The Christ Hospital IRB **Number:** 3.11
Submitted By: Erica Jones, CIP **Effective Date:** 06/05/09
Reviewed By: Michael Jennings, MD/Justin Gamble/Steve Roberts, MD
Revised/Reviewed Date: 03/17
Approved By: Steve Roberts, MD
(I.7.A, I.7.B, III.2.B)

STANDARD OPERATING PROCEDURE

Use and Investigation with Drugs, Biologics, Devices or Test Articles Under FDA Regulations and Control and Documentation

POLICY:

Under The Christ Hospital policy, clinical investigations will undergo review and performance in accordance with federal regulations of the Food and Drug Administration pertaining to human subjects protections and investigational drugs, biological products, devices or test articles. TCH IRB will make an assessment of whether or not a clinical investigation must be conducted under an investigational new drug (IND; 21 CFR 312) application or investigational device exemption (IDE; 21 CFR 812). Investigators are responsible for supplying sufficient information to the IRB to make its assessment.

For studies involving investigational devices, the IRB Chair will make an assessment of whether the device is a significant risk device. When a study claims to involve a non-significant risk device, the sponsor, through the investigator, must supply the IRB with an explanation of its claim. The IRB Chair will assess the risk status of the device according to the definition of significant risk device in FDA regulations. Whenever the IRB assessment categorizes a claimed non-significant risk device as a significant risk device, it will notify the investigator and, where applicable, the sponsor. In such circumstances, the clinical investigation may not be performed at The Christ Hospital without an effective FDA IDE application for the device investigation or other FDA approval.

Whenever an investigator holds the IND or IDE for investigational uses of test articles, the investigator acquires all the responsibility of a sponsor of the clinical investigation under the IND or IDE. The investigator status changes to sponsor-investigator. Sponsor responsibilities may be delegated to another person only by written agreement. Regulatory monitoring by The Christ Hospital for clinical investigations performed by a sponsor-investigator will include monitoring sponsor responsibilities.

PROCEDURE

I. To Ensure Handling of Investigational or Unlicensed Test Articles Meets Organization Standards Relating to Drugs, Inventory Control and Documentation:

INVESTIGATOR:

- Submits to the pharmacy for all inpatient protocols using investigational or commercially available drugs:
  - A copy of the sponsor's protocol;
  - Investigator's Brochure for IND studies, (if requested) and
  - A completed and signed Investigational Drug Data Form

- Designates personnel who may administer the medication and ensures they have the appropriate training to administer the medication safely;
- Designates where the study drug or test article will be shipped and stored;
- Describes the dispensing procedures;
- Indicates the mechanism by which the pharmacy will be reimbursed for services; (as applicable)
- Submits the executed Investigational Drug Data form together with the IRB submission.

PHARMACIST (Who is also IRB Member):

- Reviews the investigator's protocol and the Investigational Drug Data form to ensure the procurement, storage, preparation, distribution and control of the drug is acceptable under The Christ Hospital standards (see hospital administrative policy #4.20.118);
- Calculates the fee per dose or course for the investigational drug or test article to be charged to the patient, grant or other source;
- Assists the investigator in the proper storage and distribution of the drug;
- Approves the Investigational Drug Data Form and returns it to the investigator, if changes are needed;
- Prepares and labels drug or test article being dispensed;
- Records an entry of all doses received, dispensed, unused, returned and destroyed in the Investigational Drug Inventory/Dispensing log;
- Performs inventory checks on stock at regular intervals; and
- Maintains records for a period of no less than 2 years after FDA approval/IND termination or longer, if required by the sponsor, in accordance with 21 CFR 312.62.

IRB CHAIR OR DESIGNEE:

- Reviews and verifies that the Investigational Drug Data Form is completed and signed by the investigator;
- Reviews the protocol to ensure that the investigator or designated personnel are qualified to dispense and/or administer investigational drugs.

II. To Ensure Handling of Investigational or Unlicensed Test Articles Meets Organization Standards Relating to Devices, Inventory Control and Documentation:

INVESTIGATOR:

- Submits a copy of the sponsor's protocol and sponsor provided device description for all protocols using investigational or commercially available devices or test articles being used in an investigational manner;
- Designates personnel who may use the device and ensures they have the appropriate training or qualifications to administer the device safely;
- Designates where the study device or test article will be shipped and stored;
- Describes the procedures for release of devices and maintenance of inventory;
- Provides information on whether the device will be at no cost or billed to the participant or participant's insurance;
- Maintains records for a period of no less than 2 years after FDA approval or longer, if required by the sponsor, in accordance with FDA regulations.

The investigator is responsible for the investigational device accountability which includes storage, security, dispensing, administration, return, disposition and records of accountability. The investigator will delegate the responsibility for inpatient drugs/biologic accountability to The Christ Hospital Pharmacy.

IRB CHAIR OR DESIGNEE:

- Reviews the protocol and verifies that it provides a complete description of the procedures related to the use and inventory of the investigational device or test article;
- Determines if the device represents significant or non-significant risk.
- Requests additional information, if necessary;
- Does not issue approval until all required information has been received.
- Reviews the protocol to ensure that the investigator or designated personnel are qualified to use investigational devices or test articles.

REVISION HISTORY:

Date Revised	Reason For Change	Revised By