

Requirements for Protecting PHI and Clinical Research Document Storage

It is expected that all CRPs have completed required HIPAA training. All paper and electronic study related data and information must be kept secure. Password protections must be in place for electronic records. It is expected that paper documents are locked in a cabinet or a file room. Paper with protected health information should not be visible to others such as by leaving documents sitting on a desk, fax/copy machine, or in a common area. Regarding electronically stored information reasonable safeguards should be in place including automatic time-outs for devices left unattended for a period of time (10-15 minutes). For screens in a particularly public area where risks may be higher, privacy screens should be used.

Individuals who may inadvertently see such information are still bound by HIPAA as members of Penn Medicine's workforce, and by [Principle One of the Principles of Responsible Conduct](#) to exhibit ethical behavior and to always reflect trust and loyalty with respect to the University, the Health System, and members of these communities. This includes facilities and maintenance staff who have routine access to all areas, pharmacy staff, CHPS units and other research support entities who may see such data in the course of their job responsibilities.

In the event that documentation is routinely being left on fax/copier machines or in shared spaces, or it is learned that someone violated the code of responsible conduct by taking or disclosing information that does not belong to them, an incident report should be filed in accordance with HIPAA. Responsible reporting of suspected Violation should be submitted to the reporting hotline 215-726-6759 or www.upenn.edu/215comply or privacy@Uphs.upenn.edu.

Please note that following completion of a research study, it is strongly recommended that paper files be converted to secure electronic media. If teams elect not to do so, then it is expected that paper records for completed studies are archived to the records center and retained in accordance with relevant document retention policies.

Sources for Privacy Information <https://almanac.upenn.edu/archive/volumes/v51/n22/FC-ephi.html> <https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool> <https://www.hhs.gov/hipaa/for-professionals/faq/safeguards/index.html>

Relevant Policies <https://oacp.upenn.edu/oacp-principles/ethical-and-responsible-conduct/> <https://www.hr.upenn.edu/policies-and-procedures/policy-manual/performance-and-discipline/adherence-to-university-policy> <https://oacp.upenn.edu/oacp-principles/responsible-reporting-of-suspected-violations-and-institutional-response/> <https://oacp.upenn.edu/key-hipaa-principles/> <https://oacp.upenn.edu/privacy/penndata/> <https://archives.upenn.edu/records-center/resources/retention-schedules/research-admin> <https://archives.upenn.edu/records-center/resources/retention-schedules/destruction>