

**SEATTLE CHILDREN'S RESEARCH INSTITUTE
OPERATING POLICIES / PROCEDURES**

DEPARTMENT: Institutional Review Board
POLICY NUMBER: IRB-027
REPLACES: _____
EFFECTIVE DATE: June 20, 2005
REVISION DATE: July 13, 2011

TITLE: Procedures for Determining Exemptions

SUMMARY:

Certain categories of research may be exempt from the basic federal policy for protection of human research participants. To determine if a research activity is exempt in accordance with the federal policy, the researcher shall complete the appropriate application and submit to the IRB office.

POLICY/PROCEDURE:

- 027-1 Research in which the only involvement of human participants is in one or more of the following categories may be exempt [45 CFR 46.101 (b)]:
- A Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of the comparison among instructional techniques, curricula, or classroom management methods [45 CFR 46.101(b)(1)];
 - B Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior when the investigator(s) do not participate in the activities being observed unless (i) information is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation [45 CFR 46.401(b)(2)];
 - C Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under IRB 27.1(b) if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research

- and thereafter [45 CFR 46.101(b)(3)];
- D Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects [45 CFR 46.101(b)(4)];
 - E Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study or evaluate or otherwise examine (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs [45 CFR 46.101(b)(5)];
 - F Taste and food quality evaluations and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Services of the U.S. Department of Agriculture [45 CFR 46.101(b)(6)].
- 027-2 The exemption described in 45 CFR 46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research involving children; except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed [45 CFR 46.401(b)].
- 027-3 The exemption described in 45 CFR 46.101(b)(4) for research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, can only be applied if all data, documents, records, specimens are existing and on the shelf at the time of IRB review of the exemption. This exemption may not be applied to activities involving prospective collection of such materials.
- 027-4 The exemption described in 45 CFR 46.101(b)(5) for research involving public benefit projects applies only if the following criteria are satisfied:
- A The program under study must deliver a public benefit, such as a medical or financial benefit provided under the Social Security Act, or provide a public service, such as nutritional or social services provided under the Older Americans Act;
 - B The research or demonstration project must be conducted pursuant to federal statutory authority;
 - C There is no statutory requirement that the project be reviewed by an IRB;
 - D The project may not involve significant physical invasions or invasions into the privacy of participants.

027-5 The IRB, not the researcher, retains final judgment for determining if a research activity qualifies for exempt review status. To determine if a research activity qualifies for exempt review status, the principal investigator shall complete Seattle Children's application for "Exempt" Review Status and submit to the IRB office.

027-6 If the IRB concurs that a research activity qualifies for exempt review status, the IRB will designate concurrence by signing the Exempt Review Application.

Submitting Office: Institutional Review Board

Approved by:

\s\ Douglas Diekema, MD, MPH July 13, 2011
Chair, Institutional Review Board

\s\ Laurie Bolton, JD, July 13, 2011
Director, Office of Institutional Assurances