

## Things You Need to Know Before You Fill Out Your IRB Application Form

### Conditions under which you do not need to complete an IRB application

1. Only research that constitutes a “systematic investigation designed to develop or contribute to generalizable knowledge” counts as “human subjects research,” and only human subjects research requires IRB review. This means that if you are only carrying out a class project that will not involve any public presentation and will not be published in any way (such as being bound and kept in Tutt Library as a thesis), you do not need IRB approval. Do not fill out an IRB application.

2. If you are carrying out observational research in a public place in which you are not participating, this does not legally count as “human subjects research” and does not require IRB review. This is because the federal government only defines as “human subjects research” studies in which the information collected is *private*. The government defines as private only behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. (If you have any questions at all about whether your project requires an IRB proposal, please contact Amanda Udis-Kessler (x8177, [audiskessler@coloradocollege.edu](mailto:audiskessler@coloradocollege.edu)), IRB chair.)

3. Similarly, if you are interviewing people who are professionals or experts in some area, and you are only asking them questions that focus on their areas of expertise, this does not legally count as “human subjects research” and does not require IRB review. The government defines as private only information “provided for specific purposes by an individual and which the individual can reasonably expect will not be made public” (reports of personal experiences, information about personal values and beliefs, etc.). Please note that if you plan to ask a political, artistic, academic or other kind of expert personal questions, this does count as private and you do have to fill out an IRB application. As always, please contact Amanda Udis-Kessler with any questions.

*If your research project does not fall into one of the above areas, please read on.*

### Exempt projects

4. Some types of research projects are exempt from IRB review; however, you the researcher cannot determine that yourself. You still need to submit an IRB proposal if your project does not fall into one of the above categories. However, it is good news for you if your project is exempt because the IRB chair can review your proposal, determine exemption quickly, and let you know that you are free to proceed without any revisions, or without the whole IRB having to read your proposal.

How do you know if your research project is exempt? All four of the following conditions must be met:

A. The project does not involve vulnerable populations (other than children if the research is an educational study as defined below). In the US, children are defined as any subjects under 18

years old; if your research involves people in another country, the age of majority may differ in either direction. For social-behavioral research (as opposed to biomedical research), other vulnerable populations include prisoners, people with developmental disabilities, illegal immigrants, members of politically disadvantaged groups (including but not limited to poor people) and anyone who might not be completely free or able to refuse participation in your research. If your project uses children, it must fall into the educational categories below in order to be considered exempt.

B. The study uses one or more of the following four research methods and no others:

- i. Educational tests
- ii. Questionnaires (sometimes also referred to as “surveys”)
- iii. Interviews
- iv. Non-participant observation or, alternately:
- v. The project is restricted to a study of normal educational practices, conducted in established or commonly accepted educational settings or, alternately:
- vi. The project is restricted to the collection or study of already existing data, documents or records that are publicly available or where the subjects in question cannot be identified.

C. Participants cannot be identified in such a way as to link them to the information they provide or, alternately, identifiable disclosure of participant responses will not put participants at more than minimal risk of harm. Types of harm include legal, financial, employment, reputational and/or psychological. Minimal risk means that the *probability* and *magnitude* of harm or discomfort anticipated in the research are not greater than the harm or discomfort ordinarily encountered in daily life or while taking routine physical or psychological tests. For example, an interview study that addresses past experiences of depression is within the category of minimal risk if the questions are expected to cause no more harm than would a session with one’s therapist or counselor.

D. The project has been approved by the organization that is the topic of study (if relevant).

If you decide that your project might be exempt from IRB review, you will have an opportunity at the end of the proposal form to explain in your own words how your project meets the conditions described above. Please note that “having a limited amount of time to carry out my research” does not constitute a legitimate reason to have your proposal granted exempt status. Also, please note that the IRB cannot guarantee exemption of your project in advance of reviewing your proposal.

### Expedited projects

5. Some types of research are not exempt from IRB review but can be reviewed on an expedited basis (meaning that the IRB chair can approve the project rapidly without the full committee needing to review the document). Expedited reviews are desirable because you do not have to wait for the once-a-block IRB meeting to have your application reviewed and approved, or to receive any feedback about changes you might need to make. Note that almost all student proposals can be reviewed on an expedited basis; the exceptions involve projects with vulnerable

participants (such as prisoners, illegal immigrants or children) and/or those that pose a risk of harm greater than the legal minimum.

How do you know if your research proposal can be reviewed on an expedited basis? Both of the following conditions must be met:

- A. The research presents no more than minimal risk of harm (as defined above) to participants.
- B. The study uses one or more of the following research methods:
  - i. Collection of data from voice, video, digital or image recordings
  - ii. Questionnaires (sometimes also referred to as surveys)
  - iii. Interviews (including oral history interviews)
  - iv. Focus groups
  - v. Program evaluation
  - vi. Human factors evaluation; and/or
  - vii. The research focuses on individual or group characteristics or behavior (e.g. perception, cognition, motivation, identity, language, communication, cultural beliefs/practices, or social behavior)

If you are requesting an expedited IRB review, you will have an opportunity at the end of the proposal form to explain in your own words how your project meets the conditions described above. Please note that “having a limited amount of time to carry out my research” does not constitute a legitimate reason to have your proposal reviewed on an expedited basis. Please note that the IRB cannot guarantee an expedited review of your project in advance of reviewing your proposal.

### Full-Board reviews

It is rare for a student’s IRB proposal to require review by the full IRB. As noted above, the only kinds of projects that generally require full committee review are those with vulnerable participants (such as prisoners, illegal immigrants or children) and/or those that pose a risk of harm greater than the legal minimum.

Full-Board review does not necessarily mean that your project will be rejected or will require substantial reworking in order to receive approval (though these things happen occasionally). It simply means that your timetable must take into account the fact that the IRB only meets once a block and does not review proposals between those meetings. The IRB meets on the second Thursday of the block and we promise a preliminary response to you by 5 pm on the next day.

If you are in preliminary planning stages for a thesis project and want help thinking about the IRB-related pros and cons of different kinds of projects, your advisor can be of assistance. You can also contact the IRB chair for a meeting.