

Guidance and FAQs
for Student
Researchers

About the IRB

This presentation is limited solely to providing supplemental information for student researchers considering an application for IRB review. It does not replace or in any way supersede content addressed in federal regulations and/or the official University of Scranton IRB Policy and associated procedures, nor does it serve as official guidance or judgment for specific research projects and IRB applications. The official IRB policy and other official resources are available via the [IRB Website](#)

What is an IRB?

- An institutional review board, or IRB, is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.
- IRBs are mandated by, and their scope/structure defined, under regulations issued by the U.S. Department of Health and Human Services (HHS). The regulation is generally known as “The Common Rule,” and was most recently updated in 2018.
- IRBs have the responsibility to review and approve all research activities that involve human subjects under their institutional scope. The IRB is primarily concerned with assuring the welfare, rights, and privacy of those subjects, and that the investigators are taking appropriate precautions to minimize any risks that may be part of participation.
- The IRB has the authority to approve, exempt, disapprove, monitor, require modifications, or suspend human subjects’ research (HSR) activities that fall within its scope as specified by both federal regulations and its own home institution’s policy, as well as commonly accepted ethical standards.



Who is the IRB at the University of Scranton?

At the University, IRB activities involve the following individuals and groups:

- The Chief Research Officer, the institutional official responsible for all research activity conducted at the University of Scranton (Dr. David Marx, Associate Provost)
- The IRB Administrator, the institutional official charged with responsibility for the management and administration of the IRB function and its policies and procedures. Together with the IRB committee chair, the Administrator also has responsibility to review/approve expedited and exempt research applications. (Ms. Kate Yerkes, Assistant Provost)
- The IRB Committee, chaired by an experienced faculty member appointed by the Chief Research Officer, and comprised of appointed faculty and staff members. The IRB Committee is responsible for reviewing HSR projects that meet the criteria defined within the policy, generally, those requiring “Full” IRB review. (Chair, Dr. Bryan Burnham, Professor of Psychology)
- Departmental Review Boards (DRBs), which are chaired by a faculty member from departments authorized under the Policy to review and approve selected HSR projects that meet the criteria defined within the Policy. DRBs are approved within certain academic departments that regularly conduct HSR (for example, Psychology and Occupational Therapy/Physical Therapy).

Do I need the IRB?

Student researchers may be part of a research project led by a faculty member(s). Other times student researchers may be conducting human subjects research projects of their own for academic work including a class project, a research grant or student scholarship program, a master's thesis, or doctoral dissertation.

- IRB review is necessary when a project is *both* (1) research and (2) involving human subjects.
 - Are you conducting a research project?
 - Research is defined as a *systematic* investigation, including research development, testing and evaluation, designed to *develop or contribute to generalizable knowledge*.
 - Sometimes it may be tricky to decide if what you are doing is actually research. Typically, if you are preparing a paper, presentation, or publication that summarizes your research activity and findings, it is most likely research. But if you are unsure, consult your faculty advisor or the IRB administrator.
 - If yes, does that project include human subjects?
 - A Human subject is *a living individual about whom* an investigator is conducting research:
 - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; **OR**
 - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens
- If you answered **yes** to **both of the above**, you will need the IRB to review your project.

What is the IRB process, and how long does it take?

The length of the IRB review process depends upon several factors:

- The completeness/thoroughness of the IRB application:
 - Applications that include one or two lines of text, or say “see attached”, in describing how aspects of the application are being addressed nearly always do not include ample information for the to make its judgments.
 - Whether all documents are provided – including copies of all communications to subjects (e.g., recruitment messages), research tools (like a survey), and IRB training documentation
 - An application with very little/lean description, missing elements, or lacking documentation almost always result in a response from the IRB that more information is required.
- Whether Exempt, Expedited, or Full review is required:
 - Expedited and Exempt projects do not need to wait for an IRB committee meeting for review. They are reviewed on a rolling basis upon receipt. The IRB is committed to making a first review of these within seven business days.
 - However, for those requiring Full Committee Review, the IRB committee meets monthly during the academic year, and only **applications received by the published deadline** for inclusion in each meeting will be reviewed at that time.
 - For each level of review, whether during the review the IRB requires that the investigator respond to questions, provide clarification, or make certain modifications to the research design or its parts, or if there are additional documents to obtain. This process can continue until the IRB is satisfied that its questions and concerns have been addressed sufficiently.

What does the IRB need to know?

- The IRB process includes two types of applications (Exempt, or Expedited/Full) that are designed to gather the information needed to help it make a determination about what level of review, approval, and oversight is needed.
- The IRB needs to know about
 - The history/background of the project (enough to have a clear understanding of its nature and purpose)
 - A clear description of who the research subjects are, and how they were selected and recruited
 - The research design and methodology
 - When and how investigators will be interacting with human subjects
 - The types of communications, materials, and documents that human subjects will receive
 - How informed consent to participate in the study will be provided and obtained
 - Description of any potential risks that participants may encounter, and how those will be minimized
 - What personally identifiable data investigators will have or obtain about and from subjects during any part of the research project
 - What steps will be taken to secure that data appropriately

What documents and materials will I need to prepare?

- A thoroughly completed IRB application
 - This may be an exempt application, or an application for expedited or full review. More on these categories, and what is included in each type of application, later.
- In addition to the application document,
 - Documentation confirming you – and anyone else taking part in the project - have completed required IRB education/training (CITI)
 - Copies of any research tools being used (such as a survey, a list of interview questions, a test, etc.)
 - Copies of the text of any communication that will be sent to those selected to participate in the research at each phase (for example, recruitment letters, emails, posters, social media posts, etc.)
 - Copies of materials that will be used for informed consent
 - If you are doing the research at a non-University site or location, documentation that you have consent from that site do so
 - Possibly research reliance forms if your project includes researchers from outside the University
 - And, depending on your project, there may be others relevant materials to share or that you may be asked to provide

Undergraduate student IRB applications may only be submitted by a faculty or staff member.

Graduate student applications may be submitted directly by the student.



About Informed Consent

- Informed Consent is a fundamental part of HSR.
- From the federal regulation,
 - “The informed consent process involves three key features: (1) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research.”
- Consent must be legally and prospectively obtained (before participation in the research activity begins)
 - Special steps may need to be taken for minors or other protected populations
- The following are standard elements of informed consent that must be addressed:
 - A statement describing the research, its purposes, and expected duration
 - A statement that the research is voluntary, that there is no penalty for not participating, and that the subject can discontinue participation at any time
 - Any reasonably foreseeable risks or discomforts to the subject;
 - Any benefits to the subject or to others which may reasonably be expected from the research, or statement that there may be no direct benefit
 - A disclosure of appropriate alternative procedures or courses of treatment, if any;
 - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - Who to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject
 - Contact information for the IRB administrator
 - *And possibly other elements, depending upon the nature of the research project*

What are the types of responses the IRB may make to an application?

- The IRB can issue the following types of official actions
 - Acknowledge
 - The IRB has received the application.
 - Exempt
 - The IRB has received the application it is determined to be exempt from HSR regulations. Further review/IRB approval is not required.
 - Information Required
 - The IRB has received and reviewed the application, and needs more information about one or more elements.
 - Modification Required
 - The IRB has received and reviewed the application, and there are changes to the research project or materials that need to be provided to secure approval .
 - Approve with Conditions
 - The IRB has received and reviewed the application, and is approving it with a particular condition that must be met before the project can begin (often, the submission of forms, or minor changes to documentation or materials).
 - Approve
 - The IRB has received and reviewed the application, and approves the study to move forward.
 - Not Approved/Disapprove
 - The IRB has received and reviewed the application and does not approve the study to move forward.

What are some of the common areas of clarification or types of modification that the IRB may require before approving?



Request that the application include more information about the project. For example,

The application only provides a sentence or two about the background for the study. The IRB doesn't have enough information to understand what the project is about.

The application does not describe whether or not the research is contributing to an existing body of research, or whether it is new or unique in some way.

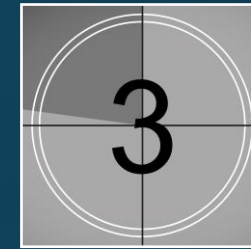


Request documents that have not been provided. For example,

The investigator will be sending an email invitation to potential participants, but did not include the actual text of the email.

The investigator plans to post fliers on campus with a QR code to help get the word out. But the flier wasn't attached.

The investigator will be using a translation service to translate documents from English to several other languages, but only provided the English version.



Update documents to be sure they do not overpromise or understate elements of informed consent. Some common examples:

A form or survey invitation tells participants that there is "no risk" to participation. However, there is never "no risk," but risk may be minimal/no more than encountered during everyday life. This language needs to be updated.

Survey responses may be described as anonymous, but the researcher has sent the survey via email and is inviting participants to share their email for a voluntary incentive drawing. In this case, anonymity cannot be guaranteed, but the researcher may say that data is "confidential."

The consent form fails to note that participation is voluntary, and that there is no penalty for deciding to not take part.

Exempt, Expedited, or Full Review?

- Exempt Research (reviewed by IRB Administrator and IRB Chair; rolling basis w/in 7 business days)
 - **Is no more than minimal risk**, participation/participant data is **entirely anonymous**, and **meets one of the federally defined classifications** for Exempt research.
 - In the context of IRB review, “anonymous” means that no one, including the researcher, can individually identify participants or connect data/responses to an individual.
 - Some research that may meet the federally defined threshold for “limited review,” where the only PI data about participants is information that is used to identify them as subjects or communicate with them (for example, an email address to send a survey) is reviewed using the University’s Expedited review process, as the information needed and level of review are the same as is gathered via the Expedited review form and process.
- Expedited Research (reviewed by IRB Administrator and IRB Chair, or a DRB; For IRB, rolling basis within seven business days; for DRBs, according to separate DRB schedule)
 - **Is no more than minimal risk**, and the only involvement of participants is within **one of the federally defined classifications** for Expedited research.
- Full Review Research (reviewed by IRB Committee, or sometimes a DRB; For IRB, according to published IRB meeting schedule; for DRBs, according to separate DRB schedule)
 - **Is more than minimal risk**, and **special precautions need to be taken to protect rights and welfare** of participants. If any of the following **protected populations**, as defined under federal regulation, are included, Full review is required: minors under the age of 18; pregnant women; economically/educationally disadvantaged persons; fetus/fetal tissue; prisoners/incarcerated persons; non-English speaking persons; mentally/cognitively impaired persons.
 - In addition, although an application may meet the criteria for a DRB to review it, the DRB may elect for the IRB to review, or the IRB may choose to review it itself.

About Risk

- IRB review is concerned with the level of risk that may be faced by those participating in HSR, that researchers are letting participants know about any possible risks, and assuring that investigators have minimized any risk as much as is possible.
- There is never no risk.
 - A common requested modification to research materials is asking researchers to remove statements like “There is no risk for participating in this study.”
 - Even a simple online survey may have risk, such as the risk of data breach that is always part of submitting any information via an electronic format.
- However, risk may be minimal, or greater/more than minimal:
 - Minimal risk means 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
 - More than minimal risk means the probability and magnitude of harm or discomfort anticipated in the research risks are more than minimal risk, but not significantly greater.

IRB Education and Training

- All persons conducting HSR at the University of Scranton must complete required IRB training.
- IRB training requirements are outlined in the IRB policy and other supporting documents.
- In general, researchers need to complete basic social and behavioral research training modules, though others may also be needed/apply based on the type of research being done.
- The University has contracted with CITI for IRB training needs. Training is free to all members of the University community.
- Training must be updated at least every three years, and a score of at least 80% on all training modules must be achieved.
- Upon completion, you can generate a certificate verifying your training. This must be provided as part of any IRB application.
- In addition to IRB procedural needs, IRB training may be part of a particular course, such as research methods.
- Visit the IRB web site for detailed information, and links to access training.

Questions? Need more Information?

- Consult with your faculty mentor or advisor
- Contact the IRB Administrator
 - Kate Yerkes at Kathryn.Yerkes@scranton.edu
- Review the IRB Policy, guidance, and other information on our web site
<https://www.scranton.edu/academics/provost/research/sub%20pages/IRB.shtml>