The Christ Hospital IRB
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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. Additionally, research protocols shall include arrangements for maintaining confidentiality of data after the conclusion of the study.

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 and 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" 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. For additional information, see TCH Administrative policy #2.47.124 - HIPAA Education and Training.

NOTE: Studies funded wholly or in part by the National Institutes of Health (NIH) and that involve collecting or using identifiable, sensitive information are automatically issued a "Certificate of Confidentiality". Researchers may also apply for a certificate of confidentiality for non-federally funded research. For further guidance see Certificate of Confidentiality below.

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.)

Certificate of Confidentiality: Certificates of Confidentiality (CoC) protect the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the participant consents or in a few other specific situations.

Covered Entity: (1) A health plan, (2) health care clearinghouse, or (3) 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 (e.g., 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: 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

1. **Initial Review:** At the time of initial review by convened or expedited procedures, the investigator shall:

    a. Complete the study application in Mentor IRB 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, including arrangements for maintaining the confidentiality of identifiable data after the conclusion of the research.

b. Submit the following HIPAA-related materials, if applicable:
- Combined Authorization (as part of the consent form)
- Standalone HIPAA Authorization
- 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

2. **Continuing Review:** At the time of submission of continuing review, the investigator shall include in the submission:
   a. Changes to the protocol involving acquisition, use or disclosure of identifiable private information or maintaining confidentiality of the data
   b. Any problems encountered in the research specifically related to preserving identifiable private information or maintaining confidentiality of the data

3. **Modifications:** The investigator shall submit 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

4. **Unanticipated Problems:** The investigator shall submit problems that require prompt reporting after the problem has been identified (ref. SOP 2.05 Reporting Unanticipated Problems).

IRB STAFF

Initial, Continuing or Modification Review: At the time of initial, continuing or modification review, if appropriate, IRB staff shall:

1. Evaluate the protocol to determine whether the following information is sufficient for presentation to the IRB for review, if applicable:
   a. Provisions for protecting the identifiable private information (data) of participants
   b. Provisions for maintaining the confidentiality of private information collected during the course of the research
   c. Methods to access, store, use and safeguard data, including after the conclusion of the research.
   d. Whether a Certificate of Confidentiality is included (see *Certificates of Confidentiality* below)
   e. HIPAA requirements are in place including:
      - HIPAA authorization or 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
- Assurance 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
    - Signature of the Chair or designee

2. Request information/materials that were not included or addressed

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

IRB

1. **Initial, Continuing, or Modification Review:** At the time of initial, continuing or modification review, the IRB or an experienced IRB reviewer for expedited review shall:

    a. Review the proposed research and approve only if there are adequate provisions to maintain the confidentiality of identifiable data
    b. Determine whether subjects have the ability to choose the purposes for use of identifiable private information including disclosure
    c. Determine, for waivers or alteration of HIPAA authorization, that:
        - 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
        - The research could not practically be conducted without access to and use of the PHI

2. **Study Closure:** Upon closure of the research study, the IRB Chair reviews and acknowledges study closure request, and may, as applicable, recommend the closure request to the convened board for consideration. The request for study closure shall include arrangements for maintaining confidentiality of identifiable data (as applicable) after the conclusion of the research study. Ref. SOP 2.07 Notice of Study Closure

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 the adequacy of the previsions. 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:

1. 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
2. Arranging the study site so arriving and departing participants cannot see each other
3. Spacing the arrival and departure of participants so they will not meet when coming or going
4. Conducting study activities at the participant's chosen site and time

CERTIFICATE OF CONFIDENTIALITY

Certificates of Confidentiality (Certificate or CoC) protect the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the participant consents or in a few other specific situations.

The CoC policy and 42 U.S. Code §241(d) defines **identifiable, sensitive information** as information that is about an individual and that is gathered or used during the course of research where the following may occur:

- Through which an individual is identified; or
- For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

Note: The law focuses on the *identifiability* of the information, and not on the *sensitivity* of the information.

Studies Funded by the NIH: Studies funded wholly or in part by the National Institutes of Health and that involve collecting or using "identifiable, sensitive information" are automatically issued a CoC. This includes institutes and centers that fall under the umbrella of the NIH. A complete list can be found in The NIH Almanac.

Studies Without NIH Funding: Investigators may also apply for a CoC for non-federally funded research. Additionally:

1. Studies funded by the CDC, SAMSHA HRSA, HIS: Investigators whose studies are funded in whole or in part by these agencies can request a CoC by contacting the agency's CoC Coordinator
2. CoCs are not issued for studies funded by AHRQ or DOJ.
3. Studies not funded by any of the above but that are under the authority of the FDA operating under an IND or IDE can contact the FDA CoC Coordinator.

Any study not addressed above can request a CoC through the NIH's online system.

Examples of Research Automatically Covered by a CoC

1. Biomedical, behavioral, clinical or other research including exempt research, except where the information is recorded in such a manner that human participants cannot be identified or the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants.
2. The collection or use of biospecimens that are identifiable to an individual or for which there are at least a very small risk that some combination of the biospecimen, a request for the biospecimen and other available data sources could be used to deduce the identity of an individual
3. The generation of individuals level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human participants can be identified or the identity of the human participants can readily be ascertained
4. Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data courses could be used to deduce the identity of an individual

If NIH funding for a study has ended but the collection of new data from research participants will continue, the investigator must apply for an additional CoC for continuity of protections. If NIH funding has ended and all enrollment and data collection is complete, the data that was collected is permanently protected under the original CoC.

Studies Covered by a CoC
When research is covered by a certificate of confidentiality, investigators shall adhere to the following.

1. **Researchers may disclose information only when**:

    a. Required by Federal, State, or local laws (e.g., as required by the Federal Food Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State or local civil, criminal, administrative, legislative, or other proceeding
    b. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
    c. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

d. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human participants in research

2. **Researchers may not**:

a. Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, the name of such individual or any such information, document or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains to; or

b. Disclose or provide to any other person not connected with the research, the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was crated or document) of the protections and limitations of certificates of confidentiality:

3. **Information to Research Participants**

a. For studies that were previously issued a Certificate, and notified participants of the protections provided by that Certificate, NIH does not expect participants to be notified that the protections afforded by the Certificate have changed, although the IRB may determine whether it is appropriate to inform participants.

b. If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer actively participating in the study, NIH does not expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented to be re-contacted to be informed of the Certificate, although the IRB may determine whether it is appropriate to inform participants.

3. **Data Sharing**

a. Investigators conducting NIH-supported research covered by a certificate of confidentiality must ensure that if identifiable, sensitive information is provided to other investigators or organizations, regardless of whether or not the research is federally funded, the other investigator or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

b. Investigators conducting research covered by a certificate of confidentiality, even if the research is not federally funded, must ensure that if identifiable, sensitive information is provided to other investigators or organizations, the other investigator or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

4. **Consent Form Language**
   Please refer to The Christ Hospital Informed Consent Document Template - Instructions to help draft and finalize an informed consent which is compliant with federal regulations and institutional expectations.

5. **IRB Consideration of Certificates of Confidentiality**
   Investigators should indicate if the research will be covered by a CoC in the Confidentiality and Privacy section of the Mentor IRB application. In some cases where the PI does not indicate plans to request a CoC, the IRB may require that a certificate be obtained. An investigator and institution issued a CoC must:

   a. Abide by the disclosure requirements of the CoC
   b. Inform any sub-awardees that a CoC is in place
   c. Inform others who receive a copy of protected information in the conduct of the research of the requirements of the CoC
   d. Inform research participants about the protections and limits to the CoC, using language approved by the IRB

6. **Amendments to Research with Approved Certificate of Confidentiality**
   When a significant change in a research project is proposed after a CoC is issued, the PI must obtain IRB approval for the change and inform the CoC Coordinator of the institute or agency issuing the CoC of the amendments. The PI must submit the amended CoC to the IRB for acknowledgement.

7. **Expiration of Certificates of Confidentiality**
   It is the responsibility of the Principal Investigator to ensure that the CoC is always valid during the study. If, at any time during the study, the CoC expires or is terminated, the Principal Investigator must immediately file an amendment with the IRB to remove the CoC wording from the consent form used to enroll new participants. Most CoCs specify an expiration date except FDA CoCs for IND studies. The latter remain valid if the IND is in effect. It is the responsibility of the researcher to ensure that the CoC remains valid if the protected personally identifiable information (PPII) can be linked to participant information.

   If the retention or collection of PPII will continue past the expiration date of the CoC, the researcher must submit a written request to the appropriate agency for an extension. Requests to extend CoC expiration dates must be

   submitted at least three months before the CoC expires. Upon receipt, the PI must submit a copy of the approved CoC extension to the IRB for acknowledgement.

   If PPII can be linked to research data when the CoC expires and no extension is obtained, the researchers must submit a project amendment to notify the IRB of the CoC expiration and address the following changes to the consent process and documents:

   a. Consent forms used to enroll new participants must be amended to remove mention of the CoC, and
   b. Revised consent document or consent addendum must be used to notify enrolled participants of the expiration of the CoC.

Additional References

- **Office for Human Research Protections**: Certificates of Confidentiality - Privacy Protection for Research Subjects: OHRP Guidance
- **National Institutes of Health**: Certificates of Confidentiality