RESEARCH WITHIN THE DISTRICT

Criteria and Guidelines for Approval of Research Studies

1. Criteria for approval of research studies within the district include the following: The research study should:

    a. Have the potential of immediate or ultimate value to the district. Research which offers no apparent benefit to the district at some level cannot be supported.

    b. Not disrupt or significantly interfere with student instructional duties and teaching or other staff duties.

    c. Be devoid of any procedure or element that might cause confusion, or interfere with student learning.

    d. Avoid duplication of existing data or literature and address relevant educational problems or issues.

2. In addition, the following guidelines must be met:

    a. Proposed research should be acceptable to the local community. Research which may be perceived as infringing on privacy, wasteful of money or resources, destructive or inhumane, or detrimental to community values would be unacceptable.

    b. The researcher must agree in writing to follow district procedures in conducting research.

    c. The district reserves the right to withhold permission to conduct research within the district. Further, the district may at any time terminate, disallow, or disapprove of any research or research procedure involving district personnel, students, or other district resources.

    d. No individual assessment/testing may be conducted with students without first obtaining informed student/parental consent in writing. This means the parent must be told what test(s) will be administered, what information will be obtained, why the test(s) will be administered, and what will be done with the results.

        In the case of federally funded projects requiring Federal Wide Assurance, all eight elements of the Informed Consent procedure must be met prior to review and approval.**

RESEARCH WITHIN THE DISTRICT (continued)

e. Before allowing group scholastic aptitude tests to be administered for research purposes, the Associate Superintendent shall obtain the approval of the Superintendent of Public Instruction, including his/her approval of a group testing plan which includes a current schedule of testing, a statement of purposes of the uses of the tests, and provisions that the tests are administered and results interpreted under the direct supervision of a qualified school psychologist, psychometrist, or school counselor.

f. The Associate Superintendent and Institutional Review Board may approve the proposed project for a period of one school year or less. To extend any project into a second year, the researcher (s) must again obtain approval.

Procedure for Conducting Research Study(ies) Within the Poway Unified School District

Before initiating any research activity within the district, the following procedure is to be followed.

1. Read the district's policy statement regarding research in the district.

2. Submit a research proposal for approval to the Associate Superintendent and to the local site administrator(s) where the research is to take place. This proposal must contain the following information (not necessarily in the order listed):

   a. Researcher's name, address, and telephone number.

   b. Site(s) where research is to be conducted.

   c. Purpose(s) of the research (Why is it being proposed?).

   d. Name of professor or person (and location) to whom the individual is responsible for conducting the research.

   e. Area in which research is being done; e.g., counseling, assessment/testing, reading, special education, etc.

   f. Aims or projected outcomes of the research.

   g. Value or benefits of the research to the district.

   h. Brief description of procedure(s) to be used in conducting the research.

RESEARCH WITHIN THE DISTRICT (continued)

(Describe the research design, method of study/investigation, how data will be collected, and how results will be evaluated and interpreted.)

i. Number and types of students or others to be involved, including control groups.

j. Number and types of classes to be involved.

k. Specific tests and types of data to be gathered.

l. Estimate of amount of instructional time of teacher and students required by the project.

m. A statement regarding any potential risks involved with the proposed research.

n. A statement regarding compensation of any type involved with the proposed research.

o. A statement regarding why the proposed research is relevant.

p. A statement regarding how the research project will be evaluated.

q. A statement of how the results will be reported to the local staff(s) involved and to district administrators.

r. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

s. If applicable, a description of staff training to be provided to all involved district/site personnel.

t. Process and elements of informed consent integral to the study.

This proposal must include sample letters to be sent to parents of students involved to inform them of the research project and to obtain permission for testing and for their child to participate. It must also include a time frame indicating proposed date of staff consultation and training, parent orientation, testing activities, summation, publication, and submission of the report to the district. The Associate Superintendent shall be responsible for informing parents and transmitting the foregoing information.

3. The research proposal must be submitted to the site and district level at least 75 working days prior to the requested commencement of the research project.

RESEARCH WITHIN THE DISTRICT (continued)

Upon submission of the proposal to the Associate Superintendent, Learning Support Services, an appointment must be made to review the research study. The researcher should be prepared to describe how the proposal will be presented to site level personnel, how approval and agreement to participate will be effected, and how staff input will be handled. The Institutional Review Board (IRB) will attend this meeting.

4. The Research Proposal Certification and District Protection Statement form (page 6) for conducting research within the district must be read and signed.

5. Written approval from the Associate Superintendent, Learning Support Services, the Institutional Review Board, and the site principal(s) must be granted prior to proceeding with the proposed research.

6. The Associate Superintendent and the site level administrator(s) must be kept informed of any changes, unusual developments, or difficulties which may develop during the course of the research.

7. At the conclusion of the research project, the Associate Superintendent, Learning Support Services, the Institutional Review Board, and appropriate site level personnel should be provided with copies of the results of the research.

Ethical Principles Governing Human Subjects Research**

The district is guided by the ethical principles regarding all research involving humans as subjects as set forth by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

1. Recognition of principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice - equitable distribution of research burdens and benefits.

2. The district acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects.

3. The district recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence including children, mentally disabled persons, or economically or educationally disadvantaged persons.

4. The district will exercise appropriate administrative overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

RESEARCH WITHIN THE DISTRICT (continued)

Staff Training in Responsible Conduct of Research**

Research proposal initiators using federal funding sources must agree to participate in training in the responsible conduct of research. Key areas of training include the following elements:

1. Basic requirement for participating in federally funded projects.

2. Research should contribute to improved behavior and moral reasoning.

3. Curricular Endpoints:

    a. Increase knowledge of ethical theory

    b. Develop core competencies in responsible conduct of research

    c. Increase appreciation for guidelines, standards, and etiquette

    d. Increase awareness of guidelines, rules, and regulations

    e. Increase understanding of making and responding to allegations of misconduct

    f. Training topics must include:

        (1) Guidelines and Regulations

        (2) Ethics and Morality

        (3) Research Misconduct

        (4) Data Management

        (5) Publication

Training should include utilization of online resources (Department of Health & Human Services, National Institutes of Health (NIH) - Office for Protection From Research Risks - Office of Human Research Protections (OHRP) Website - http://ohrp.osophs.dhhs.gov/)

Responsible District Administrator (Institutional Officer)**

The district appoints an official institutional officer to assume project leadership and to act on behalf of the district including assumption of the obligations and commitments in any

RESEARCH WITHIN THE DISTRICT (continued)

Institutional Assurance Documents required for the implementation and funding of various projects. The district-designated officer is trained and qualified in the areas of human subject research and sets the "tone" of respect for human subjects, ensuring effective districtwide communication and guidance of research, ensuring that investigators fulfill their responsibilities, and facilitating participation in research activities.

For all federally funded research studies, the institutional officer appoints the Institutional Review Board members and chair, provides necessary training and resources, and supports IRB authority and decisions.

Institutional Review Board**

An Institutional Review Board is established for the purpose of evaluating and approving proposals for all federally funded research studies to be conducted in the district. The Board's primary responsibility is to protect the rights and welfare of human research subjects recruited to participate in research activities which have been approved by the IRB for implementation. The IRB reviews proposals and has the authority to require modification in, or disapprove all research activities including proposed changes in previously approved human subject research.

Research studies, which have been approved by the IRB, may be subject to further review and approval or disapproval by district level officials.

The IRB conducts continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year.

Composition of Institutional Review Board (IRB)

The IRB will consist of five members selected on the basis of qualifications including experience and expertise, diversity of backgrounds, including considerations of their racial and cultural heritage and the sensitivity to issues such as community attitudes. The IRB promotes respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in the nonscientific areas.

The IRB shall include one member who is not affiliated with the district and who is not part of the immediate family of a person who is affiliated with the district.

The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which requires expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

RESEARCH WITHIN THE DISTRICT (continued)

Informed Consent**

Subjects may not participate in research activities unless the investigator has obtained the effective written informed consent of the subject or the subject's legally authorized representative. Informed consent is the voluntary choice of an individual to participate in research based on an accurate understanding of its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate. Informed consent elements include the following:

1. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. a description of any reasonably foreseeable risks or discomforts to the subject;

3. a description of any benefits to the subject or to others which may reasonably be expected from the research;

4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. for research involving more than minimal risk, an explanation as to whether any compensation is offered and an explanation as to whether any medical treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained;

7. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

**REQUIREMENT of Federal Wide Assurance (Federally Funded Projects)