RERB Guidance for Student Research and Class Projects

Federal regulations and university policies require Institutional Review Board 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 data, prevent publishing the results, and place 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 RERB approval. This guidance will help you determine whether you need to get approval from RERB before conducting a given activity. Please note that RERB does not have the option of granting "retroactive" approval after research is done; you should submit or consult with RERB if there is any doubt.

Student research activities include, but are not limited to, projects that result in undergraduate honors theses, master's theses, or doctoral dissertations. *RERB approval is required if human subjects are involved, either directly or through use of identifiable data about them...AND...the intent is to develop new or expanded knowledge.* Student researchers have the same submission requirements 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. It may be appropriate for a student researcher to be included on an existing project that already has RERB 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 RERB 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, mail, email, web survey, or telephone), or data from human subjects for which the researcher will have access to identifiers.

Submit Protocol Review Form 1297, either with student as PI or listed as study personnel on the faculty application; or modify the existing study if the student project is directly related.

Student researcher, co-investigators (if a group) and faculty advisor are required to have current research ethics certification.

RESEARCH 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.

Submit Protocol Review Form 1297 for RERB status.

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 RERB to make this determination.

If RERB determines that this project is not human subjects research, research ethics certification of the student(s) is not required by RERB, 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.

Submit Protocol Review Form 1297 for each activity by an individual or small group.

Student researcher, co-investigators (if a group) and faculty advisor should have current research ethics certification.

CLASS PROJECTS

Class projects are generally conducted for educational purposes and not as research. While some require submission of an RERB application or a determination that RERB approval is not required, many class projects require neither. Instructors and departments are encouraged to contact the RERB chair or board member for guidance about ways to handle topics such as privacy, confidentially, informed consent, and professional ethics when class projects are part of the course syllabus. The RERB chair or board member 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 RERB 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 RERB 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 RERB action required (neither approval nor determination of human research status)

Class instructor and department are responsible for providing the necessary training respecting 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 RERB 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 respecting the privacy of the individuals and the confidentiality of any resulting information, along with training in relevant professional ethics.

Exception:

If a student decides *after* the completion of a practicum activity to pursue additional activities with the same information for a master's project or paper, then an RERB 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).

No RERB approval required When there are several students in a class doing similar projects, a single RERB 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 RERB 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 there more individualized activities under the umbrella of a single RERB 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 NIH Tutorial online course, or the instructor may provide comparable training, with the approval of RERB.