

## **Human Research Protections Program (HRPP)**

### **Introduction**

The Medical College of Georgia (MCG) Office of Human Research Protection (OHRP) Policies, Procedures and Standard Operating Procedures (SOP) apply to all research conducted at MCG, MCGHI and the Charlie Norwood VA Medical Center. These are in addition to any Institutional Review Board (IRB) specific policies and procedures such as the Human Assurance Committee (HAC) Policies and Procedures or the Chesapeake Research Review, Inc. (CRRI) Investigator Manual or the Veterans Health Administration (VHA) 1200.5 requirements.

### **What Regulations Do We Have to Follow?**

Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) regulations apply to all research in compliance with the institution's federalwide assurance (FWA). This means that all research is treated the same way regardless of funding source or status. Please contact our office for guidance if you have questions regarding our institution's FWA requirements.

### **Purpose and Applicability**

The Medical College of Georgia (MCG) established the Human Research Protection Program (HRPP) to monitor, evaluate, and continually improve the protection of human research subjects; dedicate resources sufficient to do so; exercise oversight of research protection; educate investigators and research staff about their ethical responsibility to protect research subjects; and when appropriate provide a mechanism to intervene in research and to respond directly to concerns of research subjects. This program applies to all research conducted under the auspices of MCG, MCG Health, Inc and the Charlie Norwood VA Medical Center. MCG has designated the Office of Human Research Protection (OHRP) to function as the HRPP.

The MCG OHRP web site contains the policies, procedures, forms and educational guidance for the Institutional Review Boards (IRBs), OHRP and the members of our research community involved in the conduct of human subject and/or human derived materials research. Our research community includes the Medical College of Georgia, Medical College of Georgia Health System, Inc. (MCGHI) and the Charlie Norwood VA Medical Center (VAMC). Members of this research community are the faculty, staff and students of each institution. The web site emphasizes that the responsibility for the protection of human research subjects is shared between the investigator, the institution, the Institutional Review Boards (IRBs), and OHRP. The web site is divided into sections that outline the interrelated responsibilities of the different components of the Human Research Protections Program (HRPP).

All human subjects and/or human derived materials research conducted in our research community must comply with the policies and procedures outlined on this web site. All research projects involving human subjects and/or human derived materials conducted by

or in our research community must receive the designated Institutional Review Boards (IRBs) approval prior to initiation of the research.

### **Establishing New Policy and Procedures and Periodic Review and Revision of Current**

#### **Policy and Procedures**

The OHRP web site will be revised as needed to ensure that the web site remains current and reflects current practice. Once the need for revision is identified via external agency audits, internal review, revision to regulations or guidelines, etc., the web site will be promptly revised. The OHRP will evaluate aspects of the HRPP and the policies and procedures as needed and may recommend revisions to the web site accordingly.

MCG's HRPP policies and procedures are based, in part, on the relevant federal regulations and guidance, state and local laws, relevant MCG policies and procedures and generally accepted standards within the human subject protections field. The HRPP web site is a collaborative effort of the OHRP with our IRBs and other key stakeholders of our research community. Working together, human research protection program (HRPP) policies and procedures are established and updated on the OHRP web site.

When the need for new or revised policies and procedures is identified, the Human Protections Administrator (HPA), the key stakeholders and/or individuals involved, which may include research faculty, will form a working group with the OHRP staff to draft the policy. The Clinical Research Education and Advisory Team (CREATE), an OHRP Advisory Committee, may also participate in any revisions. The HAC Chairperson, the HAC members, representatives from Chesapeake Research Review, Inc. (CRRI), appropriate advisory committees with representation from the impacted areas established by the OHRP Director on an ad hoc basis, and, when applicable, the Charlie Norwood VA Medical Center (VAMC) will review the draft policies. Final policy drafts are presented to the OHRP Director, the HAC Chairperson and/or the Senior Associate Vice President for Clinical Research Administration for approval and implementation.

#### **Measurement and Improvement of the Human Research Protection Program**

The institution monitors and measures the effectiveness of the human research protection program by reviewing the form "Annual Review of Human Research Protection Program" provided by the OHRP. This review is conducted annually in conjunction with fiscal year budget evaluation and preparation period.

If it is noted during the review that improvements are needed, the Senior Associate Vice President for Clinical Research Administration in conjunction with the OHRP Director prepares a plan of improvement to be implemented. After implementation, these changes are monitored and measured to determine the effectiveness of improvements. If additional changes are required, these are identified and reviewed.