The Christ Hospital IRB **Number:** 3.10
Submitted By: Erica Jones, CIP **Effective Date:** 01/09/09
Reviewed By: Michael Jennings, MD/Steve Roberts, MD
Revised/Reviewed Date: 03/17
Approved By: Steve Roberts, MD
(III.2.A)

STANDARD OPERATING PROCEDURE

Misconduct in Research

POLICY:

The Principal Investigator bears the ultimate responsibility for conduct of a research project. The Investigator must comply with the requirements of The Christ Hospital's FederalWide Assurance, the FDA, State laws and with the determinations of the IRB, as outlined in minutes, guidelines and other correspondence.
Research misconduct is defined as *"fabrication, falsification or plagiarism in proposing, performing or reviewing research, or in reporting research results."*

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results or words without giving appropriate credit.

(Research misconduct does not include honest error or differences in opinion.)

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community, and
- The misconduct be committed intentionally, knowingly, or recklessly; and
- The allegation be proven by a preponderance of evidence.

A response to an allegation of research misconduct will usually consist of several phases, including:

1. an inquiry – the assessment of whether the allegation has substance and if an investigation is warranted;
2. an investigation – the formal development of a factual record, and the examination of that record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies;
3. adjudication – during which recommendations are reviewed and appropriate corrective actions determined.

NOTE: Adjudication is separated organizationally from inquiry and investigation. Likewise, appeals are separated organizationally from inquiry and investigation.

REFERENCE:
[DHHS (45 CFR.46), FDA (21 CFR.50, 56, 312, 812), PHS (42 CFR 93)]

PROCEDURES:

IRB OFFICE STAFF:

1. When made aware of an allegation of misconduct, the staff immediately notifies the IRB Chair and works with the Chair to compile any required background file information.

IRB CHAIR:

1. Will notify the funding agency/sponsor of an allegation of research misconduct if (1) the allegation involves federally funded research (or an application for federal funding) and meets the federal definition of research misconduct given above, and (2) if the institution's inquiry into the allegation determines there is sufficient evidence to proceed to an investigation.
2. When an investigation is complete, the IRB Chair will forward to the agency/sponsor a copy of the evidentiary record, the investigative report, recommendations made to the institution's adjudicating official, and the subject's written response to the recommendations (if any).
3. When the adjudication phase is complete, the IRB Chair will forward the adjudicating official's decision and notify the agency/sponsor of any correction actions taken or planned.
4. At any time during an inquiry or investigation, the IRB Chair should immediately notify the federal agency if public health or safety is at risk; if agency resources or interests are threatened; if research activities should be suspended; if there is reasonable indication of possible violations of civil or criminal law; if federal action is required to protect the interests of those involved in the investigation; if the research institution believes the inquiry or investigation may be made public prematurely so that appropriate steps can be taken to safeguard evidence and protect the rights of those involved; or if the research community or public should be informed.
   NOTE: If more than one agency/sponsor is involved in funding activities relevant to the allegation, a lead agency/sponsor should be designated to coordinate responses to allegations of research misconduct. Each agency/sponsor may implement administrative actions in accordance with applicable laws, regulations, policies or contractual procedures.

REVISION HISTORY:

Date Revised	Reason For Change	Revised By