

Human Research Protections Program (HRPP)

MCG Office of Human Research Protection

The MCG Office of Human Research Protection (OHRP) provides an internal monitoring function and educational forum to assure that all clinical studies utilizing human subjects and/or human derived materials comply with federal, state and institutional regulations and policies to protect research subjects, the university and the research team.

The primary objectives of the OHRP are to:

- Provide education and training to faculty, staff, students and Human Assurance Committee (HAC) members regarding the conduct of all studies that involve human subjects and/or human-derived materials
- Provide administrative support to the HAC and to facilitate information flow between the Chesapeake Research Review Inc. (CRRI) and the institution
- Conduct audits of all studies involving human subjects and/or human-derived materials
OHRP's goal is to facilitate research while providing the highest standards of human research protection via education, training, and compliance oversight.

Jurisdiction of the OHRP

The MCG Office of Human Research Protection (OHRP) has jurisdiction over all human subject research regardless of funding status and source conducted and has been granted the authority by the institution and the two institutional review boards to observe the consent process and the conduct of the research:

- At this institution
- By or under the direction of any employee or agent of this institution (including students) in connection with his or her institutional responsibilities
- By or under the direction of any employee or agent of this institution using any property or facility of this institution,
- Or involving the use of this institution's nonpublic information to identify or contact human subjects.

Auditing and Compliance Program

MCG established a Human Research Protection Program (HRPP) and included an Auditing and Compliance (A&C) Program that is overseen by the OHRP Director. The goal of the A&C program is to assure ongoing compliance with the requirements of the institution's Human Subjects Protection Program and to provide education, guidance and auditing/monitoring services in order to promote an environment of continuous quality improvement so that human subjects research at MCG is conducted according to the highest ethical standards. For additional information on the Auditing and Compliance program, please refer to their web site at http://www.mcg.edu/research/ohrp/audit_compl/index.asp

Resources for the Human Research Protection Program

The Vice President for Research is directly responsible for providing resources to support the MCG HRPP. Resources include, but are not limited to, providing for educational programs (initial and continuing) for HAC members, OHRP staff, and investigators; space for HAC functions; sufficient personnel to support the research protocol review process; sufficient equipment to aid OHRP, HAC and CRRI in the research protocol review process (computers, an information system, etc.); required record keeping (space and materials); and direct financial

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support (salaries, supplies, etc.). These resources are evaluated at the time of new mandates, increased growth of the human research program and annually per the State of Georgia budget reparation process.

OHRP Staffing

The OHRP Director is a member of the staff of the Vice President for Research and has day-to-day responsibilities for the operation of the human research protections program. Additionally, the OHRP is staffed by a receptionist/office assistant, three HAC Office Specialists, a Clinical Research Auditor, an Education and Training Coordinator and a Business Manager. The duties and responsibilities for all staff are found in their respective job descriptions, and their performance is evaluated on an annual basis.

OHRP Space

The OHRP currently occupies 1782.4 square feet on the second floor of Pavilion III in suite CJ-2103. This area contains six single occupancy offices, a two-person office, a three-person office, three storage rooms (two for active files and one for terminated files and general supply storage) and a copier room. A small kitchenette is included that is shared with other MCG employees. Space for the education and training opportunities are provided by the Office of Technology Transfer and Economic Development, the Division of Sponsored Programs Administration, Classroom Services, the Department of Surgery and the Division of Human Resources.