

IRB FAQs

Why should I read the IRB FAQs?

- It allows you the opportunity for easy access to the most popular questions individuals have regarding the IRB. Additionally, the FAQs provide general information that can be useful to you for the approval process.

What is the purpose of the IRB?

- The IRB's purpose is to review research involving human subjects conducted by the students and faculty of Roosevelt University.
- The IRB reviews the potential risks and benefits to human participants and ensures the subjects are fully informed and consent to the research study. Additionally, the IRB works to minimize the potential risk to human participants and protect their privacy.
- The IRB works to ensure the researcher and university are not subject to legal and other sanctions for being in noncompliance with federal regulations. Additionally, the IRB ensures that student and faculty researchers are protected from lawsuits should someone claim to be harmed by the research study.

How do I know if I need IRB approval?

- Research involving human subjects requires IRB approval.
- As defined by Federal Regulations a human subject is "a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information" (Code of Federal Regulations, 45 CFR 46.102f).
- Research includes quantitative and qualitative studies; it includes but is not limited to interviews, surveys, observations, case studies, and archival data.
- Research that is exempt from IRB approval must meet federal guidelines. **It is up to the IRB, and not the researcher to determine if a study is exempt. Researchers must still submit an application for review under exempt status.**

When should I apply to the IRB?

- IRB approval **must** be obtained from Roosevelt University **prior** to the initiation of the research study.
- IRB applications must be submitted **one week** prior to the monthly IRB meeting. Applications not submitted by this deadline may be delayed for review until the next scheduled meeting. A list of meeting dates and an IRB checklist to ensure all needed materials are completed is located on the IRB website, <http://www.roosevelt.edu/Provost/GraduateStudies/IRB.aspx>
- Researchers must re-submit their project for approval each year or notify the IRB of completion of the study.

What is CITI?

- CITI is a web-based tutorial program which must be completed by all student and faculty researchers. It ensures researchers are up-to-date with standard ethical and legal practices regarding research in their area of study. A certificate of completion is required with your IRB application. **All** individuals working on the study must produce a certificate. The CITI program and Basic Learner Instructions can be accessed at <http://www.roosevelt.edu/Provost/GraduateStudies/IRB.aspx>

How long will it take to get approval from the IRB?

-Though there is no concrete length of time to gain IRB approval, applications are generally approved within a month. The length of the IRB review is dependent upon the nature of the proposed research.

-IRB applications are reviewed on a monthly basis excluding summer sessions. After review the IRB chair will inform the investigator of the status of their application within a few days. If approved a formal approval letter via email will follow.

-The approval process may be expanded if the IRB requests amendments to the proposed research. Amendments can vary from minor changes, such as word changes, to major changes to the research that require the investigator to resubmit the proposed research at a subsequent IRB meeting.

-The type of review your research requires (e.g., expedited, full) can influence the length of time necessary for approval.

-Incomplete research applications will be returned for completion and may result in delayed IRB review

Does the IRB approve research methodology?

-No, the IRB focuses on minimizing the risk and protecting the rights of human participants. The focus of the IRB is not to approve or critique research methodology unless it is an ethical or legal concern.

If I have a question about an IRB application, who can I ask?

-Please e-mail all questions and concerns to the IRB Chair, Judith Gouwens at jgouwens@roosevelt.edu. You will receive a response in a timely manner.

Does the IRB want my project to be successful?

-Yes. Roosevelt University encourages its students and faculty to conduct research, especially studies which are ethical, legal, and protect human subjects.

Will the IRB impede my project?

-No, just the opposite. The IRB helps prevent possible sanctions against you as a researcher, which can impede current and future projects. Amendments or changes to a research proposal may be required for IRB approval. If these changes are not made the research study cannot begin. The IRB works in an efficient and collaborative manner with investigators to expedite the process.

What happens if I do research without IRB approval?

- Researchers conducting studies without IRB approval are violating Roosevelt University and federal policies. Non-compliance with the IRB process can result in termination of the study and suspension of research privileges for the investigators. Ethical implications include, among others, putting human participants at risk. Without IRB approval, Roosevelt University is not liable for any risks or incidents that occur during the study and the investigator is not protected.

If I submit an IRB application, will that absolve me of responsibility for the effects of my research?

-No. IRB approval must be obtained before the initiation of any research to be protected by the University and any changes to the proposed research study must be approved by the IRB before they are implemented. Any adverse effects that occur during the research must be reported to the IRB immediately. If you have followed your approved IRB protocol, the University will protect researchers against legal issues.

When should I talk with my advisor?

-Researchers should submit their IRB application to their advisors at least 1-2 weeks before the application is submitted to the IRB for approval. Advisors will vary on the amount of time needed to review the application and sign so best practice is to consult with your advisor beforehand on an appropriate timetable.

Where can I find samples of IRB documents?

-Sample consent forms, an IRB application checklist, the IRB application forms, and other supplemental materials can be found online at <http://www.roosevelt.edu/Provost/GraduateStudies/IRB.aspx>