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An Author's Guide to Institutional Review Board (IRB)

Why IRB is Necessary

The IRB was designed to be a collegial body that helps researchers conduct responsible research. The IRB does so by weighing the risks and benefits to the intended research subjects, and ensuring that the rights of research subjects are protected. The application, review, and approval processes by the IRB are required whenever human subjects are involved in research, whether or not you intend to publish that research.

Note that the purpose of an IRB is *not* to rewrite your research project, and the IRB's decision does not determine your project's validity or invalidity. Furthermore, the IRB does not automatically provide permission to publish your research findings.

What Counts as Research

The U.S. Department of Health and Human Services (HHS) defines research as a "systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (Title 45 Part 46 Section 102: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). A systematic investigation includes a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question. Examples of systematic investigations include the use of surveys, questionnaires, focus groups, interviews, evaluation of educational programs, as well as medical chart review studies.

When to Get IRB Approval

In accordance with the ethical standards of the U.S. Department of Health and Human Services (HHS; Title 45 Part 46: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html), all research involving human subjects requires approval by the IRB *prior* to the start of the research project.

IRB Application Process

The IRB process varies between institutions. However, most IRB processes include:

- **A training course**: The training courses are usually online and the most common training programs are CITI (http://humansubjects.energy.gov/doe-resources/citi.htm) and NIH (https://phrp.nihtraining.com/users/login.php). These programs consist of a series of learning modules with a short quiz at the end. Once you have completed all of the required modules, you will receive a completion certificate, which you will submit as part of your IRB application.

- **A submission form**: The form contains a series of questions regarding general information about the researcher, an overview of the research study, a description of the research setting and the population, how subjects will be recruited and identified, research procedures, a description of risks and benefits, as well as subject compensation, privacy, and confidentiality.

- **Instruments**: All measuring instruments, surveys, questionnaires, ads/flyers to solicit subjects, and interview protocols need to be submitted as part of the IRB packet. If the project is grant-funded, usually a copy of the grant needs to be submitted.

- **A description of the informed consent process and a consent form**: One way to protect the rights of research study subjects is by making the subjects aware that their participation in a research study is voluntary. The informed consent process documents subjects' willingness to participate in a research study by providing subjects with details about the research study, and then requesting they complete a consent form. The informed consent process begins with an oral explanation of the research study and what subjects will be expected to do. In addition, potential subjects need to be informed that their participation in the study is voluntary and they can withdraw from the study *at any time* without penalty. The informed consent process also clearly delineates the potential benefits, discomforts, and risks subjects might experience as well as information about confidentiality and compensation for their participation in the study.

The information presented to subjects in the oral script will also appear in the consent form. Most IRBs will request a consent form to be used. However, it is possible under certain circumstances (such as using an online survey or when the signature on the consent form is the only subject identifier), to get a waiver for the use of the consent form. If a consent form is not needed, subjects still need to undergo consent process (via an oral script). In order to consent, a subject must be at least 18 years of age. Usually a consent form will contain an attestation statement to document this. If a subject is under 18, a parent or guardian will have to assent to their participation in the study. An assent form, like a parental permission form, documents the willingness of an adult to allow a minor to participate in the study. All the elements previously described appear in the assent form. The parent/guardian signs the assent form and then the minor signs, indicating they consent to participate.

IRB Review

Once the IRB packet is submitted, there are three types of review, depending on the risk of the subject. The three review types are:

1. **Exempt**: Minimal risk with non-vulnerable populations.

2. **Expedited**: Minimal risk with vulnerable populations (minors, prisoners, pregnant women, fetuses, cognitively impaired persons). Studies involving the use of videotaping or audiotaping require expedited review.

Studies undergoing exempt or expedited review do not require the IRB to meet to approve the application.

3. **Full review**: If a study is considered to have greater risk than is acceptable for the categories of exempt or expedited, it will undergo full review. For full review, the IRB meets to consider the application and render a decision.

Note that the IRB's decision cannot be appealed or overruled.

To understand the IRB's decision making process, see the graphic aides provided by the Office for Human Research Protections (OHRP; http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html).

IRB Approval

The IRB will inform you in writing whether your study has been approved. The approval letter stipulates the duration of the approval. It can vary from one year to three years. If the research is not completed within the IRB approval period, the researcher needs to apply for **continuing review**. Continuing review usually requires a shorter application and a description of the progress made on the research study. Active IRB approval is required from the time subjects are recruited to the conclusion of the study. Even if no subjects are involved and the only activity is data analysis, the IRB approval must be active.

FAQs

What if my institution does not have an IRB?

Recently, undergraduate educators have become more familiar with the IRB process as they begin to convert their scholarly teaching into research investigations. Sometimes, small liberal arts colleges and primarily undergraduate institutions do not always have an IRB. Under these circumstances, the researcher should inform their institution's leadership (chairperson, Dean, or Provost) about their research endeavors involving human subjects. For K-12 students, many citywide/statewide Departments of Education do have IRBs. These IRBs are highly concerned

about the children participating in research studies and can be quite vigilant. Plan ahead and consult with the principals of the schools where you would like to recruit subjects.

I am planning to collect anonomyzed data. Is that data still subject to IRB approval?

Yes, because it is still data gathered from human subjects in a study.

I have data from a previous study, and would like to use it as a comparison for the data I plan to collect. When I apply for IRB, do I need to include information about the previous data? What if the previous data was not collected under IRB?

If you intend on using data from a prior study, you need to specify this in your IRB application. Since IRB approval is traditionally obtained prior to data collection, you might be asked to include an explanation of why you are using previously collected data.

I applied for IRB well before the semester started so that I could collect data on my new class. However, it is the middle of the semester and my application is still under review. Is there anything I can do to move the process along so that I don't miss out on any more data?

As a first step, consider having a collegial conversation with your IRB chair explaining the importance of the IRB approval to the initiation of your study. If the issue is the IRB is simply slow, consult with your institution's leadership to inform them about the time interval required to get approval for research studies.

I have come up with a new tool to collect data, but I already have IRB approval for the project. Can I submit an amendment to my original IRB?

Yes, you can submit an amendment which will include the new data collection tool. Many IRBs have an amendment form for researchers to submit. This form usually asks for an explanation of why the amendment is needed.

I changed institutions during the middle of my research study – do I have to apply to my new institution's IRB, or does the approval from my old institution cover me?

If the subjects will be at both institutions, you will definitely need to submit the original IRB to the new institution and keep the IRB active at your previous institution. If the study only involves analysis of previously collected data, you may not have to submit for IRB approval at your new institution. Consult with the IRB chair at both institutions on this question.

I am working with a colleague at a different institution – do we both need to submit an IRB application, or will one institution's IRB approval cover the both of us? What if one institution grants approval and the other one does not?

If you intend on only applying to one IRB, all researchers will need to have their names on the one IRB application and all researchers will need to meet the requirements for that IRB even though your home institution may have different standards. Many IRB applications ask if there is another IRB reviewing the study. Some IRBs are willing to accept the approval of another IRB and this moves the IRB process along more quickly since the application has already undergone review.

My IRB application was denied, but I still think my research is valuable to the educator community and I want to resubmit. What recommendations do you have for me to be successful in my second attempt?

Usually, the IRB will provide you with reasons why your application was rejected. Read the comments thoroughly and consider incorporating as many of the suggestions as you find reasonable.

I need more help with my IRB application. Is there somewhere/someone on campus I should turn to?

Usually IRB chairs, their assistants, or IRB members are willing to help. Also, if it is an educational research study, your institution's Teaching and Learning Center may also be an excellent resource.