

School of Nursing
Office of Research Policy

HIPAA Security of Research Subject Protected Health Information (PHI)

Purpose: The University of Louisville School of Nursing is committed to protecting the rights and welfare of human subjects involved in research. The Health Insurance Portability and Accountability Act of 1996, effective April 14, 2003, provides federal safeguards with regard to protected health information (PHI) collected as part of a research study. PHI includes demographic information such as, name, address, age, gender, medical history, results of physical examinations and laboratory tests, medications taken and results of a Research Study. The use or disclosure of PHI for research or by a third party is not permitted unless it is authorized by the individual research subject or the data meets one of the exceptions in the HIPAA regulations. Research subjects prior to participating in a research study involving disclosure of PHI must sign a HIPAA compliant "Research Authorization." This permits the use and disclosure of their PHI for purposes of the Research Study, regulatory approval(s) and other specified purposes by the researchers and other third parties as indicated in the "Research Authorization". Consistent with this regulation all nursing faculty conducting research must take steps to develop appropriate safeguards to protect PHI of subjects enrolled in their research projects. Examples of safeguards include:

- Restricting access to PHI to individuals who are compliant with HIPAA regulations and are directly involved with the research project.
- Passwords on computers (setting computers to go into protected standby mode when left on and unattended).
- Using locked file cabinets to store data.
- Computer storage of PHI collected for research purposes is compliant with the 42 HIPAA security specifications including Administrative safeguards, physical safeguards and technical safeguards.
- Not leaving identified data in plain sight.

The purpose of this policy is for faculty and staff within the School of Nursing to be compliant with the University policy concerning research and HIPAA (http://research.louisville.edu/UHSC/HIPAA_Research.pdf).

Procedure: PHI collected and stored as part of a research project conducted by faculty within the School of Nursing must comply with Health Insurance Portability and Accountability Act of 1996. Computerized storage of PHI must comply with the HIPPA Security Specifications. Local hard drives which store PHI must meet these security specifications. Compliance with these security specifications for PHI stored on University of Louisville common drives is the responsibility of the University's Information Technology Department. Access to PHI stored on University of Louisville common drives is the responsibility of the project's Principal Investigator and is restricted to individuals who are compliant with HIPAA regulations and are directly involved with the research project. This access to PHI stored on University of Louisville common drives will also include the appropriate University administrator(s) and staff who have administrative authority over the specific University of Louisville common drives and who comply with the HIPPA Security Specifications.

Accepted 3/9/05