Research with Human Subjects

Quick Reference Guide for New Investigators

Bucknell University Institutional Review Board (IRB)

What is the IRB?

The Institutional Review Board (IRB) at Bucknell is charged by federal law with safeguarding the welfare, rights, and privacy of anyone who participates in research conducted by Bucknell researchers. To do this, we review all research projects involving human subjects conducted at Bucknell.

Further Information & Resources

IRB Website: http://my.bucknell.edu/irb.html

Online Submission System: https://buapps.bucknell.edu/script/irb/

For General Questions:
Eric Kennedy (IRB Chair):
irbchair@bucknell.edu
570-577-2013

Office of Human Research Protection: http://www.hhs.gov/ohrp/

Does my project need approval?

If your research involves human subjects, then the answer is probably "*yes!*" — keep reading. If your research concerns only non-human subject matter, like asteroids, ferrets, or viruses, you can safely stop reading.

First, what does "research" refer to?

Research is defined by the Office for Human Research Protections as any systematic investigation designed to develop or contribute to *generalizable knowledge*. Certain scholarly and journalistic activities — including oral history, journalism, biography, literary criticism, legal research, and historical scholarship — are normally excluded from the requirement of IRB review, even though there's a sense in which they involve human subjects. For some projects, it's not always clear whether they fit this definition. In these cases, just get in touch with the IRB chair.

Okay, I'm doing human subject research, but I think that my project is classified as "exempt". Do I still need to submit a proposal?

Short answer: *Yes*. As you may know, IRB proposals are placed into three different categories of review (*full*, *expedited*, and *exempt*) corresponding to different levels of review required (see "How long…?" below). In fact, "exempt" means something closer to "exempt from continued IRB oversight," not "exempt from any review." Investigators are not permitted to determine for themselves that their projects fall into this status. Any project considered to be *research* that involves human subjects must be submitted for review.

I would like to receive IRB approval for a project that I started last year; how do I do that?

It's important to recognize that the IRB cannot provide retrospective approval, as this severely limits our ability to protect the rights and interests of human subjects. Thus, if you believe that there is a *possibility* that your project will result in generalizable knowledge, it's a good idea to seek IRB approval beforehand just in case you decide to disseminate your results (i.e., treat your project as research). Most journals will not allow human subjects research that has not been properly approved in advance by an IRB to be published.

I'm a student — do I need to go through the IRB process?

If your project involves human subjects and aims to contribute to the production of generalizable knowledge outside of a classroom environment, then *yes*. Honors/senior theses, independent or faculty-sponsored research projects, and similar projects involving human subjects all need to be approved by

the IRB. Students can be considered as principal investigators (PIs) or co-principal investigators and will be asked to go through the same review process as faculty and staff (with the addition of a review by their faculty sponsor). Again, if you have any questions about whether your project needs review, just get in touch with the IRB chair.

What about classroom exercises?

While prior IRB review and approval is not required for classroom projects, it is the responsibility of the instructor to ensure that classroom work involving human subjects meets Bucknell's ethical and scientific standards. Some instructors voluntarily submit a "general protocol" describing a set of classroom exercises involving human subjects for IRB review and approval (for more information, see §11 of the IRB Policies & Procedures manual: http://adminprojects.bucknell.edu/IRB/IRB-policies-procedures.pdf). Students and faculty are invited to consult with the IRB chair or other members of the IRB for advice on best practices for human subjects research.

How do I submit a proposal?

If IRB review is required, you will complete an online form that describes the details of your research with special attention to the role that your subjects will play. To begin the process, go here: https://my.bucknell.edu/x56250.html.

What materials do I need to have ready?

The online proposal will walk you through a number of questions about, for example, how your subjects will be recruited, what they will be told about the research, whether there are any risks or rewards involved, and so on. Your research plans should be well thought out when you submit your proposal, but you may save your proposal and come back to it later if you wish. In the last stage of the proposal, you will upload a number of documents:

- All final copies of the materials you wish to give to your subjects (such as surveys or stimuli) and/or documents describing in more detail the nature of your interaction with them (such as interview questions, outlines of topics for focus groups, and so on).
- An informed consent form that the participants in your study will be asked to sign. There are sample informed consent forms available on the IRB website (see also §6 of the Policies & Procedures manual).
- Evidence of training in human subjects research for each researcher on the project (see below).

My project is a collaboration with researchers at another institution. Does each institution's IRB need to review our project?

Not necessarily. In fact, changes to the Common Rule going into effect on January 20th, 2020 will require certain cooperative research projects to designate a single IRB as the overseeing body. For now PIs may either submit their project for review by each institution's IRB (making clear in their proposal that this is occurring) or ask for one institution's IRB to serve as the reviewing/overseeing IRB for the entire project. This involves completing a short form that is signed by officials at each institution. Please consult with the IRB chair if you would like to pursue this option.

What "training" is required for human subjects research?

Bucknell subscribes to the Collaborative Institutional Training Initiative (CITI) that provides researchers with training on conducting human subjects research (and other subjects). Each researcher (whether faculty, student, or other research assistant) planning to work with human subjects (including existing data derived from human subjects) is required to complete the Basic Course for Social/Behavioral/Educational Research. Certification is good for two years and may be renewed via a

"Refresher Course," For more information about registering for this system and selecting the relevant courses, please see https://myweb.bucknell.edu/academic-areas/provost/institutional-review-board/training-requirements.

How long will IRB review take?

When you submit your proposal, the online system will use your responses to automatically (and provisionally) classify it as requiring one of the three types of review mentioned above. For proposals requiring full board approval, you should expect a 2–3 week turnaround during the academic year (assuming that significant changes are not required). Proposals requiring full review cannot generally be reviewed during the summer, so researchers are advised to plan ahead for summer research projects and be in touch with the IRB chair about timing for late-spring proposals. Exempt and expedited projects are reviewed on a rolling basis throughout the year and are returned in 1–2 weeks (often less).

After Approval

Can I make changes to my project after it's approved?

Minor changes to an approved project — e.g., adding a researcher, changing survey items, modifying subject pools or recruitment methodologies — are straightforward: simply email the IRB chair with a request that describes these changes. Please put your IRB tracking number in the subject field of the email. More major changes that might change risks posed to subjects may require an additional review to consider the revised protocol. For such changes, please use the "renewal" form in the IRB submission system to describe the changes and update your approval. If you are unsure in which category your proposed changes would fall into, just get in touch with the IRB chair.

Can I renew my project's approval if it's going to continue past the approved window?

Only projects requiring full board approval need to be renewed (and only while data collection is ongoing); to do so, just fill out the renewal form in the online submission system. You will be asked to submit information about your progress thus far (including the number of subjects involved and any new information about risks) as well as any proposed changes. Exempt and Expedited projects do not need to be renewed (unless there are changes in your protocols).

Other Questions?

The IRB Policy & Procedures Manual has more detail on all aspects of human subjects research compliance. Don't hesitate to get in touch with the IRB Chair or any member of the IRB if you have other questions.