

Human Research Protections Program (HRPP)

Human Research Protection Program Educational Requirements

Initial Requirements

The MCG HRPP includes on-going educational requirements for the entire research community. The HRPP education program consists of an initial mandatory training session for all individuals who are involved in the conduct, review, or oversight of human subject research. No individual identified as key research personnel on a project will be allowed to participate in research activities involving human subjects until the initial training requirement is met. The initial training requirement is fulfilled by completing the on-line Collaborative Initial Training Initiative (CITI) course.

HIPAA Requirements

If the research involves the use of protected health information (PHI) from MCG or MCGHI, the researcher and all persons involved in the conduct of the research must also complete the MCG HIPAA research training course. Educational offerings from other institutions will be evaluated on a case-by-case basis for equivalency to MCG standards.

HIPAA Compliance and HIPAA Education Program

The Health Insurance Portability and Accountability Act (HIPAA) [45 CFR 160, 164] outlines a set of regulations that govern privacy, security, and electronic transactions standards for health care information. Congress requires that all “covered entities” comply with each set of HIPAA standards.

The Medical College of Georgia, Medical College of Georgia Health System, Inc., and the Physician’s Practice Group has been classified a “Hybrid Entity” under HIPAA. A “Hybrid Entity” is defined as a covered entity that is made up of health care and non-health care components, but whose covered functions are not its primary function. Non-health care examples of the institution include the many educational programs as well as the non-human research programs. HIPAA only applies to the covered functions within the Hybrid Entity. In addition to the penalties outlined in the HIPAA regulations, MCG and MCGHI employees who fail to comply with HIPAA are subject to sanctions from the institution that could include dismissal. For further information regarding the institution’s policies regarding HIPAA refer to <http://www.mcg.edu/audits/>

Human subjects research activities that use or disclose health-related information that is Protected Health Information (PHI) may be subject to the HIPAA Privacy Rule requirements [45 CFR 160, 45 CFR 164]. At MCG, health-related information **is considered to be PHI** if any of the following apply:

- The researcher obtains it directly from a healthcare provider, a health plan, a healthcare clearinghouse or an employer (other than records relating solely to employment status)
- The records were created by any of the entities noted above and the researcher obtains the records from an intermediate source which is NOT a school record or employment record related solely to employment status
- The researcher obtains it directly from the subject in the course of providing treatment/health care to the subject.

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The Privacy Rule requires that each institution "train all members of its workforce on the policies and procedures with respect to protected health information required by this subpart, as necessary and appropriate for the members of the workforce to carry out their function within the covered entity." This education requirement applies to investigators and research staff (research coordinators, research assistants and other key research personnel) who (a) are conducting human subjects research, (b) are conducting research that involves protected health information, and (c) are also within the covered entity.

In order to be compliant with the HIPAA educational requirements, researchers must complete the MCG HIPAA Training Course.

Continuing Education

All investigators and key research personnel involved in human subject research are also encouraged to seek continuing education in human subject protections. Educational opportunities may be found by attending approved educational offerings on campus (OHRP) or approved conferences or educational courses dealing with human subjects' research within MCG or outside of the institution. For more information, please see the OHRP Education & Training web site at <http://www.mcg.edu/research/ohrp/training/index.asp>

HAC Member Education

The educational requirements for HAC members and OHRP staff are discussed in the corresponding sections of the web site.