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## STANDARD OPERATING PROCEDURE

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### Undue Influence

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#### 1.0 PURPOSE

This procedure establishes processes of The Christ Hospital (TCH) Human Research Protection Program (HRPP) for the prevention of undue influence and management of any allegations of undue influence in research at The Christ Hospital.

#### 2.0 POLICY

The Institutional Review Board (IRB) review process and the implementation of IRB policies and procedures must be conducted objectively and without undue influence. IRB activities must remain independent and free from organizational pressures and financial conflicts, upholding participant rights and safety.

Undue influence is defined as a real or perceived action that may influence the review of human subjects research outside of the scientific, regulatory, and ethical principles that guide such review. These actions may include, but are not limited to, attempts to influence decisions based upon financial concerns of the organization or a department, personnel actions such as denying promotion, or verbal harassment. Undue Influence policy is upheld by:

##### 2.1 Independence

The IRB is required to conduct its business independent of other institutional interests, operating independently of institutional financial/business goals, and preventing commercial interests from swaying decisions. The IRB shall therefore maintain independent and ultimate authority over human subjects research. Its disapproval cannot be overridden by other institutional bodies or business interests including conflicts of interest and general pressures to conduct research absent a thorough review.

##### 2.2 Prohibition of Conflicts

Individuals responsible for organizational business development may not serve as IRB members, may not be involved in daily operations of the review process, and may not discuss business development with IRB members.

### 2.3 **Reporting Mechanisms**

Any TCH staff, research investigator, or IRB member of TCH IRB who becomes aware of an allegation of coercion or undue influence of the HRPP, and/or who has reasonable belief or evidence that the independent nature of the IRB is threatened, must report the incident(s) immediately to the IRB Chair. The chair, along with a selected unaffiliated member of the IRB, will initiate an inquiry into the allegation and a report to the Institutional Official of The Christ Hospital. The Institutional Official will resolve the issue and notify the IRB of the outcome.

### 2.4 **Investigation**

The Institutional Official or a designee investigates reports of undue influence, potentially involving legal counsel if conflicts arise.

## 3.0 **PROCEDURE**

### 3.1 **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 Institutional Official on behalf of the Chair.

### 3.2 **IRB CHAIR:**

When made aware of an allegation of undue influence, the Chair, along with a selected unaffiliated member of TCH IRB, will initiate an inquiry into the allegation and initiate a report to the Institutional Official.

### 3.3 **Institutional Official:**

The Institutional Official will take appropriate action to resolve the issue and will notify the IRB of the outcome.

## 4.0 **REFERENCES**

4.1 United States Department of Health and Human Services  
[Ethical Codes: Belmont Report, Declaration of Helsinki, Nuremberg Code](#)

4.2 AAHRPP Domains and Elements: [I.1.D](#)