

EXAMPLE SCHOOL DISTRICT POLICY for the PROTECTION OF HUMAN SUBJECTS INVOLVED in RESEARCH.

A) District Commitment

The XXX School District is committed to protection of all students who are asked to or who do become involved as subjects in research endeavors.

In practice, the District will conduct research under the rules generated from the Department of Education (34 CFR 97) and the four subparts of 45 CFR 46.

In order to fulfill these promises, any research activity must be coordinated through the district office.

B. Limits on research

1. The District will not become involved in any research without the Board of Trustees approval.
2. The District encourages some areas of study:
 - Student initiated research
Students involved in research involving humans will adhere to the rules found in the Science Fair guidelines.
 - Evaluation research is encouraged.
Quality assurance efforts intended to be used solely within the district is not research
 - Evaluation that is mandated in a grant is likely to be research.
3. Student data may be used in research if it is sent to a researcher without identifiers and cannot be identified using student demographics.

C. Protections included

1. *Dissemination:* This policy will be kept on file in the Student Support Services Director's Office and in the Superintendent's Office.
2. *Contracts:* Contracts involving human subjects (ED 424 question 13 on OMB 1890-0017) shall be signed only by the Superintendent.
3. *Budget:* Any budget shall include sufficient funds to fund the necessary protections. Budget items may include:
 - Staff time
 - IRB costs
 - Coverage for injuries

- Duplication
 - Teacher time
4. *Education about protection of human subjects* All persons involved in the research shall, at a minimum:
 - Read the Belmont Report
 - Read this policy
 - Complete the OHRP web module for investigators or the CITI Program modules on social and behavioral research.
 5. *Problems:* All problems associated with the research will be reported to the Superintendent within 3 days.
 - Unanticipated problems: Anything that is a surprise or that was not noted as a possibility in the protocol, must be reported within 24 hours.
 - Physical injury: Any injury resulting or possibly resulting from participation must be reported within 24 hours.
 - Problems and injuries must be reported to the IRB at the same time or as required by the IRB conditions of approval.
 4. *Consent, Parental:* All research consent must be active consent. The elements of consent in the regulations shall be included. All research consent forms will be reviewed by the IRB.
 5. *Consent, Student:* Participation in research must be voluntary. Consent must be sought from all students asked to be in the research. Non-stigmatizing and reasonable alternatives must be available to those who refuse.
 6. *IRB review:* No study may proceed without approval from an IRB. Such an IRB must be listed on the FWA or must be willing to sign a document signifying that the district is relying upon the IRB of another institution.

An institution has the right to refuse to allow an IRB-approved study to be conducted. No institutional person can authorize conduct of a disapproved study.

Conditions set by the IRB must be incorporated into the research protocol and or into district policy.
 7. *Records:* Prior to conducting any research, the researcher must have on file in the district office:
 - the IRB-approved protocol – a description of the study
 - any IRB-approved recruitment and consent documents
 - the IRB approval letter
 - A quick reference phone list of those who are knowledgeable about the study including the grant manager at the federal level.
 9. *Compliance*

The investigator shall designate one district person who will have the right to monitor and audit investigator records.

D COMMITMENT TO THE PUBLIC

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1. Results will be available within one month of their publication. Should they not be published, results will be available within 6 months of study completion.
2. No student will be denied participation due to financial reasons. No student will be forced to participate.

Acting officially, in an authorized capacity on behalf of this school district, I assure protections for human subjects as specified above.

Signature: _____

Title: _____

Date: _____