What is an IRB and what is Human Subjects Research (HSR)?

An institutional review board (IRB) is a committee composed of elected faculty that has authority to approve, monitor, and review biomedical, social, educational, and behavioral research involving humans in agreement with all federal, institutional and ethical guidelines. Human Subjects Research is defined as a “systematic investigation” that can include either (or all) interventions, interactions, and/or observations of living human beings as research subjects.

Why are they important?

Federal law requires the careful review of research involving human subjects. Federal laws and regulations concerning research involving human subjects have detailed requirements for the IRB and its administration at each institution. Additionally, the IRB also operates under the principles of the Belmont Report, a report that was created in response to unethical human research and it details basic ethical guidelines to protect human subjects.

Penalties for failure to follow federal guidelines appropriately can result in significant loss of federal funding, including federal student loans!

Do I need to submit an application to the RU IRB for my project?

If you are thinking of conducting research with human subjects, the first question you must ask yourself is—Is it research? What exactly is research? Research includes activities that develop or contribute to “generalizable knowledge” by using a systematic approach to the investigation, which may include development, testing or evaluation conducted through observation, interaction or intervention.

The second question you must ask is—Does it involve human subjects? A human subject means “a living individual about whom an investigator (whether a professional or student) conducting research obtains (1) data through intervention or interaction with the individual including observational research, or (2) identifiable private information.” The regulations also tell us that an “intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.” These definitions may be found at 45 CFR 46.102. When in doubt, contact the IRB Office for guidance as it is better to be safe than sorry!

What are IRB review categories and how can I tell what category my project falls under?

Research studies may fall into one of three different types of review categories. The review categories are mainly based on levels of risk to participants and participant characteristics, and are subject to changes in federal, state or university policies. The three federal review categories are as follows: Exempt (which doesn’t really mean exempt, as in excluded from review), Expedited, and Full Board.
Radford University, along with many other universities, also allows a 4th category called “Classroom Exercise” but please note that there are many restrictions associated with this category including the fact that it may **NOT be used for individualized projects such as capstones or theses** and is **only** intended for very minimal risk **classroom-based** activities.

Please see the RU IRB Review Categories web page located at [http://www.radford.edu/content/research-compliance/home/irb/irb-review-categories.html](http://www.radford.edu/content/research-compliance/home/irb/irb-review-categories.html) for more information.

**What do I need to do before I submit my IRB Application?**

Depending on specific institutional policies, the process of IRB protocol submission and approval may vary. Here at Radford University, the initial IRB submission process is as follows:

First, you must create an account with IRBNet ([www.irbnet.org](http://www.irbnet.org)). This is the online system that RU currently uses to process and file research activities being reviewed by the IRB. Please refer to the “IRBNet How To’s” on the following RU IRB: [http://www.radford.edu/content/research-compliance/home/irb/IRBNet-how-tos.html](http://www.radford.edu/content/research-compliance/home/irb/IRBNet-how-tos.html)

Next, it would be a good idea to understand how IRBNet works. This can be confusing for some, but there are tutorials that are recommended for those who have never used the system before. You can find these tutorials on RU’s IRB website: [http://www.radford.edu/content/research-compliance/home/irb/IRBNet-how-tos.html#par_text_1](http://www.radford.edu/content/research-compliance/home/irb/IRBNet-how-tos.html#par_text_1)

Before you submit a project, you should complete the appropriate required IRB-related CITI training. All researchers involved in the study are required to complete one of two Human Subjects Research ethical training courses provided by CITIprogram.org. More information can be found here: [http://www.radford.edu/content/research-compliance/home/irb/irb-training.html](http://www.radford.edu/content/research-compliance/home/irb/irb-training.html)

**How do I submit my IRB Application?**

After you have designed a research study that you wish to conduct, it is time to create and submit a new submission (project) in IRBNet. The submission’s application form guides you to describe research rationales and detailed methodology for your study so that the IRB may determine if the study is sound, ethical, and if all researchers involved in the study are sufficiently qualified and trained.

There are a few documents that are required in each submission here at RU- you must use the official RU IRB Application (always use the most current version that is available on IRBNet) and Investigator Agreement forms (one each for everyone on the study and all students will need their form “co-signed” by the faculty PI.) You will also need to include curriculum vitae (or resumes) for all researchers involved in the study, along with any consent or recruitment documents as applicable. Depending on the study, more items may be required.

All the necessary forms are available on RU’s IRB Forms and Templates web page or IRBNet’s Forms and Templates library. Once all necessary documents are completed on your
desktop and then uploaded onto IRBNet in your newly created Project, the Principal Investigator must electronically sign the project within IRBNet and click on Submit.

**I’ve submitted my IRB application and other documents. Now what?**

You will hear back from the IRB office in 2-3 business days with pre-review comments that need to be revised and then re-submitted. Feel free to contact the IRB Office if you haven’t heard from us after this time.

After the revisions are made and reviewed by the IRB Office, your project will be sent to a protocol reviewer and, again, any comments about items that require revision will be sent to you. Once you have addressed all of the reviewer comments and re-uploaded the changes into IRBNet, it will be sent through the final review and approval stage. Depending on the submission, the final review may be approved or it might require additional revisions or a full committee meeting.

**Note to remember:** The entire review and approval process varies for each individual protocol, with an *average three week turn around*. In order to expedite the review process, it is recommended that you plan ahead and submit the project 1-2 months prior to the date you wish to start. The IRB cannot guarantee a protocol will be approved on the day you wish, so it’s better to be safe (submit early!) than sorry. But please inform the IRB Office when a research project needs to be completed within a semester and they will try to hasten the review process where possible.

**Where do I go and who do I contact for more information?**

For more information, please see:

- The RU IRB home page at [http://www.radford.edu/content/research-compliance/home/irb.html](http://www.radford.edu/content/research-compliance/home/irb.html)
- The RU IRB FAQ page at [http://www.radford.edu/content/research-compliance/home/irb/irb-faqs.html](http://www.radford.edu/content/research-compliance/home/irb/irb-faqs.html)

To contact the IRB Office:

- Email the IRB Administrator/Research Compliance Manager at irb-iacuc@radford.edu
- Email the IRB GA’s at irb-iacue-ga@radford.edu.