Curry College Institutional Review Board

FREQUENTLY ASKED QUESTIONS

Do I need to submit a proposal for IRB review?

If your research involves human subjects, you need to apply for IRB review.

Our IRB has a FederalWide Assurance (FWA) to comply with the basic principles in The Common Rule, 45 CFR 46. These regulations are overseen by the U.S. Department of Health and Human Services, and the Office of Human Research Protections.

For research purposes, the federal government defines human subjects as, "systematic investigation designed to develop or contribute to generalizable knowledge."

How does the IRB define "research"?

Research is broadly defined as a "systematic investigation designed to develop or contribute to generalizable knowledge."

This would include –but is not limited to—any clinical investigations. It does not matter whether you intend to publish from the study.

Under the revisions to the Common Rule (effective January 2019), there are several limited exclusions to the federal definition of "research." These exclusions include some "scholarly activities" involving: "oral history, biography, literary criticism, journalism and legal research." Please note that this exclusion involves *activities* (not entire disciplines) which have been deemed not to qualify as research under this definition. OHRP provides the following guidance on this exclusion: "The objective of the activities in this category is to provide an accurate and evidence-based portrayal of the **individuals involved**, and not to develop generalizable knowledge." In addition, there are other exclusions involving mandated public health, criminal justice, or national security officials (most of which would usually not apply to research on our campus). To see if your project qualifies, please contact the IRB administrator.

What is a human subject?

Our IRB follows the federal guidelines for research, which are defined in 45 CFR 46.102e.1 as follows:

(e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

What are some examples of research that would require IRB review?

Examples of human subjects research include (but are not limited to): Surveys, questionnaires, cognitive perceptual experiments, focus groups, program evaluations, and more.

Do students need to go to the IRB for their research?

Yes. If the project involves research with human subjects (as defined above). This would include surveys and questionnaires. All student research must be submitted through, and overseen by, a faculty advisor. If the research involved involves no more than minimal risk, faculty should utilize the "Class Research Form." If the research involves vulnerable populations, or sensitive topics, it generally involves more than minimal risk, and should be submit through the Full Proposal form. The revised guidelines in the Common Rule (effective 2019) allow IRB's to provide some "limited IRB review" even for studies which qualify as Exempt.

I don't plan to publish my research. Do I still need to submit a proposal to the IRB for approval?

Yes. Even if you do not plan to present or publish the findings, studies that involve human subjects require IRB approval, if only to evaluate and mitigate the risk to the potential participants.

Why are IRB's important?

In the past, many abuses have taken place in the name of science, with varying good and bad intentions. The Belmont Report was established to guide review boards in helping to produce sound risk while minimizing risk to human subjects. We've learned much about how to help participants make fully informed decisions about whether to engage in research, as well as how to minimize risk, and maximize potential benefit.

Our IRB is committed to upholding the principles of the Belmont Report, which include:

- **Respect for Persons**
  - Treating individuals as autonomous agents
  - Providing detailed and clear Informed Consents for potential participants
- **Beneficence**
  - Committed to maximizing benefits while minimizing harms
- **Justice**
  - Committed to equitable subject selection

The IRB can help researchers consider different possibilities, and suggest terms to mitigate risk, both for the human subjects involved, as well as for the researchers.

What are the three types of IRB review? How will I know which review is appropriate for my project?

There are three types of review: **Full Board, Expedited, and Exempt** processes. To determine where your proposal may fall, consider the following flow charts [INCLUDE CHARTS HERE]. You may want to consult with the IRB Chairperson to determine which form to fill out. A simple guide, however, is that **Exempt** research is research where individuals can give free and informed consent, where there is no or limited risk, and the release of data can cause no potential harm to subjects. The new OHRP guidelines both expands the types of research that is Exempt, as well as outline that even some Exempt research can go through "limited IRB review" in an expedited route. For a detailed list of exemptions, please review the flowchart. Generally, **Expedited Review** is appropriate for proposals that present no more than minimal risk. It is actually a Full Review, only done by one person (the IRB Chairperson or his/her appointed representative member). (Expedited Reviews can not disapprove any proposal; if there is a question of whether or not a proposal should be approved, it must be reviewed at the Full Board level.) Full Reviews occur for any research that falls outside the limitations stated above for Exempt and Expedited reviews.

What can happen if I fail to submit my proposal for review and engage in research without approval?

For faculty, engaging in human subjects research can be risky for several reasons. First, many journals and publications now require IRB certification prior to

publication. So, moving forward without approval can stop the research from being published. Further, many funding sources require IRB approval, and without it, the allocation of funds may not occur.

Second, engaging in research without IRB approval means that the Principal Investigator is acting outside the scope of authority granted by the institution. Therefore, the College may not provide resources for any liability which may result from such research. Finally, research misconduct could be cause for disciplinary action by the College.

Any projects that are federally funded have additional stipulations, per 45 CFR 46, depending upon which agency is involved. In general, such agencies will withhold funds until IRB approval is obtained.

For students who engage in unapproved human subjects research, credit (for the course or assignment) may be withheld. Thesis work may not be accepted for credit. Publications may refuse to publish the work.

Do IRB's often reject proposals?

No. More often, IRB's (and our IRB, in particular) make suggestions or require modifications to study designs to help strengthen the design while mitigating risk and maximizing benefits to the subjects involved. In general, members of the IRB are experienced researchers who support quality research, who see our role as one which is designed to strengthen ethics in the research process.

Do you have any tips for creating an Informed Consent form?

Informed Consents should be, above all, clear for potential participants. As the Belmont Report articulates, potential participants should know what the study is about so they can make a free and informed decision about their involvement in it. Here are some guidelines for researchers to remember, as they put together their own Informed Consents:

- Detail what the study is about, and what is being asked of them, in clear language. This statement should be up front, at the top of the page.
- Detail who is running the study, why it's being done, and any risks or benefits involved. Be specific about risks, in particular.
- If appropriate, explain that there is no penalty for skipping a question or stopping their participation.

- Explain why the person is being asked to participate (Is it because they belong to a particular group? Is it a convenience or random sample?)
- Explain if there is any compensation for their participation.
- Detail who participants can contact for more information. Use professional contact information (not personal cell phones).
- Explain how the person's information is going to be protected (For example: Will researchers be assigning pseudonyms or numeric identifiers? Are the files kept on password protected computers? Will hard copies of consents be kept in locked file cabinets? When will data be destroyed, if at all?).
- Explain whether the study is confidential (where a person's name is concealed in the research) or anonymous (where a person's identity is not known by the researcher).
- Write the Informed Consent at an eighth-grade reading level. Avoid academic sounding jargon.
- Please list the IRB Chairperson's name and email on this form as well, for people to contact if they have questions about their rights as a participant.
- Provide a copy of the form for participants to keep for their own records.

Who is on the IRB?

The constitution of the IRB is guided by regulations specified in 45 CFR 46.107, which mandate that the IRB must be comprised of at least five members who have "..varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution." The composition of the IRB must, 1) have diverse research backgrounds (representing both qualitative and quantitative scientific areas), 2) include at least one scientist and one non-scientist, and 3) be comprised of qualified members from both genders, representing racial and cultural diversity. Lastly, at least one community member must be on the IRB as well. In addition to these voting members, Curry's Board also several ex-officio members, including the Director of Institutional Research, the Dean of Faculty, and the Grants Coordinator. All IRB members must be appointed by the Institutional Research Representative, which at Curry College is the Provost.

The Curry IRB is comprised of experienced researchers from many different disciplines. In addition to upholding the Common Rule, we see our role as being a resource to supporting strong research in College community. A full list of current members is on the IRB portal page.

If I'm working on a project that involves quality assurance, or evaluating learning outcomes or assessment, do I need IRB review?

Many quality assurance projects, or internal evaluation projects designed to improve efficiency or effectiveness done within an internal organization, do not require IRB approval. For instance, if the library wished to learn more about faculty usage patterns of database usage through a survey, they would not need IRB approval. To confirm whether your proposal fits this category, please consult your IRB chairperson.

What if I am having students work on this research? Are there any special trainings they should engage in?

Having students engage in research can be a productive, engaging process. Keep in mind that students do need some training in order to execute research both productively and ethically. The key to making this work is preparing the students— both in the discipline specific topic, as well as in executing human subjects research— before having them engage. One resource to help prepare students for this opportunity is to require them to take CITI online modules before they begin any research activities. Our College maintains an institutional membership, so any student can take complete this training as part of their preparation. (https://about.citiprogram.org/en/homepage/)

For classes where multiple students are engaging in one or more projects, if there is no more than minimal risk in the research, faculty can use the Class Research Form to submit their proposal. If you are unsure whether your class's project(s) fit here, please contact the IRB Chairperson for guidance on which form to submit.

How often does the IRB meet? How long does the vetting process usually take?

We meet at least one time per month during the semesters. The review process for any proposals requiring Full Board Review will take no more than one month. We have added meeting times during busy times of the semester to help speed the process for proposals. Expedited or Exempt Reviews occur on a rolling basis, and are generally completed within a week. During the summer, the Chairperson is available for consult and possible review on an as needed basis.

Do I have to attend the IRB meeting when my proposal is discussed?

No. Researchers are not present during the IRB's meeting. If there are questions about the proposal, the Chairperson will contact the Principal Investigator for clarification.

If I've already received IRB approval, but I want to modify my study, what should I do?

Send a detailed note to the IRB Chairperson. If the modifications are minor, the Chair should be able to respond in expedited fashion, usually within a week. If the changes are major, the revised proposal may need to go back to the full Board for review.

Is there a way to extend the approval date for a study that has been approved through the IRB?

Yes, this can be done by requesting an extension from the Chairperson. In general, IRB approval periods are for one year. For multi-year projects, Principal Investigators must submit reports annually on the study's project to maintain current approval status. Any request should for an extension should detail the reason, as well as the period of time needed for the extension.

I'm teaching a Research Methods class. Would an IRB member be available to come and speak about the importance of IRB's?

Yes. We welcome the opportunity to educate students and faculty both on the role of the IRB generally, and on how to design research that is in compliance with the Belmont Report.

Can I use students as participants in my study?

Using students is permissible, as long as certain conditions are met. It is important to note that students may naturally feel some pressure to take part in a study if their professor requests them to do so, primarily because of the power differential that exists between faculty and student. This creates some vulnerability for the student population. The IRB is interested in making sure there is no coercion or undue influence for students to participate. For instance, offering excessive extra credit, or making a student's participation in a study a required part of a class grade, would be inappropriate for a principal investigator. The key to avoid these pitfalls is in implementing a methodology where students are able to make free and informed consent, where risks and benefits are spread evenly over various populations (and not weighed too heavily on convenience samples from a faculty member's classes), and where respect for person's is central in the study.

Can I get training from a member of the IRB if I'd like to know more?

IRB members regularly offer training on campus. You may request to have an IRB member provide training.

If I still have questions, who should I contact?

Contact the IRB Chairperson. (LINK)