The Christ Hospital IRB **Number:** 2.11
Submitted By: Erica Jones, CIP **Effective Date:** 03/27/09
Reviewed By: Michael Jennings, MD/ Steven Roberts, MD
Revised/Reviewed Date: 03/17
Approved By: Steve Roberts, MD
(I.1.D, II.2.H)

STANDARD OPERATING PROCEDURE

Identification and Communication of Human Subjects Research to The Christ Hospital Affiliated External Sites

POLICY:

When research procedures take place in settings not under the direct control of the investigator, both internal and external to the hospital, these sites must be informed of the intended research and must prepare for the implications that the research may have on the site. Investigators are responsible for coordinating the identification and communication among the various sites.

PROCEDURE:

INVESTIGATOR:

- Identifies proposed external sites and describes the types of research activities proposed for each site for review by the IRB in the study application.
- Notifies TCH IRB of any changes in external sites for approved research.
- Notifies each external site of proposed research activities through:
  - Communication to the designated contact person at each TCH-affiliated site, or
  - Written documentation of an entity's willingness to serve as a external site by a suitably authorized individual.
- For each non-TCH-affiliated external site, inform TCH IRB of the following:
  - Whether the site has its own IRB.
  - Whether a site's IRB has approved or disapproved the research.
  - Whether a site intends to rely on TCH IRB.
  - Have an Authorization Site Agreement in place if relying on TCH IRB.
  - Provide documentation of local IRB approval of research from non-TCH-affiliated external sites, when applicable.
- For each non-TCH affiliated external site, when the TCH investigator is the lead investigator of a multi-site study, informs TCH IRB of the following:
  - Unanticipated problems involving risks to subjects or others
  - Interim results
  - Protocol modifications
- Provides written documentation of site's willingness to serve as an externalsite and/or IRB approval.
- Notifies external sites of TCH IRB's approval of research activity, if requested.

- Complies with a external site's policies and procedures related to the conduct of research activities.
- Submits modifications to the protocol adding and removing external sites as they occur.
- Informs and trains, as necessary, all external site personnel who are involved in the research regarding research procedures.

IRB OFFICE STAFF:

- Reviews IRB submission to identify and ascertain concordance in all documents pertaining to external sites.
- Documents that external sites are listed in Study Application.
- Verifies that the investigator has submitted appropriate documentation for external sites.
- Requests appropriate documentation from investigator regarding external site, if not included with the protocol submission materials.
- Verifies changes to and permissions from external sites related to proposed or approved research activities.
- Upon request, notify TCH-affiliated external sites of IRB approval of research after both initial and continuing review.

REVISION HISTORY:

Date Revised	Reason For Change	Revised By
06/04/15	Changed performance to external	Becky