

Children's

Hospital & Regional Medical Center
Office of the Vice President for Research

OPERATING PROCEDURES/POLICIES

Committee:	<u>Institutional Review Board</u>
Policy Number:	<u>IRB 27</u>
Effective Date:	<u>June 20, 2005</u>

POLICY TITLE:

Procedures for Determining Exemptions

POLICY:

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 application for Exempt review status and submit to the IRB office. An IRB Coordinator shall review the request and make an initial assessment if the research qualifies for exempt review status based on the materials. Any study deemed by the IRB Coordinator to qualify for an exemption shall be referred to the IRB Chair or IRB Manager who shall make the final determination.

PROCEDURE:

- 27.1 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)].
- 27.2 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)].
- 27.3 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.

- 27.4 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.
- 27.5 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 Children's application for "Exempt" Review Status and submit one signed copy to the IRB office. (Appendix 12.C.) In establishing if a research activity qualifies for exempt review status, the IRB Manager and IRB Chair may refer to OHRP decision charts on exemptions. (See Appendix 7).
- 27.6 If the IRB Manager or Chair is uncertain about designating a research activity as exempt or determines the activity does not qualify for exempt review status, the PI will be notified in writing and requested to submit an application to the IRB for full or expedited review.
- 27.7 If the IRB Manager or Chair concurs that a research activity qualifies for exempt review status, the Manager or Chair will designate concurrence by signing the Exempt Review Application. The PI will receive one copy of the Exempt Review Status application signed by the IRB Manager or Chair and a letter documenting that the IRB concurs that the research activity qualifies for exempt review status. (Appendix 17.L) The letter to the PI shall document the specific category for exemption under the federal regulations that applies to the research activity. An exempt review status is valid for 5 years.
- 27.8 If the Exempt Review Status involves use of existing medical records or existing tissue or specimens, the IRB office shall send a copy of the IRB letter concurring that the research activity meets the criteria for exempt

review status to appropriate Departments, e.g., Health Information Services (formerly Medical Records), or the Laboratory Department.

27.9 Exempt Review Status Applications are assigned an Exempt Review Application Number. The application number assigned begins with X, followed by the year the exempt review status was granted, followed the sequential number of exempt review applications granted in that year. For example, the fifth exempt review status application in year 2005 would receive the application number X-05-005.

27.10 Exempt Review Status Applications are filed by year in an Exempt Review Notebook. The applications are filed alphabetically under the Principal Investigator's last name. Exempt review status applications are entered into the IRB database as an exempt status application granted a five year approval.

Submitting Committee: Institutional Review Board

Approved by: Douglas S. DeBruin 6/20/05
Chair Date

Elizabeth Trias 6/20/05
Manager Date