

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

**SUBJECT: Human Research Review Board (HRRB) Jurisdiction
and Authority**

POLICY

I. Purpose:

- A. The Human Research Review Board (HRRB) has been formally designated to review and approve all research studies conducted at Children’s Hospital of Wisconsin (CHW) and/or institutions that have a Federal Wide Assurance (FWA) in effect designating the CHW HRRB as the Institutional Review Board (IRB) for review of studies conducted at that institution (hereinafter, “FWA-Affiliated Institution”). The authority of the CHW HRRB is derived from both federal laws, Medical/Dental Staff By-laws and institutional policy. This policy grants the CHW HRRB jurisdiction and authority to the fullest extent needed in order to conduct its reviews and other activities in such a manner as to provide adequate protection to human research subjects.
- B. The CHW HRRB has also been formally designated to review and approve all research studies requiring access to nonpublic information from patient health care records maintained by CHW and/or FWA-Affiliated Institutions in accordance with the federal Health Insurance Portability and Accountability Act (HIPAA).

II. Policy:

- A. The jurisdiction of the CHW HRRB extends to all “research” as defined in regulations promulgated by the Office of Human Research Protection (OHRP) and the Food and Drug Administration (FDA).
 - 1. “Research” is defined in OHRP regulations as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” “Human subjects” are defined as “living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”
 - 2. “Research” is defined in FDA regulations as “any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act,

or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.”

- B. All research under the jurisdiction of the CHW HRRB shall be reviewed by the HRRB prior to enrolling subjects **unless** the HRRB has (1) specifically exempted the research study from review or (2) has deferred full HRRB review based on prior review and approval by a non-local Institutional Review Board (IRB). [See related policies “Exemption from HRRB Review” and “Non-local IRB Review”]
- C. The jurisdiction of the CHW HRRB also extends to “research” as defined by HIPAA. Meeting exempt criteria under OHRP regulations does not automatically waive the requirement for subject authorization and HRRB review, as the designated Privacy Board, under HIPAA.
- D. The HRRB shall have the authority to:
 - 1. Approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.
 - 2. Suspend or terminate research that is not being conducted in accordance with applicable laws and HRRB or institutional policies, or that has been associated with unexpected serious harm to subjects.
 - 3. Approve requests for a waiver or alteration of subject authorization for use or disclosure of protected health information in accordance with the Children’s Hospital and Health System Policy entitled “Privacy – Uses and Disclosures of Protected Health Information for Research Purposes.”
 - 4. Provide ongoing oversight of approved research studies, which may include, but is not limited to: conducting audits, investigating complaints, reviewing reported protocol deviations and/or reports of scientific misconduct, and requiring third-party verification. [See, related policy, “Scientific Misconduct”]
 - 5. Ensure prompt reporting to the FDA and other authorities, as appropriate, of: (1) any unanticipated problems involving risks to subjects or others or any instance of serious or continuing noncompliance by an investigator; or (2) any suspension or termination of IRB approval.
 - 6. Request any documentation and information it deems necessary beyond the protocol and sample informed consent form, such as budgets and financial disclosure forms. The IRB shall notify all investigators via bulletin or other method of the minimum documentation that must be submitted with the completed application for HRRB review.

- E. The HRRB Chair or other member(s) designated by the HRRB Chair to conduct expedited review or make determinations of exemption shall have all the authority of the HRRB in D.1., except that reviewers (1) may not disapprove a study under expedited review procedures and (2) may not approve or disapprove an exempt research study.
- F. Research that has been approved by the HRRB shall still be subject to other reviews and approvals required by CHW (e.g., administrative, legal, facility and/or finance reviews). CHW may not, however, approve research that has been disapproved by the HRRB.

PROCEDURE

- A. This section has been intentionally left blank. Please refer to related policies for applicable procedures.

References:

- A. 45 CFR 46.111
- B. 45 CFR 46.113
- C. 21 CFR 50.1
- D. 21 CFR 56.102
- E. 21 CFR 56.108

Approved by the Medical Executive Committee 08/07/2006

Approved and Signed :
Jon E. Vice, President CHHS, Inc.