



Institutional Review Board Policy

Action research, inquiry projects, and other forms of applied assignments within Reach Programs are specifically intended to fall into the “exempt category” and to therefore not require Institutional Review Board approval.

Background Information:

The Code of Federal Regulations, *Title 45 CFR Part 46*, identifies several different categories of minimal risk research as being exempt from Federal Policy for the Protection of Human Research Subjects.

Prior scientific review by the Institutional Review Board committee¹ is not required for research that fall within the exempt category.

IRB reviewers do not actually approve an exempt study but instead make a determination that the project meets at least one of the federal exempt categories criteria.

Basic Exempt Criteria for Educational Strategies, Curricula or Classroom Management Methods, *45 CFR 46.101(b)(1)*

- ✓ Research takes place in established or commonly accepted educational setting
- ✓ Involves study of normal educational practices (e.g., regular and special education instructional strategies; studies effectiveness or comparison among instructional techniques, curricula, or classroom management methods)

Additional General Requirements or Considerations

- When children are studied in school or other institutional settings, approval from relevant school official (including the school system IRB or research review committee, if available) must be attached to this application at the time it is submitted to Reach. Typically, studies of teacher pedagogy do not include children as the subject of the study, even if student data is used to evaluate the pedagogical practices in question.
- If children are studied, investigators must provide a rationale for why a particular age range was selected, indicate their expertise in working with children.

Normal Educational Practices Considered Exempt from Full Committee Review May include data sources such as:

- Students' curriculum-related written work, test scores, grades, artwork and other work samples produced by children
- Students' curriculum-related oral and non-verbal communicative responses individually, such as in an interview, in small groups and with the whole class

¹The Reach Institutional Review Board consists of the members of the Academic Committee, and the operating rules for the two committees are the same.

- Students' responses (written, oral or behavioral) to curriculum-related activities
- Students' level of active participation in curriculum-related activities
- "A normal educational setting" means preschool, elementary, secondary, and higher educational facilities, and after-school programs (if the project relates to tutoring, or homework help.)
- In Special Education, normal educational practices correspond to the Individualized Educational Program (IEP), which is tailored to each student with an identified disability and may be implemented in diverse settings (e.g., school, home, work, community).

Data collection methods in exempt settings might include:

- Videotapes and photographs of curriculum-related classroom activities—audio tapes of teacher-student and student-student discourse related to the assignment
- Teacher's non-participant observation of curriculum-related activity of individual children or groups of children, noting what will be observed and how it will be analyzed, or whether it will be used as anecdotal evidence in the study
- Teacher's commentary on students' curriculum-related written work, artwork and other artifacts produced by children
- Student journals and communication books related to the curriculum
- Student grades and test scores
- Teacher journals, notes and reflective comments on student responses and participation in curriculum-related activities
- Questionnaires or interviews with students, parents and family members, teachers and administrators
- Non-participant classroom observations by colleagues, with the class teacher's permission, stating what will be observed and how it will be used, i.e. how data will be analyzed or whether it will be used as anecdotal evidence.

Policy:

- Two members of the Reach IRB committee must determine that a study, inquiry project, or other applied assignment is exempt. For inquiry projects included in the regular curriculum, IRB committee members may determine that the project or requirement are exempt generally (as opposed to approving each student's application of that project).
- For Action Research projects (as opposed to regularly assigned applied practicums) students must complete and submit, for review by two IRB committee members, the following:
 - The research proposal (including information about who will participate in the study, the educational sites where the research will be conducted and why, whether and how children will be studied, how participants will be selected for participation, methods used including instruments, and how data will be analyzed).
 - "Confirmation of Exempt Research" worksheet
 - A sample of the Informed Consent Letter participants will sign
 - A letter approving research from the site principal or equivalent
 - If identifiable student information will be included in the published material, a sample of the Informed Consent Letter that will be signed by the parent (if under 18 years of age) or the student providing permission. Schools may have on file a general letter for students meeting this requirement, and if so a generic copy of this letter may be included
- If any reviewing member of Reach IRB committee concludes that the research is not exempt, then the study will be recommended for a review by the IRB committee prior to approval.