UNIVERSITY OF OKLAHOMA

HIPAA Policies

Title: PHI in Research	**Approved:** March 8, 2012
Effective Date: March 8, 2012	**Last Revised:** 4/1/2018, 7/22/22

I. PURPOSE

To establish permitted Uses and Disclosures of PHI in Research and requirements for protecting Research-related PHI.

II. POLICY*

A Health Care Component may Use and Disclose PHI for the purposes of Research only in accordance with University's Office of Human Research Participant Protection (HRPP) policies, including the HRPP HIPAA Policies. The University's Institutional Review Board shall serve as the University's Privacy Board.

"Research" is defined under HIPAA as a systematic investigation -- including research development, testing, and evaluation -- designed to develop or contribute to generalizable knowledge.

The Use or Disclosure of PHI in Research requires one of the following, in accordance with HRPP policies:

a. Authorization for the Use of Disclosure of PHI;
b. Waiver of the Authorization requirement by the Privacy Board;
c. De-identification of the PHI in accordance with the HIPAA *De-Identification/Re-Identification of PHI* policy; or
d. Use of a Limited Data Set, with accompanying Data Use Agreement (available on the HIPAA forms webpage and from the HRPP Office.)

Authorizations must comply with the HIPAA *Authorization to Use or Disclose PHI* policy and applicable HRPP policies.

III. PROCEDURE

A. All Research that will involve the Use or Disclosure of PHI, including for reviews prepatory to Research, must be submitted to the Privacy Board and must be accompanied by the appropriate IRB HIPAA Privacy forms. Revisions to these forms must be approved by the Privacy Board and University Privacy Official.

B. The Privacy Board will determine whether the proposed Use or Disclosure of PHI

complies with the applicable provisions of HIPAA and HRPP policies. It may seek input from the Director of Compliance and HIPAA Privacy Official.

C. Research involving the Use or Disclosure of De-Identified Health Information or Limited Data Sets must comply with HRPP policies as well as HIPAA *Limited Data Set* policy, and HIPAA *De-Identification/Re-Identification of PHI* policy.

D. Persons conducting Research involving PHI are responsible for logging Disclosures, pursuant to the HIPAA *Accounting of Disclosures* policy.

E. Any violations of the University's HIPAA policies during the course of Research must be reported to the HRPP office and the University Privacy Official as soon as possible, in compliance with the HIPAA *Complaint and Incident Reporting and Tracking* and *Breach of Unsecured PHI/ePHI* policies. Examples of HIPAA violations that may arise in Research include **but are not limited to**:

1. Failure to obtain a signed Authorization
2. Sharing PHI with individuals or entities not listed on the Authorization or permitted under the HIPAA Regulations.
3. Storing PHI on unencrypted devices or in unapproved cloud storage.
4. Failing to secure paper or electronic copies of PHI.
5. Emailing PHI via unencrypted transmission.

IV. REFERENCES

A. HIPAA Privacy Regulations, 45 CFR § 164.512(i)
B. Office of Human Research Participant Protection, SOP 1001, and related forms