

# Children's

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

## OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board  
Policy Number: IRB-26  
Effective Date: June 20, 2005

### POLICY TITLE:

### ADVERSE EVENT REPORTING

### POLICY:

The IRB shall review reports of unanticipated problems (adverse events) involving risks to research participants as dictated by federal regulations, sponsor requirements, and institutional policy. Researchers shall submit reports of adverse events in a timely manner to the IRB. The IRB shall evaluate the adverse event reports to ensure the ongoing safety and protection of participants enrolled in studies affected by the reports.

### DEFINITIONS:

**Adverse events (experiences)** are unfavorable effects, signs (including abnormal laboratory values), symptoms, or disease temporally associated with the use of a medical treatment, drug, device, or procedure. In a research context a medical treatment, drug, device or procedure may be referred to as the **study agent**.

**Unexpected adverse events** are any adverse experiences, the nature, severity or frequency which are not consistent with the current investigator's brochure (for investigational new drug studies - IND) or manufacturer's brochure (for investigational new medical device studies - IDE), or with the risk information provided in the research protocol and consent form.

**Expected adverse events** are any adverse experiences, the nature, severity or frequency which have been identified and reported in the current investigator's or manufacturer's brochure, if available, and in the risk information in the research protocol and consent form.

**Relatedness** refers to the adverse event's relationship to the research study treatment,

drug, device, or procedure. **Not related** is any adverse event clearly not related to the study agent or procedure. **Unlikely related** is any adverse event doubtfully related to the study agent or procedure. **Probably related** is any adverse event likely related to the study agent or procedure. **Definitely related** is an adverse event clearly related to the study agent or procedure.

**Serious adverse event** refers to any adverse event resulting in death, life-threatening risk, inpatient hospitalization or prolongation of inpatient hospitalization, persistent or significant disability or incapacity, or a congenital anomaly or birth defect. An adverse event may be considered serious if based upon medical judgement may require a medical or surgical intervention to prevent one of the previously listed outcomes (e.g., death, hospitalization). [21 CFR 312.32]

**Other adverse event** refers to events which do not meet the classification of serious. These other events may range from **severe** which require therapeutic intervention and interrupt daily activities; **moderate** which may require simple therapeutic intervention and may impact daily activities; and **mild** which are transient and do not require therapeutic intervention or interfere with daily activities.

#### **PROCEDURE:**

- 26.1 Any unexpected adverse event to research participants enrolled in research that is active at Children's shall be reported to the IRB in accordance with FDA regulations, sponsor guidelines, and Children's adverse event reporting guidelines. (Appendix 14.A.)
- 26.2 Any adverse event that is unexpected and occurs in a participant enrolled under Children's IRB approval shall be reported in accordance to the adverse event reporting guidelines referred to in 26.1 above and on Children's Adverse Event Report Form. (Appendix 14.B.)
- 26.3 Any adverse event report that is expected and occurs in a participant enrolled under Children's IRB approval shall be reported on Children's IRB Status Report at the time of continuing review. Expected adverse events that occur at other sites for multicenter studies shall be reported on Children's IRB Status Report if the information is made available to the principal investigator by the study sponsor. (Appendix 12.D.)
- 26.4 The IRB Chair shall review all adverse event reports to determine the appropriate action to take. Appropriate actions are based on the information provided and the data and safety monitoring plan in place. For multicenter studies with independent data and safety monitoring boards (DSMB) the IRB shall utilize the recommendations of the DSMB in determining appropriate actions to take. Possible appropriate actions of the IRB Chair include:
  - A. The adverse event report is reviewed and noted by the IRB Chair. No further action required. The adverse event report is filed in the IRB application file

and is annotated with the date the report was reviewed and noted by the IRB Chair.

- B. The adverse event report is reviewed by the IRB Chair and additional information is requested from the principal investigator or study sponsor. The request for additional information is addressed to the principal investigator. Upon receipt of the additional information the adverse event report may be noted and filed with no further action required or the information may be referred to designated IRB members or the full IRB for review.
- C. The adverse event report is forwarded to other IRB members designated by the IRB Chair with expertise to assist in the evaluation of the report. Designated IRB members shall generally be a physician or pharmacist. If the adverse event report does not significantly alter the risks or benefits of the research, the adverse event report may be handled under Expedited review procedures by a Subcommittee consisting of the IRB Chair and designated members. If the adverse event report provides significant new safety information that could affect the willingness of participants to continue or new participants to enroll, the new safety information will be referred to the full IRB for review and action. This would be reviewed as a full Board modification.
- D. In reviewing adverse event reports, the Subcommittee or the full IRB shall determine the significance of the new information, if the new information warrants a change in the approved consent form, and whether and how to notify currently or previously enrolled participants of this new information. The IRB's decision (Subcommittee or Full IRB) will be documented in the IRB's correspondence with the principal investigator. For adverse event reports handled under expedited review procedures, the Subcommittee's actions are reported to the full IRB in the Adverse Event Report (when the event involves participants enrolled under Children's IRB approval) and/or in the Modification Report when the adverse event requires modification of the protocol and/or the consent form.

26.5 Adverse event reports that occur in participants enrolled under Children's IRB approval are reported to the full IRB in the Adverse Event Report. (Appendix 17.C.) Documents regarding the adverse event report shall be made available to IRB members upon request. Members of the IRB may request that the adverse event reports reviewed by the IRB Chair or a Subcommittee be reviewed by the full IRB.

Submitting Committee: Institutional Review Board

Approved by:

<i>Douglas S. Duhren</i>	<i>6/20/05</i>
Chair	Date
<i>Elizabeth Tracy</i>	<i>6/20/05</i>
Manager	Date