Institutional Review Board (IRB) FAQ for Students

Slide 2 – Test your Knowledge of History
Here is a test of your knowledge of history. Which of these studies actually took place? Studies like these can be found throughout the history of research. Some of them are quite famous, others not so well known. Many of these studies occurred at elite institutions by researchers who were well-respected and well-funded. Unfortunately, there are many such stories of researchers abusing their positions and losing the trust of the public as they were swept up in their zeal for new knowledge, career advancement, and other motivators. In hindsight, we can clearly see that the risks outweighed the benefits. Run your cursor over Yes for studies that you believe were conducted; No for studies that you believe were not conducted.

Slide 3 – What is the purpose of an IRB?
In order to provide broad consideration of the ethical impact of a proposed study, an IRB will examine benefits and risks from the perspectives of the subjects providing data, the researcher, the copyright holders of all data collection instruments, the stakeholders who belong to the community impacted by the data collection and results, and the university. Judging risks and benefits is not always easy. So the worldwide community of researchers has decided that the best approach is to subject research studies to peer review by other researchers who are more distanced from a study and can provide feedback and approval regarding the study’s risks and benefits. Different countries will vary in how they apply the “peer review” concept, but in the USA, these peers are called Institutional Review Boards (or IRBs). Here is a statement of the first purpose of the IRB.

Slide 4
The most difficult part for the researchers is usually managing the multiple layers of requirements facing all researchers including international standards, federal regulations, state laws, university requirements, and academic requirements. Here is a statement of the second purpose of the IRB.
Slide 5 – What is the IRB?

Walden’s IRB is responsible for providing a personalized check of each study’s research procedures to confirm that the study’s benefits outweigh the risks in a way that is in full compliance with all requirements. At Walden, we actually have multiple boards that specialize in different types of research. For example there is one board that specializes in educational research. These boards are staffed by research faculty members who have special training in helping researchers with ethical challenges. The IRB reviews a researcher’s application, which is a series of questions that will give the board enough information to evaluate the multiple dimensions of the study in relation to all the relevant requirements. Researchers cannot “fail” IRB review. It is a feedback and revision process, through which the IRB helps the researcher meet the many layers of requirements.

Slide 6 – What is the mission of Walden’s IRB?

Here is the IRB’s stated mission, which gives a good overview of the approval criteria. The Institutional Review Board’s Research Ethics Review will provide clear, timely feedback to ensure that all university research projects meet the following ethical standards.

Slide 7 – Is this really about ethics or is it just about regulations?

Three ethical principles undergird the regulations adopted by the US for the protection of human subjects. From course work or training you may have undertaken already, can you recall these three principles and where they were proposed in 1979? Write your answers in the box provided, then run your cursor over the word Submit to check your answers.
Slide 8 – What are the criteria for IRB approval?

Minimizing risks is the main way we operationalize the ethical principle of beneficence. These days, most social science research involves some level of privacy risk, rather than physical risk to one’s health. Another common type of risk for social science research has do with the potential to negatively impact a participant’s standing in their job, in their school, or among their peers or family members. The IRB application includes a checklist of common risks, focusing on those that typically arise in social science.

Slide 9 - What are the criteria for IRB approval?

This next criterion addresses both the principles of beneficence and justice. Risks are inevitable and cannot be removed completely. Every researcher is asked to disclose whether participation in their study might be expected to introduce additional risks to the participant, beyond what is normal for everyday activities. The IRB can approve activities involving some risks, as long as the research design is strong enough to offer potential benefits to offset the risks.

Slide 10 - What are the criteria for IRB approval?

Equitable selection of participants is another way the principal of justice is maintained. Historically, some groups have been understudied for various reasons while other groups have been overstudied (due to their availability as a “captive” population such as military personnel, prisoners, and schoolchildren). One modern, universal goal of quantitative social science is to generate knowledge that applies to as many different types of people as possible, which requires a representative sample of participants. Toward this goal, inclusion and exclusion criteria must be articulated and defended by the researcher using the checklist in the IRB application. Qualitative research often has goals that are different from generalizability, so participant selection simply needs to be based on a solid theoretical rationale.
Slide 11 - What are the criteria for IRB approval?

Informed consent helps assure that respect for persons will be maintained. Informed consent is a process not a form. Informed consent is simply “full disclosure” about the study, before the person is asked to make a decision about whether to participate or not. Informed consent should be a conversation, with questions and clarifications. It is typically, but not always, documented with a signature. Alternative means of documenting informed consent might include audiorecording or contingent actions (such as directing a participant to complete a survey if they have read the information and feel comfortable enough with the study to participate). Since privacy is one of the main risks of social science research, the IRB will always help researchers look for ways of providing better privacy to participants. And sometimes that means the IRB will ask you to remove signature lines from forms.

Slide 12 - What are the criteria for IRB approval?

Respect for persons also means that only true volunteers are involved in research. This is a very common challenge at Walden, since so many researchers collect data in their “own backyard” so to speak. Anyone collecting data in their own school or workplace must be very careful that they will not leverage existing relationships to recruit research participants into the study that will earn them a doctoral degree. Therapists in particular have an ethical duty to keep the therapist’s “personal gain” out of the therapeutic relationship between the therapist and client. The same principle can be applied to teachers. Students will feel pressure to help a researcher who happens to be their teacher. This is an inappropriate dynamic for research that is meant to be voluntary and also harms the instructional relationship between student and teacher. The same principle can also be applied to supervisors and subordinates. All researchers will be encouraged to collect data from students, employees, or clients other than their own. However, this certainly does not mean that there is any prohibition on analysis of organizational data. Analysis of existing data is highly encouraged! Whenever possible, the IRB will help researchers figure out how to get students’, clients’, or subordinates’ de-identified data released to them by an authority higher than the researcher, in a way that does not harm teacher-student relationships, supervisor-subordinate relationships, or therapist-client relationships.
Slide 13 – Who needs IRB approval?
Walden’s standards are indeed a little stricter than other universities. Here is a sampling of different kinds of research. Which ones involve IRB approval? Run your cursor over Yes or No for each one to check your answers.

Slide 14 – What happens if a researcher collects data without IRB approval?
We need to take a brief moment to be clear about what happens if a student or faculty member fails to obtain IRB approval. There is a formal set of procedures for evaluating the circumstances of data collection.

Slide 15 – What if there is a problem once data collection begins?
Sometimes a researcher might find that a particular IRB-approved protocol is not working well or that the IRB-approved site is no longer able to cooperate. Before any changes are made to the research procedures, the researcher must submit a brief, one-page Request for Change in Procedures form. These are typically eligible for expedited review and get a response back within a week or so. If something comes up unexpectedly, such as an unforeseen risk or a very upset participant, the event must be reported to the IRB within one week. Click on each of the captions to view a copy of the relevant form.

Slide 16 – How long does an IRB review take?
Every now and then a student submits a perfect IRB application that is approved “as is” but most require minor revisions or clarifications that are resolved after two rounds of feedback (the first round points out ethical issues needing resolution and the second round confirms that the ethical issues have been addressed). Researchers should allow five to ten business days for each round of feedback and the typical student IRB experience of an expedited review goes like this: First, the researcher receives a round of feedback within 5-10 business days of their IRB submission. Then the researcher makes some revisions or provides clarifications and resubmits the materials. The amount of time needed will vary depending on the researcher’s schedule. The IRB’s review of the resubmission also takes 5-10 business days. The average researcher would receive IRB approval at this point, unless they failed to address the issues that were identified in the first round of feedback. Since the typical researcher needs to make two submissions to the IRB, with a some work in–between, researchers doing minimal risk research with non-vulnerable populations should allow at least 4 weeks for the IRB phase of their study. However, a determined researcher who carefully reads the instructions in the IRB application can often obtain IRB approval in less than 4 weeks. Studies involving vulnerable populations, such as children, cannot be expedited and require review by the full board. The boards meet
weekly but they need some time to receive and read the materials. So each round of feedback for non-expedited review takes at least 10 business days. That means that researchers working with vulnerable populations should allow at least six weeks for their IRB phase.

**Slide 17 – Does IRB approval expire?**

IRB approval lasts one year and is renewable. The researcher will receive the notice of expiration 30 days before it takes effect. If they wish to renew the IRB approval at that time, they can complete the two page renewal form accompanying the notice.

**Slide 18 – What can cause delays in IRB approval?**

For doctoral students, the IRB review comes right after the committee’s formal approval of the proposal, just when the student’s head is brimming with old ideas and new ideas and the proposal is being prepared for final sign-off. It is very easy to let the various components of the proposal fall out of sync. This happens frequently but can be avoided if the researcher proofreads the IRB application carefully, to check that indeed the final set of data collection procedures are described in the IRB application. Researchers are welcome to ask questions and request pre-reviews at any time. Sometimes students use the Walden consent form template without tailoring it to their population and setting. Please don’t assume that Walden prefers the “standard” form—it is just a starting point. To authentically inform potential participants about the study, a researcher must use everyday language that will be understandable. If there is a mismatch between the data collection and research question, or there is a hole in the research design, then the data collection cannot be approved. The difficulties of “backyard research”, especially pertaining to researchers who hold roles as teachers, supervisors, or therapists, are also a frequent cause of delays for students, either because they are struggling to come up with ways to protect the existing relationship, or because they are struggling to locate an organization (other than their own) that will cooperate in the data collection process. Researchers should think about these issues early in the prospectus process. The IRB can often suggest ways of analyzing data without harming instructional, supervisory, or therapeutic relationships.

**Slide 19 – Is there anything I can do to have a smoother IRB review?**

To summarize, here are a few general tips that will help IRB review go more smoothly. Use anonymous methods if possible. Separate the researcher role from all others. Check that all IRB materials reflect the final set of research questions and procedures. Only collect data that directly addresses the research question(s). And finally, use existing instruments whenever possible. Most committees will discourage home-made measures because establishing the validity and reliability of a new instrument can be equivalent to the work of several dissertations! But we recognize that sometimes creation of a new measure is necessary. From an IRB point of view it comes down to whether the potential benefits outweigh the potential
risks. But students creating homemade measures must be prepared to do the extra work required to validate a new instrument.