

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-37</u>
Effective Date:	<u>June 20, 2005</u>

POLICY TITLE:

SUSPENSION OR TERMINATION OF IRB APPROVAL OF RESEARCH

POLICY:

The IRB shall have the authority to suspend or terminate approval of research that is associated with unexpected serious harm to subjects or that is not being conducted in accordance with the IRB's requirements. Any suspension or termination of approval shall document in writing the reason's for the IRB's action and shall be reported promptly to the principal investigator, the principal investigator's Department and Division Directors, the Vice President of Research, other appropriate institutional officials, and the Office for Human Research Protections (OHRP) and the U. S. Food and Drug Administration (FDA), when the research involves FDA regulated products.

PROCEDURE:

- 37.1 If the IRB Chair, receives information regarding unexpected serious harm to subjects or of serious or continuing non-compliance that adversely effects the safety and well-being of the participants enrolled, the IRB Chair shall immediately suspend enrollment of additional participants. This suspension shall be reported immediately to the Principal Investigator, the principal investigator's Department Director and Division Director, the Vice President for Research, and the Medical Director. The IRB Chair shall determine in consultation with said institutional officials and directors what immediate actions are required to protect the safety and well-being of currently enrolled participants. The safety and well-being of the enrolled participants shall be the primary concern in determining what immediate actions are to be taken.
- 37.2 Any suspension of research by the IRB shall be reported by Children's

institutional official, the Vice President for Research, to the Office for the Protection of Human Research Participants (OHRP), the U.S. Food and Drug Administration (FDA), if the study is regulated by the FDA, and any sponsors of the research. The report shall be made within one month of the suspension and is to preliminarily advise these officials of the suspension, the findings to date regarding the serious or continuing non-compliance or unexpected serious harm, and the actions taken to date by the principal investigator, the IRB, and the institution. After the investigation and resolution of non-compliance a follow-up report shall be submitted to OHRP, FDA, when it is an FDA regulated research study, and study sponsors. The follow-up report shall notify these officials on the findings, the corrective actions taken, and the resolution of the serious or continuing non-compliance or unexpected serious harm that led to the study suspension.

- 37.3 When the IRB suspends a research activity, other departments or committees within the institution affected by the suspension of the research shall be advised immediately of the IRB's action. These may include but are not limited to: Pharmacy, the Scientific Advisory Committee and the Clinical Research Center, the Medical Device Committee, the Human Tissue Committee, and the Office of Risk Management.
- 37.4 The convened IRB shall review a detailed report of the non-compliance or unexpected serious harm reported to the IRB that led to the suspension of the research. The IRB shall review what actions have been taken to immediately address the serious non-compliance or unexpected serious harm and the proposed corrective actions. It shall be the convened IRB's responsibility to determine if the actions taken to date and the corrective actions proposed are adequate to protect research participants and to determine if the suspension will be lifted and under what conditions.
- 37.5 The convened IRB may terminate the research activity based on its review of the detailed report and corrective actions proposed. If the IRB terminates the research, the convened IRB shall determine the steps required to terminate the research activity in a manner that is safe and protects the rights and well-being of the participants.
- 37.6 The IRB's determinations to lift the suspension or to terminate the research shall be documented in the minutes for the meeting and in writing to the Vice President for Research. The reasons for the IRB's action to lift the suspension or to terminate the research shall be documented. In consultation with the Vice President for Research, a letter will be prepared for the principal investigator documenting the IRB and institutional decision and the reasons for its actions. The letter to the principal investigator shall be copied to the Vice President for Research, the Department and Division Director of the principal investigator, and to the Medical Director.
- 37.7 Any termination of a research study shall be reported to the Office for Human

Research Protections (OHRP), the U.S. Food and Drug Administration (FDA), if the study is regulated by the FDA, and any sponsors of the research.

37.8 All terminations of research must be reported to affected departments, e.g., Pharmacy, Medical Device Committee, Scientific Advisory Committee, Office of Risk Management.

Submitting Committee: Institutional Review Board

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

Elizabeth Tries 6/20/05
Manager Date