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

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 the Health Insurance Portability and Accountability Act (HIPAA). The Privacy Official shall review all non-research privacy issues and provide guidance on research-related privacy issues at the request of the IRB.

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 designee shall conduct the 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 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 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 by a verification (Privacy Form 7).

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

1.2.5 When a research project involves health information that is identifiable only by identifiers specified by HIPAA, the identifiers are considered a limited data set, as documented by an investigator on a verification

(Privacy Form 9). If the investigator plans to release the limited data set to another covered entity, a written agreement or 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

These policies and procedures apply to all research that involves the collection, use, and sharing of protected health information.

3. RESPONSIBILITY

The IRB, acting as the Privacy Board, has the authority and the responsibility to review all research projects for privacy issues.

The Investigator is responsible for submitting verification of the manner in which PHI is collected, used, and disclosed for research purposes.

The HIPAA 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.

The HRPP Director or designee is responsible for bringing HIPAA issues for clarification to the HIPAA 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 amendment submissions to determine that those studies involving the collection of PHI include the appropriate HIPAA documentation.

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

7.3 The IRB Chair or 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 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 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 Privacy Official for a determination. These projects do not require further involvement by the IRB.

APPROVED BY:_____ **DATE: 09/01/2009**

NEXT ESTABLISHED REVIEW DATE: MAY 2012