

What is the Institutional Review Board (IRB)?

There are several federal and state regulations that are designed to protect human subjects in research. The Institutional Review Board (IRB) is a federally mandated committee created to ensure that investigators abide by those regulations, and protect human subjects in research.

The main function of the IRB is to review and approve all research that involves human subjects prior to an investigator beginning that research. The IRB is responsible for determining that a proposed research protocol sufficiently addresses the following issues (45 CFR 46.111):

- Risks to subjects are minimized and are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result;
- Selection of subjects is equitable;
- Informed consent will be sought, and appropriately documented, from each prospective subject;
- Adequate provisions exist for monitoring the data collected to ensure the safety of subjects;
- Adequate provisions exist to protect the privacy of subjects and maintain the confidentiality of data;

- When some or all of the subjects are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, etc.), additional safeguards have been included in the study to protect these subjects.

What is Human Subjects Research?

Human subjects research is defined in the Code of Federal Regulations (45 CFR 46):

- *Research* is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- A *Human subject* is a living individual about whom an investigator conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

Human subject research can include many different kinds of research, from internet surveys, classroom observation and analysis of pre-existing records to clinical trials involving behavioral or medical interventions.

Some things that do not qualify as human subjects research include quality improvement of Suffolk services, student satisfaction surveys, and other research conducted with purely internal goals in mind.

If you are unsure whether your planned project constitutes human subjects research, please contact the IRB Administrator.



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The Institutional Review Board & Human Subjects Research

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Human Subjects Research and the IRB

Who Does This Apply to?

All human subjects research conducted by any Suffolk University student, faculty, or staff member is overseen by the IRB. This includes all three branches of the University: the College of Arts and Sciences, the Sawyer Business School, and the Suffolk University Law School. The IRB is also responsible for granting permission for any outside investigator to conduct research on Suffolk campus.

Submitting a Protocol to the IRB

If you plan to conduct human subjects research, you must submit your protocol according to the following steps:

- Complete certification in Human Subjects Protection Education and provide a copy to the IRB Administrator.
- Check the IRB website (see front page) or contact the IRB Administrator for the most current forms and instructions.
- Complete the 'Request for Approval of Research Using Human Participants' form, and attach any additional documentation.
- Submit the packet of materials to the IRB Administrator for processing and review. Materials must be submitted both electronically and in hard copy.

Research can only begin *after* the IRB

has reviewed and approved the protocol. Approvals expire within one year after the approval date, and require submission of an application to renew approval to continue the research. Any modifications made to the protocol after approval is obtained must also be reviewed and approved by the IRB prior to implementation. Once the research has been completed, a closure report should be submitted to the IRB.

Types of Review

A research protocol submitted to the IRB will be classified and reviewed under one of three (3) types of review:

Exempt Research - Exempt research falls under one of six (6) specific categories listed in the federal regulations, and is exempt from IRB review under the federal regulations. However, **only the IRB can make the determination that a protocol is exempt, not the investigator.** Therefore, Suffolk policy requires that any research that might qualify as exempt be submitted to the IRB for preliminary review to confirm its classification, and to ensure that the protocol meets university standards for research.

Expedited Review - Research involving no more than minimal risk, and falling into one of nine (9) categories specified in the federal regulations, may be reviewed using the expedited review process. These reviews are conducted by two IRB members instead of the convened IRB.

Full Board Review - Full Board review is conducted for any research that involves greater than minimal risk to participants, at a convened meeting of the IRB. It may also be used to review research involving vulnerable subject populations, or protocols studying matters that may be particularly sensitive to subjects.

Timeline

The following approximate timeline applies to initial processing and review of the three review categories:

Exempt Reviews: 10 business days

Expedited Reviews: 14 business days

Full Board Reviews: Last Thursday of each month, at convened meeting (September – May)

The above estimates do not include any time that may be taken up with questions or requested revisions. Therefore, it is extremely important to plan a protocol and submit an IRB application for it *as far in advance as possible*. Accommodations for grant applications or other deadlines will be made by the IRB Administrator if possible, but are not guaranteed.

Human Subjects Protection Education

All investigators are required to complete a course in human subjects protection before they can conduct human subjects research or interact with research subjects. It is also the PI's responsibility to make sure that the entire research team has completed the training prior to IRB approval. Suffolk University uses the Collaborative Institutional Training Initiative (CITI) program to educate its investigators. Further details can be found on the IRB website. Each researcher must recertify every two (2) years.