

**Children's Hospital and Health System, Inc.
Administrative Policy and Procedure
Children's Research Institute**

SUBJECT: Institutional Review Board (IRB) Exempt Research

POLICY

I. Purpose:

To define appropriate circumstances in which a research project may be deemed "exempt" from IRB review.

II. Policy:

- A. Federal regulations govern which research projects require oversight by an IRB. Research activities may be exempt if they meet all applicable criteria of one of six categories set forth by federal regulations outlined under section B below. [45 CFR 46.101(b)] This means that once the determination has been made that the study is exempt, the IRB will not conduct subsequent reviews of the study. If there are any modifications in the project, these need to be submitted to the IRB for review.
- B. Research activities in which the only involvement of human subjects will be in one or more of the following six categories are generally exempt from IRB review.
 - 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - a. research on regular and special education instructional strategies, or
 - b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - b. 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.

NOTE: This exemption DOES NOT apply to research involving children, except for research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.

3. 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. For the purpose of this exemption, all of the data needs to be in existence prior to the start of the research. Linkage includes the use of numbered coding and other techniques that allow the investigator to determine the identify of the subject.
 4. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - a. public benefit or service programs;
 - b. procedures for obtaining benefits or services under those programs;
 - c. possible changes in or alternatives to those programs or procedures; or
 - d. possible changes in methods or levels of payment for benefits or services under those programs.
 5. Taste and food quality evaluation and consumer acceptance studies:
 - a. if wholesome foods without additives are consumed; or,
 - b. 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 (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- C. Studies that are found not to be exempt from IRB review are eligible for submission to the IRB for review by the full panel or expedited review, if appropriate. [See "Expedited Review" policy]
- D. The IRB Chair or designee will be responsible for the final determination of whether a research project meets the criteria for exemption.
- E. The following may not be exempt from IRB review:

1. Research that may place participants at risk of physical injury due to intervention(s) performed by the investigator.
 2. Research involving the use of an investigational drug, biologic or medical device that has not received FDA approval or its proposed use is not within the scope of the FDA's approval (i.e., off-label usage).
 3. Research involving prisoners under Subpart C of the regulations.
 4. Certain research described in section B., above, which involve fetuses, pregnant women, neonates of uncertain viability, or nonviable neonates under Subpart B of the regulations.
- F. IRB members shall be advised of research studies that have been determined to be exempt at the next IRB meeting, and such determination shall be noted in the IRB meeting minutes along with the regulatory authority justifying the exemption.
- G. Meeting exempt criteria does not automatically also waive the requirement for subject authorization under the Health Insurance Portability and Accountability Act (HIPAA). [See "Privacy – Uses and Disclosures of Protected Health Information for Research Purposes"]
- H. This policy also does not apply to other Children's Hospital of Wisconsin (CHW) administrative reviews (e.g., Human Resources review for studies involving CHW employees).

PROCEDURE

- A. If the investigator feels that his/her research project qualifies for exempt status, a completed Request for Exempt Status form and Exempt Review Check List along with the applicable supporting materials shall be submitted to the IRB Coordinator via IRBNet.
- B. The IRB Coordinator shall forward the submission to the IRB Chair or designee. This person will make a ruling and the investigator shall be notified in a letter on IRBNet of approval or disapproval of exempt status. As noted above, studies determined not to be exempt can be subsequently submitted for full board or expedited review, as appropriate. The procedures outlined in the applicable policy should be followed when resubmitting the study for further consideration.
- C. Meeting minutes of the next IRB meeting shall include all research determined to be exempt and the regulatory authority justifying the exemption.

References:

- A. 45 CFR 46.101(b)
- B. 45 CFR 46.401(b)

Documentation (Documents & Forms):

- A. IRB Request for Exempt Status
- B. IRB Exempt Review Check List

(signed copy on file)

Peggy Troy, President CHHS