The Christ Hospital IRB **Number:** 3.16
Submitted By: Erica Jones, CIP **Effective Date:** 06/05/09
Reviewed By: Michael Jennings, MD/Steve Roberts, MD/Whedon
Revised/Reviewed Date: 03/17
Approved By: Steve Roberts, MD
(II.3.D, II.3.E)

STANDARD OPERATING PROCEDURE

Confidentiality of Data / HIPAA

POLICY:

It is the policy of The Christ Hospital that investigators and staff conducting research involving human subjects will be accountable for the confidentiality of data. In order to approve research, the IRB will determine that there are adequate provisions to protect the confidentiality of research data in accordance with federal regulations at 45 CFR 46, 21 CFR 56 if applicable, or the regulations of federal agencies and applicable state or local laws and regulations. This standard will apply to initial review, continuing review and review of modifications of research by the convened IRB or expedited review procedures.

Research involving human subjects is a covered function for TCH designated health care components under HIPAA. Covered research activities will be conducted in accordance with the HIPAA privacy regulations at 45 CFR Parts 160, 164. The IRB is authorized to review proposed authorizations for research to assess whether the standards and specifications for a valid authorization for research at 45 CFR 164.508 are satisfied and to implement the standards for use and disclosure of protected health information for research purposes (i.e., HIPAA waivers of authorization) in accordance with 45 CFR 164.512(i).

Investigators will describe in the study application their plan to protect PHI from improper use and disclosure. The Christ Hospital IRB Informed Consent template includes the "Authorization for Use and Disclosure of Medical Information" as part of the Confidentiality section. This authorization must be contained in every TCH IRB-approved consent form.

For purposes of patient recruitment into research studies, it may be necessary to grant a "HIPAA Request for Full or Partial Waiver to Individual Authorization" for individuals recruiting subjects who are not employees of The Christ Hospital. These waiver forms must be completed and submitted to the IRB with the protocol submission. (Also see TCH Administrative policy 2.26.125, HIPAA Privacy and Security Training.)

DEFINITIONS:

Authorization: A written document signed by a patient of a Covered Entity allowing Protected Health Information (PHI) to be shared for purposes specified in the authorization. The authorization will be developed by the Covered Entity and will have the elements required by HIPAA. (For Christ Hospital studies, this authorization is included in the informed consent document.)

- Copies of any HIPAA privacy notices, authorizations, and/or waivers from non-TCH designated performance sites for IRB review.

- At the time of submission of continuing review, includes:
  - Changes to the protocol involving acquisition, use or disclosure of identifiable private information or maintaining confidentiality of the data;
  - Any problems encountered in the research specifically related to preserving identifiable private information or maintaining confidentiality of the date;

- Submits modifications to the research related to acquisition, use and disclosure of identifiable private information and maintaining confidentiality for review and approval prior to initiation of the changes unless change is immediately necessary to protect from an immediate hazard to the participant's privacy and confidentiality.

- Submits problems that require prompt reporting after the problem has been identified (See SOP 2.05).

IRB STAFF:

- At the time of initial, continuing or modification review, if appropriate, evaluates the protocol to determine if the following information is sufficient for presentation to the IRB for review:

  - Provisions for protecting the identifiable private information (data) of participants;
  - Provisions for maintaining the confidentiality of private information collected during the course of the research;
  - Methods to access, store, use and safeguard data;
  - Whether a certificate of confidentiality is proposed;
  - HIPAA authorization or a HIPAA waiver (in whole or in part) for the data being collected for the research;
  - Copies of privacy notices and/or HIPAA authorizations/waivers from non-TCH designated performance sites.

- Ensures that documentation of HIPAA waivers include the following:
  - Identification of the IRB issuing the waiver and the date the waiver was approved;
  - Statement that the IRB has determined the criteria for a waiver is satisfied under the regulations;
  - Brief description of the PHI for which use or access has been determined to be necessary by the IRB for the research to be practicably conducted;
  - Statement that the waiver has been issued under either convened or expedited review; and
  - Signature of the Chair or designee.

- Requests information/materials that were not included or addressed;

- Forwards reports of problems regarding confidentiality that require prompt reporting to the Chair and to the convened IRB.

REVISION HISTORY:

Date Revised	Reason For Change	Revised By
6/18/15	Add full HIPAA Waiver information	Becky