

The Christ Hospital IRB

Number: 1.20

Submitted By: Erica Jones, CIP

Effective Date: 01/12

Reviewed By: S. Roberts, MD & M. Jennings, MD

Revised/Reviewed Date: 03/17

Approved By: Steve Roberts, MD

(I.I.D)

STANDARD OPERATING PROCEDURE

Undue Influence

POLICY:

The Christ Hospital Institutional Review Board requires its investigators, research staff, and research sponsors to conduct research responsibly and carry out ethical treatment of human subjects in research. The Christ Hospital has a systematic and comprehensive Human Research Protection Program (HRPP) that is designed to protect the rights, dignity, and welfare of human subjects who participate in the research studies at the Institution. The program is based on the ethical principles outlined in the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. Any TCH staff, research investigator or member of TCH IRB who becomes aware of an allegation of undue influence or coercion regarding IRB policies and/or procedures must report the incident(s) immediately to the IRB Chairman. The Chairman along with a selected community member of the IRB will initiate an inquiry into the allegation and initiate a report to the President/CEO of The Christ Hospital. The President/CEO will resolve the issue and notify the IRB of the outcome.

PROCEDURE:

IRB OFFICE STAFF:

When made aware of an allegation of undue influence, the staff immediately notifies the IRB Chair, works with the Chair to compile any required background file information, and documents the allegation in writing to the President/CEO on behalf of the Chair.

IRB CHAIR:

When made aware of an allegation of undue influence, the Chair along with a selected community member of TCH IRB will initiate an inquiry into the allegation and initiate a report to the President/CEO.

TCH PRESIDENT/CEO:

The President/CEO will take appropriate action to resolve the issue and will notify the IRB of the outcome.

REVISION HISTORY:

Date Revised/Reviewed	Reason For Change	Revised By
4/09/15	Change to Michael Jennings, MD	Becky