

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

OPERATING PROCEDURES/POLICIES

Committee: Institutional Review Board
Policy Number: IRB-30
Effective Date: June 25, 2009

POLICY TITLE:

INVESTIGATIONS OF NON-COMPLIANCE

POLICY:

Researchers have a responsibility to promptly report to the IRB protocol deviations, protocol violations, non-compliance (whether deemed serious or otherwise by the researcher), and unanticipated problems involving risk to subjects or others as they occur. This policy focuses on such matters that constitute non-compliance, which are often initially recognized as protocol deviations or protocol violations.

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 Researchers/investigators have a responsibility to promptly report to the IRB protocol deviations, protocol violations, non-compliance (whether deemed serious or otherwise by the researcher/investigator), and unanticipated problems involving risk to subjects or others as they occur. The manner of such report

- shall be by correspondence from the Principal Investigator (PI) that notifies the IRB of the matter(s) and includes all relevant details known by the PI at the time of the report as well as all relevant documentation.
- 30.2 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.
- 30.3 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).
- 30.4 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.
- 30.5 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.
- 30.6 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.
- 30.7 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.
- 30.8 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.
- 30.9 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.
- 30.10 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.

