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.)

Covered Entity: 1) A health plan. 2) A health care clearinghouse. 3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by HIPAA.

HIPAA: An acronym for Health Insurance Portability and Accountability Act of 1996. HIPAA establishes national standards for health care transactions, unique health identifiers, code sets for the data elements of the transactions, security of health information, and electronic signature.

Private Information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Privacy Rule: Privacy Rule refers to the Standards of Privacy of Individually Identifiable Health Information Portion of HIPAA. The Privacy Rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996.

Protected Health Information: Refers to individually identifiable health information (with limited exceptions) in any form, including information that is transmitted orally, or in written or electronic form, under HIPAA privacy regulations at 45 CFR 160.103. Examples of PHI include patient's name, address, zip code, birth date, social security number, and telephone number.

PROCEDURE

INVESTIGATOR:

- At the time of initial review by convened or expedited procedures, completes the study outline describing:
  - Any risks to disclosure of identifiable private information of participants and proposed provisions to protect the participant's identity during the course of the research (e.g., will participants be approached in a public place to participate, designation markings on files or accounts to indicate that the individual is a research participant);
  - Strategies for maintaining the confidentiality of identifiable private information collected during the course of the research (i.e., how identifiable private information will be handled, used/managed and/or disclosed);
  - Methods of accessing, storing and safeguarding the data;

- Submits the following HIPAA-related materials, if applicable:
  - HIPAA authorization (as part of the consent form), if applicable;
  - Request and justification for waiver (in whole or in part) or alteration of HIPAA authorization for the data being collected for the research;

- 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.

IRB:

The IRB or an experienced IRB reviewer for expedited review at the time of initial, continuing or modification review:

- Reviews the proposed research and approves only if there are adequate provisions to maintain the confidentiality of identifiable data;
- Determines whether subjects have the ability to choose the purposes for use of identifiable private information including disclosure;
- Determines, for waivers or alteration of HIPAA authorization, the following:
    - The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
        - An adequate plan to protect the identifiers from improper use and disclosure;
        - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
        - Adequate written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

    - The research could not practicably be conducted without the waiver or alteration; and
    - The research could not practically be conducted without access to and use of the PHI.

SPECIAL PRIVACY CONCERNS:

Some research projects pose risk to participants simply because they are involved in the study. In such cases the IRB will ensure that the study design and data collection protect the privacy of the participants. At the time of initial protocol review, the IRB Chair and/or IRB members will consider the potential for harm to participants if their participation in the study should become known. If the potential for harm is greater than minimal, the IRB Chair and/or IRB members will assess the protections written into the protocol to ensure their adequacy. If the protections are inadequate, the IRB Chair and/or IRB members will recommend revisions to increase protection of participants' privacy. Methods of protection the privacy of participants may include any of the following:

- Recruiting by allowing the participant to contact the investigator (for example, by telephone) when the participant feels there is sufficiency privacy to make the contact.
- Arranging the study site so arriving and departing participants cannot see each other.
- Spacing the arrival and departure of participants so they will not meet when coming or going.
- Conducting study activities at the participant's chosen site and time.

REVISION HISTORY:

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