

Does my project require IRB review and approval?

IRB review and approval is required for projects that:

- ✓ **Meet the definition of research**
 - ✓ **Involve human subjects**
 - ✓ **Include any interaction or intervention with human subjects or involve access to identifiable private information, including identifiable biospecimens**
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Does your project meet this definition of Research?

Research is defined as a **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**.

A Systematic Investigation follows a predetermined plan for looking at a particular issue, testing a hypothesis or research question, or developing a new theory that may include:

- Collection of quantitative or qualitative data
- Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups
- Collection of data using experimental designs such as clinical trials
- Observation of individual or group behavior

Contribute to Generalizable Knowledge means that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied. This may include one or more of the following:

- Presentation of the data at meetings, conferences, seminars, poster presentations, etc.
- The knowledge contributes to an already established body of knowledge
- Other investigators, scholars, and practitioners may benefit from this knowledge
- Publications, including journals, papers, dissertations, and master's theses

If the project does not meet the definition of research (i.e. is not a systematic investigation or does not contribute to generalizable knowledge), as described above, then the project does not require IRB review and an IRB application is not required.

Does your project involve Human Subjects?

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.

If the project does not meet the definition of research or the project does not include human subjects, as described above, then the project does not require IRB review.

Does your project include any interaction or intervention with human subjects or involve access to identifiable private information, or identifiable biospecimens?

- An **Interaction** is any communication or interpersonal contact between the investigator(s) and the subjects. This includes in-person, mail, telephone, etc. Online surveys (even if anonymous) involve interaction.
- An **Intervention** includes physical procedures or manipulations of the subject or their environment (e.g. taking blood samples, exercise studies, use of devices, cognitive tasks, etc.)

Access to Identifiable Private Information

- **Private Information:** Information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place (e.g. person's home, exam room, public restroom, etc.) OR has been provided for specific purposes with a reasonable expectation that it will not be made public (e.g. medical records, student records, employee file, etc.)
- **Identifiable Information:** The identity of the individual is or may be readily ascertained by the investigator or others either directly or indirectly using codes or a combination of data points.

If the project does not include any interaction or intervention with human subjects or include any access to identifiable private information, then the project does not require IRB review. If even one of the above categories are met (interaction, intervention, access to identifiable private information), an IRB application is required.

Does Academic Assessment Data Require IRB Review?

It depends. Most often, academic assessment data (e.g., grades, course work, surveys, interviews, etc.) are only used to provide feedback to students, improve a course or program, or to report findings to the Office of Planning and Assessment for University-wide educational program improvement. For such cases, BU IRB approval is not required. However, at times, there are plans to disseminate results outside of the University (e.g., publish, present findings at a conference, report findings to a granting agency). For such cases, BU IRB approval is required. Please consult the [Activities Requiring Approval flowchart](#) for help deciding whether IRB approval is required.

Before collecting assessment data from students (e.g., survey, focus group), classroom data (e.g., coursework, senior projects), or student academic data, ask yourself whether you intend to disseminate findings or would disseminate if the findings are interesting / valuable. If the answer to either of these questions is 'yes', IRB approval is required PRIOR TO the collection of data.

Note: Releasing data to accrediting agencies to present evidence of improvement of student learning does not constitute dissemination of research results/data, and therefore does not require IRB approval.

Examples of Studies that Generally Require IRB Review

- Pilot studies that involve human subjects
- Master's theses
- Dissertations
- Use of identifiable information from medical records, student records, employment records, or other private sources
- Research studies that collect data about human subjects through interaction or intervention with subjects, such as surveys (paper, online, telephone, etc.), interviews, focus groups, cognitive testing, etc.
- Research studies that include subjects to examine devices, products, food, drugs, supplements, etc.

Examples of Studies that Generally Do Not Require IRB Review

- Data collected for internal departmental or administrative purposes, such as teaching evaluations, student performance data, etc.
- Activities designed solely for quality improvement or evaluation of a particular program, course, etc.
- Oral histories or biographies (unless data will also be used to contribute to generalizable knowledge)
- Training activities unless the training activity is conducted for research purposes
- Single case studies

Sources:

- Office of Human Research Protections – Division of U.S. Dept of Health & Human Services
<https://www.hhs.gov/ohrp/>
- PRP 3990 Institutional Review Board (IRB) for Human Subjects Research
https://intranet.bloomu.edu/policies_procedures/3990
- Virginia Tech University IRB
<https://www.irb.vt.edu/pages/researchers.htm>
- Boston University
<https://www.bu.edu/researchsupport/compliance/human-subjects/determining-if-irb-approval-is-needed/>