SOP 1001: HEALTH INSURANCE PORTABILITY
AND ACCOUNTABILITY ACT (HIPAA PRIVACY RULE)-Privacy Board

1. POLICY
The HRPP/IRB/Privacy Board protects and safeguards protected health information (PHI) created, acquired, and maintained during the conduct of human participant research in accordance with the Privacy Regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), applicable state laws, and the University HIPAA Privacy 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 University has designated a Privacy Official who assures the University remains compliant under the Privacy regulations within HIPAA. The University Privacy Official shall provide guidance on research-related privacy 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 determine if the Investigator has access to and/or is using PHI and whether 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 shall be consulted as needed.

1.2 HIPAA Determinations

1.2.1 The written Authorization documents permission from the human research participants to collect, use, share, and disclose their PHI. (Privacy Forms 1-4).

1.2.2 The Privacy Board may determine a Waiver of Authorization is appropriate when direct permission from the human research participant is either not necessary or not possible, as documented by an investigator on a Waiver of Authorization document (Privacy Form 5).

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

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

1.2.5 When a research project involves health information that is identifiable only by certain specified identifiers, the data is considered a limited data set, as documented by an investigator (Privacy Form 9). If the investigator plans to release the limited data set to another covered entity, a written agreement (Data Use Agreement) (Privacy Form 10) must be utilized.
1.2.6 When the investigator is reviewing PHI only to ascertain the feasibility of a research project, the investigator must submit verification of such activity (Privacy Form 6). PHI may not be removed from the custodian of the PHI for such activity.

2. SCOPE
This SOP applies to all human research that involves the collection, use, and sharing of protected health information.

3. RESPONSIBILITY
3.1 The IRB, acting as the Privacy Board, has the authority and the responsibility to review all human research projects for Privacy issues.
3.2 The Investigator is responsible for submitting verification of the manner in which PHI is collected, used, and disclosed for research purposes.
3.3 The University Privacy Official is responsible for providing current guidance to the Privacy Board and HRPP Director regarding HIPAA regulations. The HIPAA Privacy Official is also responsible for updating HIPAA Privacy Forms.
3.4 The HRPP Director or designee is responsible for bringing HIPAA issues for clarification to the University Privacy Official.

4. APPLICABLE REGULATIONS AND GUIDELINES
Health Insurance Portability and Accountability Act, 45, CFR parts 160 and 164, August 2003

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
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
7. PROCESS OVERVIEW

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

7.2 The IRB Chair or IRB designee or the convened IRB reviews the collection, use, and/or sharing of PHI for each submission to determine if an authorization, waiver, Data Use Agreement, or verification of research activity is needed.

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

7.4 The IRB Administrator contacts the investigator to request an alternate 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.

7.6 Upon review, the University Privacy Official documents indicated instructions 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.

7.8 Projects determined by the IRB to be non-research, but which require review regarding Privacy 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: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016