IRB. In order for human subject research to qualify for exempt review the research must pose **minimal risk** (little to no risk) to subjects and the research must fit one of the following categories laid out in Code of Federal Regulations, Part 46, section 104. According to 45 CFR 46.102 (f), **Minimal risk** “means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”. Please see the Types of Research Reviewed by the IRB for more information on Exempt Review.

To apply for exempt status, researchers must complete the following steps before proceeding with research:

1. **Complete the Track 1 application process on moodle**. The exempt review process involves supplying information about the researcher(s), the project, and submission of the following files via moodle.
 - a. **Completed IRB Application form** (available on moodle)
 - b. **Samples of data collection instruments** (e.g. survey questions, interview guides)
 - c. **Samples of consent forms** (recommended: use templates)
 - d. **Certificate of successful completion CITI training**.
2. **Complete training on research with human subjects from the CITI Program & submit training certificate** (CITI training is free to researchers with rocky.edu email addresses).

To ensure prompt review, be sure that your materials are clearly written, proofread, and provide sufficient detail for the IRB board to review the project.

Track 1 - Expedited Review

Overview: Certain kinds of research that involve minimal risks to participants may be approved by expedited review or by the IRB Chair or by one or more experienced reviewers designated by the Chair from among the members of the IRB, according to policies and procedures in section 110 of 45 CFR 46. According to 45 CFR 46.102 (f), *Minimal risk “means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests”.*

To apply for expedited review, researchers must complete the following steps before proceeding with research:

1. **Complete the Track 1 - application process on moodle**. Like the Exempt review process, the process for applying for expedited review involves supplying information about the researcher(s), the project, and submission of the following files.
 - a. **Completed IRB Application form** (available on [moodle](#))
 - b. **Samples of data collection instruments** (e.g. survey questions, interview guides)
 - c. **Samples of consent forms** (recommended: use templates)
 - d. **Certificate of successful completion CITI training.**
2. **Complete training on research with human subjects from the CITI Program & submit training certificate** (CITI training is free to researchers with rocky.edu email addresses).

To ensure prompt review, be sure that your materials are clearly written, proofread, and provide sufficient detail for the IRB board to review the project.

Track 1 - Full Review

To apply for full review, researchers must complete the following steps before proceeding with research:

1. **Complete the Track 1 - application process on moodle**. The process for applying for full review involves supplying information about the researcher(s), the project, and submission of the following files.
 - a. **Completed IRB Application form** (available on moodle)
 - b. **Samples of data collection instruments** (e.g. survey questions, interview guides)
 - c. **Samples of consent forms** (recommended: use templates)
 - d. **Certificate of successful completion CITI training.**
2. **Complete training on research with human subjects from the CITI Program & submit training certificate** (CITI training is free to researchers with rocky.edu email addresses).

To ensure prompt review, be sure that your materials are clearly written, proofread, and provide sufficient detail for the IRB board to review the project.

Track 2 - Class-based or program evaluation-style research that will not be disseminated.

Researchers conducting class-based and program evaluation-style research projects that use human subjects are not systematic or generalizable —i.e. they are not intended to use surveys, tests, or evaluation in order further generalizable knowledge in the field via publication or another form of dissemination outside of the classroom or institutional setting — must request a *non-reviewable determination letter* from the IRB using the [Track 2 submission portal on the IRB moodle page](#).

To request a non-reviewable determination letter, researchers must complete the following steps before proceeding with research:

1. **Completed IRB Application form** (available on [moodle](#))
2. **Samples of data collection instruments** (e.g. survey questions, interview guides)
3. **Samples of consent forms** (recommended: use templates)
4. **Certificate of successful completion CITI training.**
5. **Before conducting research, wait for a non-renewable determination letter from the IRB** notifying the researcher that their IRB materials have been received and that they may proceed with research.

To ensure prompt review, be sure that your materials are clearly written, proofread, and provide sufficient detail for the IRB board to review the project):