

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-30</u>
Effective Date:	<u>June 20, 2005</u>

POLICY TITLE:

INVESTIGATIONS OF NON-COMPLIANCE

POLICY:

The IRB shall promptly investigate all reports or allegations of researchers' noncompliance to ensure that the safety, rights and welfare of human research participants are protected in accordance with federal regulations, institutional policy and IRB requirements for approval.

DEFINITIONS:

Non-compliance is defined as failure to comply with the federal regulations, institutional policies, and IRB's conditions for approval as they apply to the specific research activity. Non-compliance may be of a minor nature or of a serious nature. Non-compliance may be of a continuing nature or a one-time occurrence.

PROCEDURE:

- 30.1 Any report or allegation of non-compliance made to the IRB shall be referred promptly to the Manager of the IRB. If the initial report or allegation appears minor, an IRB Coordinator acting on behalf of the Manager, may obtain additional information. Initial reports or allegations that appear to be of a serious or of a continuing nature, the IRB Manager shall consult, with the IRB Chair, and if appropriate with the Vice President of Research (institutional official for the IRB), and other appropriate officials as to the manner in which to initiate investigation of the allegation or report.
- 30.2 If the non-compliance is of a minor and non-recurring nature the principal investigator will be required to complete a report for the IRB detailing the non-compliance and the corrective actions put in place after the incident of non-

compliance to prevent future recurrences. Examples of minor non-compliance include failure of the person obtaining consent to have the consent form dated by the participant or their legally authorized representative; failure to send a copy of the signed consent form to Medical Records for filing when the research provides treatment or diagnosis; failure to submit documentation required by the IRB, as long as the documentation has been procured, e.g., letter of cooperation from a participating site, a copy of the federal Certificate of Confidentiality (which are issued only after IRB approval).

- 30.3 All reports of minor and non-recurring non-compliance shall be reviewed by the IRB Chair. If the IRB Chair determines the event is minor and non-recurring and the corrective actions taken are adequate, no further action is required. The report of non-compliance will be filed in the IRB office file for the study.
- 30.4 If the non-compliance appears to be of a serious or continuing nature (pattern of recurrence of the same non-compliance) the IRB Manager will inform the IRB Chair and the institutional official, the Vice President for Research, of the allegation or report of serious or continuing non-compliance. The IRB Manager shall begin immediate inquiries to investigate the report or allegation. The purpose of this initial investigation is to understand what non-compliance has occurred and the principal investigator's knowledge of the non-compliance. The IRB Manager shall attempt to determine if the principal investigator understands that he or she is out of compliance and whether the non-compliance appears intentional or the result of error, oversight, or lack of knowledge of the requirements for approval of the research.
- 30.5 The IRB Manager shall document in writing the initial findings. These findings along with any written information or documentation received shall be forwarded to the IRB Chair and Vice President for Research for immediate review. Based on the initial findings, the IRB Chair, the IRB Manager, and the Vice President for Research shall determine the next steps in the investigation of the alleged or reported non-compliance. Possible next steps include but are not limited to:
 - A. The allegation or report and any initial findings shall be referred to the Office of Clinical Research for review under Children's Clinical Trials Compliance Review Program (CTCRP). The investigation will be handled in accordance with CTCRP compliance monitoring procedures. A detailed report from the CTCRP shall be submitted to the IRB Chair and Vice President for Research;
 - B. The Vice President for Research may hire an independent auditor or consultant to investigate the alleged or reported non-compliance and submit a detailed report to the IRB and Vice President for Research;
 - C. When the initial findings of the non-compliance are of a nature that represents scientific misconduct, the findings shall be forwarded for review in accordance with Children's Policy on Scientific Misconduct; or
 - D. The IRB Chair or Vice President for Research may send a written request to the Principal Investigator (PI) of the research activity to submit a

detailed report outlining the non-compliance that occurred and a plan of corrective action. The report shall be addressed to the IRB Chair and the Vice President for Research and shall be provided by the PI in as quick a manner as possible, generally within one week.

- 30.6 For most cases where serious or continuing non-compliance has been alleged or reported, the IRB Chair will advise the PI to temporarily and voluntarily suspend further enrollment of participants in the research until review of the non-compliance is satisfactorily resolved.
- 30.7 If the PI does not voluntarily suspend enrollment of participants and the alleged or reported serious or continuing non-compliance adversely affects the safety and well-being of participants enrolled, the IRB Chair shall immediately suspend enrollment of further participants. If the IRB Chair suspends a research activity immediate actions required to protect the safety and well-being of currently enrolled participants shall be implemented, as described in IRB policy 37. The requirements for reporting a suspension to institutional officials, the Office for Human Research Protections, and the Food and Drug Administration shall be implemented as described in IRB policy 37.
- 30.8 Upon completion of the investigation into the serious or continuing non-compliance a detailed report shall be submitted for review by the convened IRB. Included with the report shall be the principal investigator's proposed corrective actions and any additional corrective actions required by the institution. Institutional corrective actions shall be documented in writing by the Vice President of Research.
- 30.9 The principal investigator is offered the opportunity to attend the meeting to discuss directly with the convened IRB the incident(s) of serious or continuing non-compliance and the proposed corrective actions to prevent future recurrences.
- 30.10 The convened IRB shall review the detailed report of non-compliance and the proposed corrective actions. It shall be the convened IRB's responsibility to ensure that the corrective actions taken are sufficient to protect the safety and welfare of enrolled participants and to prevent future recurrences of such non-compliance. The IRB's determinations shall be documented in the minutes for the meeting and in writing to the Vice President for Research. The Medical Director shall also be notified in writing, when the non-compliance involves issues of safety or well-being of Children's patients.
- 30.11 The principal investigator shall be notified in writing of the IRB and the institution's response to the report of non-compliance and their determinations regarding the corrective actions needed to prevent future recurrences. This notification will address requirements for continuation of the research if the research has been suspended. The Division and Department Directors of the principal investigator, institutional officials involved in the oversight of research or

the safety of patients, shall be copied on the written notification sent to the principal investigator.

30.12 A complete copy of all correspondence and documentation submitted to or received by the IRB in the investigation of non-compliance shall be filed in the IRB file for the specific research activity. If the non-compliance is of a serious or continuing nature and is reported to the Office of Human Research Protections, the Food and Drug Administration, or the sponsor(s) a complete copy of documentation shall also be retained in the IRB Manager's files.

Submitting Committee: Institutional Review Board

Approved by:	<u>Douglas S. Dehema</u>	<u>6/20/05</u>
	Chair	Date
	<u>Elizabeth Trias</u>	<u>6/20/05</u>
	Manager	Date