

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

SUBJECT: Human Research Review Board (HRRB) Reporting

POLICY

I. Purpose:

- A. To outline the steps to be taken by the Children’s Hospital of Wisconsin (CHW) Human Research Review Board (HRRB) to determine if an event is reportable to federal agencies and others and, if reportable, the requirements of filing such a report.
- B. This policy only applies to the reporting of disclosed events. See “HRRB Adverse Events” and “HRRB Protocol Deviations / Unanticipated Problems in Human Subjects Research” policies for investigators’ responsibilities to report events to the Children’s Hospital of Wisconsin (CHW) Human Research Review Board (HRRB).
- C. This policy also does not apply to reports of suspected scientific misconduct (e.g., plagiarism, falsification, fabrication). (See “HRRB Scientific Misconduct” policy)

II. Policy:

- A. Federal regulations require that the following are promptly reported:
 - Unanticipated problems that involve risks to subjects or others;
 - Serious or continuing noncompliance with regulations or the requirements of the Institutional Review Board (IRB); and
 - Suspension or termination of IRB approval.
- B. The HRRB Chair will promptly notify CHW’s designated Institutional Official of any unanticipated problems involving risks to subjects or others, serious or continued noncompliance, or suspensions or terminations of HRRB approval.
- C. The Institutional Official, in consultation with the Human Protections Administrator, the Corporate Vice President General Counsel and HRRB Chair will determine if an event is reportable and submit any report on behalf of CHW.

1. For a more serious event, the goal is to submit the initial report within 5 working days.
 2. For a less serious event, the goal is to submit the initial report within two weeks.
 3. It may be appropriate to send an initial report, and indicate that a follow-up or final report will be followed by the earlier of:
 - a. A specific date; or
 - b. When an investigation has been completed or a corrective action plan has been implemented.
- D. The following information will be included with each reportable event:
1. Name of the institution;
 2. Title of the study and/or grant proposal in which the problem occurred;
 3. Name of the principal investigator;
 4. Number of the study assigned by the HRRB and the number of any applicable federal award(s) (e.g., grant, contract or cooperative agreement);
 5. A detailed description of the problem; and
 6. Actions CHW is taking or plans to take to address the problem.
- E. A copy of the report will be shared with government agencies and sponsors to the extent legally and contractually required, and with any others as deemed appropriate by the Institutional Official, in conjunction with the Human Protections Administrator and Corporate Vice President General Counsel. Possible recipients include:
1. Office of Human Research Protections (OHRP) if the study is federally funded and subject to regulation by OHRP;
 2. Food and Drug Administration (FDA) when the research is subject to regulation by the FDA;
 3. Funding agency when funded by a government entity (e.g., the Departments of Defense, Education, and Justice);
 4. Licensing and accrediting bodies, where the report or some portion thereof implicates standards or regulations administered by those bodies;
 5. HRRB Chair and members;
 6. Principal investigator;
 7. Principal investigator's Department Chair or supervisor;
 8. Any other external sponsor, when the research is sponsored;

9. Other CHW departments who require notification (e.g., pharmacy, GCRC, etc.)
- F. The copy of the report(s) will be placed in the applicable study file, as well as any other files that are maintained during the investigation to determine whether an event is reportable.

PROCEDURE

- A. Investigator(s) and support personnel will cooperate with any investigation(s) and provide any requested supporting documentation.
- B. If the CHW Institutional Official has determined that the event is reportable and the investigation cannot be reasonably completed within the timeframe specified above under section II.C., an initial report shall be submitted with a follow-up or final report to follow once all investigations have been completed.
- C. The HRRB Coordinator will place a copy of the report(s) and any supporting documentation in the applicable study file and retain in accordance with applicable policy.

Approved by the Medical Executive Committee 10/02/2006

Jon E. Vice, President CHHS, Inc.

References:

- A. 45 CFR 46.103(b)(5)
- B. 21 CFR 56.108(b)