SOP 1001: HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA PRIVACY RULE) – PRIVACY BOARD

1. POLICY

The HRPP/IRB/Privacy Board reviews requests for waivers or alterations of Authorizations with the goal of ensuring participant protected health information (PHI) that is accessed, created, acquired, disclosed, or maintained during the conduct of human participant research is protected in accordance with the Privacy Regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), applicable state and federal laws, and the University HIPAA Privacy and Security Policies.

Under HIPAA, a covered entity must establish a Privacy Board or delegate authority to the IRB to serve as a Privacy Board to review uses and disclosures of PHI in research. The University has designated the IRB to serve as the Privacy Board for research.

The Privacy Board shall consist of at least two members with varying backgrounds and appropriate professional competency necessary to review the effect of research protocol on the research participant’s privacy rights. At least one member must not be affiliated with the University or any University research sponsor (or related to such individuals). No Privacy Board member shall review a project if the member has a conflict of interest (see IRB SOP 104B: Conflict of Members – IRB Members).

The University has designated a University Privacy Official and a HIPAA Security Officer who work to assure compliance with HIPAA regulations. The University Privacy Official and HIPAA Security Officer shall provide guidance on research-related HIPAA issues at the request of the Privacy Board or HRPP Director.

Specific Policies

1.1 Role of the Privacy Board

The Privacy Board shall review each research project submitted to the IRB and, if it determines that PHI is involved, ensure that appropriate HIPAA Authorizations/waivers are utilized.

Either the IRB or IRB Chair or IRB designee shall conduct the human research project review. The University’s HIPAA Privacy Official and/or HIPAA Security Officer shall be consulted as needed.

1.2 HIPAA Determinations

The Privacy Board shall make the following determinations:

1.2.1 Whether the written Authorization appropriately documents permission from the research participants for the University to collect, use, and disclose their PHI (Privacy Forms 1-4).

1.2.2 Whether a Waiver of Authorization is appropriate when direct permission from the research participant is either not necessary or not possible, and, based on documentation provided by an investigator on a Waiver of Authorization document (Privacy Form 5), whether the use or disclosure of PHI involves no more than a minimal risk to the research participant’s privacy, consistent with the elements identified on
Privacy Form 5 (45 CFR 164.512(i)(2)(ii)). Clinical research will generally not qualify for a waiver if the research participant will be asked to sign an informed consent form.

1.2.3 Whether a limited data set is being used. When a research project involves health information that is identifiable only by certain identifiers specified under HIPAA, the data are considered a limited data set, as documented by an investigator on Privacy Form 9. If the investigator plans to share the limited data set with another entity, a written agreement (a Data Use Agreement), described in Privacy Form 10, must be utilized.

1.2.4 Whether proposed access to PHI qualifies as access preparatory to research. When the investigator is seeking to review PHI preparatory to research, such as to prepare a research protocol, prior to accessing PHI the investigator must submit verification of such activity on Privacy Form 6. PHI may not be removed from the custodian of the PHI for such activity.

The Privacy Board shall comply with the following:

1.2.5 An Authorization is not required for research that involves only the PHI of decedents, as documented by an investigator on Privacy Form 7.

1.2.6 An Authorization is not required for research that involves health information that is non-identifiable to a participant, as documented by an investigator on Privacy Form 8.

2. SCOPE

This SOP applies to all human research that involves the access to or creation, acquisition, disclosure, or maintenance of protected health information.

3. RESPONSIBILITY

3.1 The IRB, acting as the Privacy Board, has the authority and the responsibility to review human research projects for privacy issues, consistent with the University’s HIPAA “Research” policy and applicable law, as well as for security issues, consistent with the University’s HIPAA Security policies.

3.2 The investigator is responsible for submitting verification via the appropriate Research Privacy form or other documentation of the manner in which PHI is accessed, collected, used, maintained, and/or disclosed for research purposes.

3.3 The University Privacy Official and HIPAA Security Officer are responsible for providing current guidance to the Privacy Board and HRPP Director regarding HIPAA regulations. The University Privacy Official is also responsible for updating HIPAA Privacy forms and policies.

3.4 The HRPP Director or designee is responsible for bringing HIPAA issues for clarification to the University Privacy Official or HIPAA Security Officer.

4. APPLICABLE REGULATIONS AND GUIDELINES

Health Insurance Portability and Accountability Act, 45, CFR parts 160 and 164, August 2003, as amended, including by HITECH.
5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs.

6. ATTACHMENTS

1001-A  Research Privacy Form 1: Use or Disclose PHI for Research
1001-AA Research Privacy Form 1: Use or Disclose of PHI for Research - Spanish
1001-A-1 Research Privacy Form 1: Use or Disclose PHI – Norman Campus
1001-B  Research Privacy Form 2: Psychotherapy Notes for Research
1001-C  Research Privacy Form 3: Use or Disclose PHI for Repository
1001-D  Research Privacy Form 4: Use or Disclose PHI and Repository
1001-E  Research Privacy Form 5: Waiver of Authorization
1001-F  Research Privacy Form 6: Review Preparatory to Research
1001-G  Research Privacy Form 7: Decedent Information
1001-H  Research Privacy Form 8: De-Identified Information
1001-I  Research Privacy Form 9: Limited Data Sets
1001-J  Research Privacy Form 10: Use Agreement on Limited Data Sets
1001-K  University of Oklahoma Notice of Privacy Practices
1001-L  Authorization for Use/Disclosure of Individual Protected Health Information for Research Purposes – Saint Francis Hospital

HIPAA Policy - Research

7. PROCESS OVERVIEW

7.1 The IRB Administrator conducts a preliminary review of all new research, continuing review, and modification submissions to determine that those studies involving the collection of PHI include the appropriate HIPAA documentation and comply with relevant HIPAA policies.

7.2 The IRB Chair or IRB designee or the convened IRB reviews the acquisition, creation, use, maintenance, and/or disclosure of PHI for each submission to determine if an Authorization, waiver, Data Use Agreement, or other Research Privacy form or documentation is needed.

7.3 The IRB Chair or IRB designee or the convened IRB alerts the IRB Administrator if a particular or different HIPAA form is indicated based on the review of PHI usage.

7.4 The IRB Administrator contacts the investigator to request an alternate or additional HIPAA form if indicated upon either preliminary review or IRB or IRB Chair request.

7.5 The IRB Administrator directs HIPAA-related issues requiring additional guidance to the HRPP Director or designee, who confers with the University Privacy Official and/or HIPAA Security Officer, as appropriate.

7.6 Requests for revisions to the University’s HIPAA forms are forwarded to the University Privacy Official, who documents any indicated instructions or revisions to documentation and returns to the HRPP Director or designee, who forwards to the appropriate IRB Administrator.
7.7 The HRPP Director or designee serves as a liaison between IRB Chairs and the University Privacy Official and HIPAA Security Officer.

7.8 Projects determined by the IRB to be non-research but requiring review regarding HIPAA issues shall be forwarded to the University Privacy Official for a determination. These projects do not generally require further involvement by the IRB.

APPROVED BY: ___________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020