

Chapter 9

Institutional Review Boards: Purposes and Applications for Students



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Abstract The objective of this chapter is to introduce students to the processes involved with applying for institutional review board (IRB) approval. I discuss what human subjects review is and its purpose, then move on to a discussion of the potential make-up of an IRB and the related roles of the members. Lastly, I describe some of the processes associated with applying for IRB approval and some of the main elements necessary for an application.

The objective of this chapter is to introduce students who will be working with human subjects for their dissertation work or otherwise to the processes involved with applying for institutional review board (IRB) approval. First in this chapter I discuss what human subjects review is and its purpose. I then move on to a discussion of what an IRB might look like and the roles of the board. Later, I discuss some of the processes associated with applying for IRB approval and some of the main elements necessary for an IRB application.

University-Sponsored Research with Human Subjects: Purpose

An IRB or a committee is charged with performing an ethical review of proposed research. It does so by examining the methods of a proposed study with the intent to ensure that they are ethical and do not “harm” participants. That is, the researchers who designed the study did so in ways that ensure the rights and welfare of human

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subjects or participants who will take part in the study. The board's review is a means of safeguarding ethical conduct of research and the protection of participants.

An IRB at a university may consist of faculty, staff, and community members. However, all university IRBs are steered by federal guidelines and the Department of Health and Human Services. In addition and depending on the study, research may be further advised by the Office for Civil Rights, National Institutes of Health, the Food and Drug Administration, and/or the National Science Foundation. You can find the federal guidelines here: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/45-cfr-46/index.html>

Why Is IRB Approval for Research Necessary?

It wasn't always the case that universities required IRB approval for research with human subjects. After World War II when a variety of events were discovered, committed by the Nazis, the Nuremberg Military Tribunal developed the Nuremberg Code, which was used to judge the Nazis in court. Significantly, the Nuremberg Code initiated the official consent process whereby participants of research studies must be presented with information about the study such that they understand their contribution and they must voluntarily consent to participate. Further, the researcher is responsible for obtaining consent. You can read more about the Nuremberg Code here: <https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code>

Since the establishment of the Nuremberg Code, similar principles for research have been institutionalized such as the Declaration of Helsinki, which created the means for the approval and monitoring of research by independent committees. Additionally, the "Tuskegee Study" or the 40-year-long US Public Health Service Syphilis Study at Tuskegee (you can learn more about the Tuskegee Study here: <https://www.cdc.gov/tuskegee/index.html>) encouraged legislation to further protect research participants and provide informed consent, including the risks and benefits associated with a study. The Tuskegee Study also resulted in the creation of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission published the Belmont Report, which called for three basic and ethical principles that researchers must employ when conducting research with human participants. These principles include respect for persons, beneficence, and justice. You can read the Belmont Report here: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>

What we now know as "IRB" was created in 1974 through the National Research Act. The Act called for a system to regulate research involving human participants. Later, in 1991, federal agencies adopted the primary regulations in a common Federal Policy for the Protection of Human Subjects or the "Common Rule."

The Federal Policy for the Protection of Human Subjects or the "Common Rule" was codified in separate regulations by 15 federal departments and agencies. It

... outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance. Human subject research conducted or supported by each federal department/agency is governed by the regulations of that department/agency. The head of that department/agency retains final judgment as to whether a particular activity it conducts or supports is covered by the Common Rule. (U.S. Department of Health and Human Services, n.d., n.p.)

A human subject or participant, according to the Common Rule, is a living individual who will participate in a study (data will be collected from/about them). Within the Common Rule are additional protections for vulnerable populations including human fetuses, neonates, prisoners, children, the financially vulnerable, and the elderly. There are also extra protections for those who are cognitively impaired. If you wish to work with individuals from these groups, you will be required by IRB to attain additional information, that is, assent (agreement to participate in a study, from, for example, a parent or guardian, who is able to provide legal consent).

IRBs are particularly concerned about “risk” and particularly for members of the previously mentioned groups, that is, what are the risks to the human subject related to participating in a study. Importantly, there is no such thing as a study with no risk. Risk is determined by the potential harms that may be experienced by a participant as a result of partaking in a research study. Factors associated with risk may include the procedures involved in a study, the setting or context in which the study takes place, the equipment associated with the study, the researcher(s’) level of training and/or experiences, and the health or age of the participant. Many studies are considered “minimal risk,” which indicates that “The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (U.S. Government Printing Office, n.d., p. 135).

What Students Can Anticipate with an IRB Application

If a student is intending to work with human subjects directly in their study, then they should count on some form of required IRB review. The IRB application and process can vary across institutions, but there will be certain items necessary for the application to ensure that it gets reviewed. However, IRB approval is required before any research activities begin. Students typically need a faculty advisor on their projects.

As noted previously, IRB applications and processes vary across institutions; therefore, it is difficult to expand on what exactly the process might look like. Some institutions will ask the researcher to decide which type of review they want, exempt, expedited, or full. Whichever type you choose or are assigned by an IRB, the type is not related to time, that is, expedited does not equate to “quick.” Rather, the type of review refers to how many folks will review the application. A full board review indicates there is greater than minimal risk to participants and there may be seven to ten individuals who review the application. Expedited refers to not more than minimal

risk to participants and the application may be reviewed by one person. And finally, exempt does not mean that it is exempt from review. It means that according to the federal regulations, the project describes one of six categories of research that is exempt from some of the requirements of human subjects research, including continued review by IRB or all of the required elements of consent.

Your IRB may have a “determinations” process where they will take a preliminary review of your study and decide on the level of review required. At the University of Iowa, for example, researchers can complete a Human Subjects Determination Form, where before completing and submitting the IRB application, researchers are asked a few key questions regarding the study and then the IRB advises whether or not the study is or is not human subjects research.

What Will You Need for Your IRB Application?

IRB applications require multiple elements. First, each researcher involved in the study will need to complete the required human subjects training through the Collaborative Intentional Training Initiative (CITI). Depending on the area of research (biomedical, social-behavioral), there are separate online trainings available. Educational institutions have subscriptions to CITI, and the training is free for those associated with the institution. You can learn more about CITI training here: <https://about.citiprogram.org/en/homepage/>

If you are conducting a study in a school or school district, it is likely that you will need permission from the superintendent(s) and/or the principal(s) of the districts and/or schools. Likewise, if you are working with individuals at an institution of higher education, you may need permission from particular offices at the relative institutions. Note that these letters of permission may be required/requested from IRB.

If you are planning to conduct research outside of the USA, you should plan on obtaining IRB approval from your home institution *and* from the local context. For example, if you are working with an institution of higher education you should work with their IRB office or equivalent. If an in-country IRB is not available, the researcher should identify a local expert who is willing to evaluate the proposed study in terms of local and contextual standards. Most universities have a form or a template for the expert to complete regarding the study and the local context. Gaining this local permission may take considerable time.

The IRB will also want to know that you have done some preliminary investigation into the scholarship as it relates to your study—such that your study will be an original and necessary contribution to the field. Thus, there may be a space in the application where you are to provide a short review of the literature and a list of related references.

Moreover, you should be prepared to explain and justify to the IRB the number of participants that will be included in the study and how you will protect their identities (if applicable). Further, you will need to supply the research questions guiding the study and the main ambitions of the investigation.

Additionally, you should have your ideas for participant consent clearly articulated. If you want to waive the consent process, that must be clearly articulated and justified. If you ask participants to read and sign a consent form, you must provide that form with your application. Most IRBs have exemplars and/or templates of such forms.

Next, you should have your data collection instruments ready. This may include interview protocol(s) (list of questions) that you will use in your interviews or the survey(s) or questionnaire(s) you plan to distribute to the participants. The IRB will also be interested in knowing about the research methodologies you plan to apply in the study.

Finally, the IRB will want to know who else, outside of your research team, will be interacting with the data. For example, if you will have your interviews transcribed by a person or company outside of your research team, they will want to know who that person is and may require some additional information from them. IRB will also want to know how you will store and transport the data related to the study.

It is not uncommon for IRB to request more information on an initial application. However, eventually most IRB applications are approved. IRB applications may seem cumbersome; however, they are there to make sure all the necessary precautions have been addressed in order to best protect the interests of the participants in a study. Students should consult with their IRB office early about the application process and requirements. Doing so will save time and energy.

Final Thoughts

It is possible to make changes to an IRB application after initial approval. For example, if the number of participants increases or if you see that now you should, for example, distribute a survey in addition to conducting interviews, you can make those “modifications.” Incorporation of any measures or techniques that were not addressed in the initial application should be handled through a modification process through the same IRB office.

Lastly, once IRB approval has been obtained, it has an expiration date. Typically, IRBs approve a research project for one year. If all aspects of the study are not completed within one year, the researcher(s) may ask for the approval to be extended.

References

- U.S. Department of Health and Human Services. (n.d.). Federal policy for the protection of human subjects ('Common Rule'). Retrieved from <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>
- U.S. Government Publishing Office. (n.d.). 45 CFR § 46.102—Definitions. Retrieved from <https://www.gpo.gov/fdsys/search/searchresults.action?st=45+C.F.R.+%C2%A7+46.102%28i%29>