



BRIGHAM YOUNG UNIVERSITY–HAWAII

Institutional Review Board Quick Guide

To Submit or Not to Submit IRB?

IRB review and approval is necessary whenever we engage in **research** with human subjects.

Definition and examples of **research**:

[The United States Department of Health and Human Services](#) define **research** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A "systematic investigation" is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

Examples of systematic investigations include:

- surveys and questionnaires
- interviews and focus groups
- analyses of existing data or biological specimens
- epidemiological studies
- evaluations of social or educational programs
- cognitive and perceptual experiments
- medical chart review studies

Investigations designed to develop or contribute to generalizable knowledge are those designed to:

- draw general conclusions,
- inform policy, or
- generalize findings beyond a single individual or an internal program (e.g., publications or presentations.)

Research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication. Research that never is published is still research. Participants in research studies deserve protection whether or not the research is published.

OVERVIEW: STUDENT RESEARCH

Student researchers have the same submission options as any investigator. They may submit as Principal Investigator (PI) with a faculty advisor as co-signator, which may be appropriate for new projects where the student has a leading role. Alternatively, it may be appropriate for the student researcher to be included on an existing project that already has IRB approval, if the student activity is (or will be, after modification) subsumed under that existing study. This latter option would mean that a separate IRB application is not needed from the student. Each research scenario has its own set of circumstances that will dictate handling. Below are some common scenarios, with likely processing requirements:

RESEARCH that involves direct interaction with individuals (e.g., in person, or via mail, email, web survey, or telephone), or data from human subjects for which the researchers will have access to identifiers.	→ IRB approval required. Submit IRB application form, either with student as PI or listed as study personnel on faculty application.
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Examples of activities that typically are not generalizable include:

- Course-related activities that are designed to provide opportunities to practice research methods (e.g., interview, observation and survey techniques; data analysis; research design) that are limited in scope, present no more than minimal risk and do not result in generalizable research.
- Information gathered informally for class discussion or to provide ideas for creative work
- Class demonstrations and laboratory exercises using students enrolled in an academic program
- Class demonstrations using participants not enrolled in the course if said demonstrations involve standard educational/developmental demonstrations or assessments (e.g., Piagetian stages, infant behavior, etc.) that do not provide information that might be used to categorize and/or diagnose (e.g., IQ tests, measures of behavior problems, measures of social functioning).
- Student teaching and educational internships
- Clinical internships and practice
- Informational interviews and surveys that are not about individual human beings.
Examples of these types of projects might include:
 - Surveys or interviews of natural resource managers about policies and practices governing the protection of endangered species.
 - Interviews of clinical practitioners about the types of therapies available to treat certain conditions.
 - Requests for aggregated, non-identifiable demographic data about specific populations (such as those enrolled in a school).
 - Interviews about the structure, purpose, strategies, or environmental challenges of organizations.
- Oral histories and biographies

- Journalism and documentary production not intended to produce generalizable knowledge.
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the BYUH community
- Case studies of particular individuals or small groups in very specific contexts not intended to produce generalizable knowledge

OVERVIEW: CLASS PROJECTS	
<p>Class projects are generally conducted for educational purposes and not as research. While some may require submission of an IRB application or a determination that IRB approval is not required, many class projects require neither.</p> <p>Instructors and departments are encouraged to contact the IRB for guidance about ways to handle topics such as privacy, confidentiality, informed consent, and professional ethics when class projects are part of the course syllabus.</p> <p>The BYUH's IRB can provide information on managing risks of deductive disclosure, coercion-free recruiting, informed consent, and special considerations for projects that include potentially vulnerable individuals. These issues may still remain even when IRB approval is not required, in which case instructors, advisors, departments and schools play an even greater role in providing the appropriate guidance and oversight. Common scenarios:</p>	
<p>CLASS PROJECTS involving secondary data analyses that are assigned and conducted as educational exercises, using data that are either publicly available data, de-identified or otherwise impossible to be linked to personal identities.</p>	<p>→ No IRB action required (neither approval nor determination of human research status).</p>
<p>CLASS PROJECTS involving secondary data analyses that are assigned and conducted as educational exercises, and that use datasets that include private information and codes that link to identifiers, but the students do not have access to the identifiers.</p>	<p>→ No IRB action required (neither approval nor determination of human research status).</p> <p>Class instructor and department are responsible for providing the necessary training in respecting the confidentiality of the data.</p>
<p>CLASS PROJECTS or PRACTICA that involve direct interaction (e.g., in person, via mail, email, web surveys, or telephone), but where the purpose is training, an educational exercise or professional development, and not research. The project or practicum is not “research” even if students ask people questions as part of learning how to conduct interviews or surveys, take histories, administer assessments, or perform “in-house” evaluations as requested by the practicum site.</p> <p>Exception: If a student decides <i>after</i> the completion of a practicum activity to pursue additional activities with the same information for a master’s project or paper, then an IRB</p>	<p>→ No IRB action required (neither approval nor determination of human research status) but may be requested if instructor or students are unsure, or if documentation is required by gatekeepers (e.g., schools, businesses) for access to participants.</p> <p>Class instructor and department are responsible for providing the necessary training in respecting the privacy of the individuals and the confidentiality of any resulting information, along with training in the relevant professional ethics.</p> <p>Instructor provides information about the assignment for the students to distribute to people who participate in these class projects.</p>

<p>application describing research use of secondary data should be submitted for approval, as above.</p>	<p>List the instructor as the appropriate contact person should questions arise.</p>
<p>CLASS PROJECTS or PRACTICA that involve direct interaction or secondary analyses of private identifiable data and are undertaken as both an educational experience and as research (e.g., results of these activities will be presented publicly or otherwise disseminated, or the data will be stored and used by the students or others as research data).</p> <p>Submission Tip: Such projects may be very similar to one another. For example, each student may interview one or more persons for a group of oral histories, or conduct telephone surveys as part of a yearly poll, but all in the class follow the same general script or guidelines. If class projects follow different protocols, a table or chart can describe these more individualized activities, under the umbrella of a single IRB application.</p>	<p>→ IRB approval required.</p> <p>When there are several students in a class doing similar projects, a single IRB application may be submitted by the course instructor as PI, listing all students who will be involved. If projects vary greatly, then it may be preferable to submit individual IRB applications with the student(s) as PI.</p> <p>The PI must have research ethics certification. Taking into account the sensitivity of the information to be collected, the instructor can require that students complete the CITI online course, or the instructor may provide comparable training, with the approval of the IRB.</p>