

IRB GUIDANCE FOR STUDENT RESEARCH AND CLASS PROJECTS

Federal regulations and university policies require Institutional Review Board (IRB) approval for research with human subjects. This applies whether the research is conducted by faculty or students, by individuals or a group. *Failure to obtain proper approval in advance may jeopardize your data, prevent you from publishing the results, and place you and the university in violation of federal regulations.* At the same time, many class projects are conducted for educational purposes and not as research, and will not require IRB approval. This guidance will help you determine whether you need to get IRB approval before conducting a given activity. Please note that the IRB does not have the option of granting “retroactive” approval after research is done; you should err on the side of submitting or consulting with the IRB if there is any doubt. Additional guidance is available at ohre.unc.edu

STUDENT RESEARCH

Student research activities include, but are not limited to, projects that result in undergraduate honors theses, masters theses, or doctoral dissertations. *IRB approval is generally required if the intent is to develop new or expanded generalizable knowledge AND human subjects are involved, either directly or through use of identifiable data about them* 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 precludes the need for a separate IRB application 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.**

*→ Human Subjects Research, therefore IRB approval required
→ Submit an IRB application, either with student as PI or listed as study personnel on faculty application; or modify existing study if student project is directly related.*

Student researcher, co-investigators (if a group) and faculty advisor are required to have human subjects protection training.

RESEARCH that is limited to **secondary analysis** of data, records or specimens that are either **publicly available, de-identified or otherwise impossible to be linked to personal identities.**

→ Not Human Subjects Research, but if you need documentation from the IRB, submit an IRB application

A data use agreement between the researcher and the data custodian may still be required to verify that the researcher will not have access to identifying codes. It is this “de-linking” of data from personal identifiers that allows the IRB to make this determination.

If the IRB determines that this project is not human subjects research, human subjects protection training is not required by IRB, but may be required by the faculty advisor.

RESEARCH-like activities using departmental subject pools (e.g., Psychology, Business, Political Science, Journalism and Mass Communication) even when the activity is conducted for educational purposes as a class requirement.

→ IRB approval required → submit an IRB application for each activity by an individual or small group

Student researcher, co-investigators (if a group) and faculty advisor should have human subjects protection training.

Class Project scenarios are discussed on the next page...

CLASS PROJECTS

Class projects are generally conducted for educational purposes and not as research. While some require submission of an **IRB application** or a **determination that IRB approval is not required**, many class projects require neither. Instructors and departments are encouraged to contact the relevant 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. IRB chairs and staff can share expertise related to 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:

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.

→ **No IRB action required (neither approval nor determination of human research status)**

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.

→ **No IRB action required (neither approval nor determination of human research status)**

Class instructor and department are responsible for providing the necessary training in respecting the confidentiality of the data.

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.

→ **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.

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.

Exception:

If a student decides *after* the completion of a practicum activity to pursue additional activities with the same information for dissemination (e.g., master’s project, conference paper, article), then an IRB application describing research use of secondary data should be submitted for approval, as above.

Instructor provides information about the assignment for the students to distribute to people who participate in these class projects. List the instructor as the appropriate contact person should questions arise.

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).

→ **IRB approval required** → 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.

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.

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.