The Christ Hospital IRB **Number:** 3.02
Submitted By: Erica Jones, CIP **Effective Date:** 01/9/09
Reviewed By: Steve Roberts, MD **Revised/Reviewed Date:** 09/22
Approved By: Steve Roberts, MD
(I.2)

STANDARD OPERATING PROCEDURE

Establishment, Maintenance and Utilization of IRBs

POLICY:

The Christ Hospital is committed to establishing and maintaining an appropriate number of IRBs to accomplish timely and thorough review of it's human subjects research activities. Establishment of IRBs is based upon the volume and types of research activities conducted at the Hospital. (The Christ Hospital does not conduct research on prisoners.)

The Christ Hospital may contract with independent IRBs to satisfy IRB functions. When it participates in cooperative projects or multi-institutional studies, TCH may use joint review, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. All IRBs utilized by The Christ Hospital will possess sufficient knowledge to meet the local research context requirements of federal regulations.

PROCEDURE:

The Christ Hospital currently, and has always, maintained one IRB, based on approximately 75-100 new protocols per year. The IRB meets the second Tuesday of each month, and consists of at least 5 members, including the Chair, with multidisciplinary expertise backgrounds, and affiliations as required by federal policy and FDA regulations. The Institutional Official will assess the adequacy of the number of IRBs utilized by TCH annually during the time of budget development.

When it contracts with an independent IRB or relies on another organization's IRB, TCH will remain responsible for maintaining a system to protect human subjects. TCH may choose to delegate in writing some of its responsibilities to an independent IRB or the IRB of another organization. When responsibilities are delegated to outside IRBs, TCH will ensure that external IRBs meet similar standards of performance as its internal IRBs. TCH will retain ultimate responsibility for human subjects protection performed within its local research context, which includes safeguarding the rights and welfare of human participants; educating the members of TCH's research community in order to promote a culture to comply with federal regulations and institutional policies on human research protections; and implementing appropriate oversight mechanisms to ensure compliance with IRB determinations.