

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

### **Office of Clinical Investigative Services (OCIS) Health System Review Office (HSRO)**

The purpose of OCIS HSRO is to review clinical research studies in order to ensure adherence with institutional regulations and policies. The OCIS HSRO will help verify the proper allocation of all resources and expenses associated with clinical research studies. A representative from the OCIS HSRO attends the HAC meeting.

OCIS HSRO review is communicated to the HAC administrative office via an email to the [OHRP@mcg.edu](mailto:OHRP@mcg.edu) address. The HAC administrative office serves as gatekeeper for this review for all studies that meet these criteria for studies that the HAC reviews.

OCIS HSRO review is communicated to the OHRP via an email to the [OHRP@mcg.edu](mailto:OHRP@mcg.edu) address. The OHRP serves as gatekeeper for this review for all studies that meet these criteria for studies that CRRRI reviews.

### **Institutional Biosafety Committee (IBC)**

The purpose of the IBC is to ensure institutional compliance with laws and regulations governing research with biohazardous materials to include pathogenic microorganisms, infectious materials, recombinant DNA, and select agents; to establish policies, procedures, and practices to ensure that research at MCG does not present unacceptable risks to the health or safety of faculty, staff, students, visitors, or the general public; and finally, to assist researchers in safely conducting research with biohazardous materials. A member of the IBC also serves on the HAC.

The IBC implements Center for Disease Control (CDC) guidelines published in Biosafety in Microbiological and Biomedical Laboratories, 4th ed, 1999; National Institutes of Health (NIH) guidelines published in Guidelines for Research Involving Recombinant DNA, 1998; and federal regulations governing CDC/USDA Select Agents published in 42 Code of Federal Regulations Part 1003, Possession, Use, and Transfer of Select Agents and Toxins; Interim Final Rule, December 13, 2002.

IBC review is communicated to the HAC administrative office via an email to the [HAC@mcg.edu](mailto:HAC@mcg.edu) address. The HAC administrative office serves as gatekeeper for this review for all studies that meet these criteria for HAC reviews.

IBC review is communicated to the OHRP via an email to the [OHRP@mcg.edu](mailto:OHRP@mcg.edu) address. The OHRP serves as gatekeeper for this review for all studies that meet these criteria for studies that CRRRI reviews.

### **Institutional Chemical Committee (ICC)**

ICC review is communicated to the HAC administrative office via an email to the [OHRP@mcg.edu](mailto:OHRP@mcg.edu) address. The HAC administrative office serves as gatekeeper for this review for studies that meets these criteria for HAC reviews. A member of the ICC also serves on the HAC.

ICC review is communicated to the OHRP via an email to the [OHRP@mcg.edu](mailto:OHRP@mcg.edu) address. The OHRP serves as gatekeeper for this review for all studies that meet these criteria for studies that CRRRI reviews.

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### **Radiation Safety Committee**

Radiation Safety Committee, Human Use Sub-Committee review is only required in the event radioactive materials or radiation producing devices are requested to be used in conjunction with a research proposal and the use of the isotope or radiation-producing device is outside the “standard management of the patient’s condition.” If the procedure utilizing the radioactive material or radiation-producing device is within the standard management of their condition, the Radiation Safety Committee (RSC) does not need to approve its use.

RSC review is communicated to the HAC administrative office via an email to the [HAC@mcg.edu](mailto:HAC@mcg.edu) address. The HAC administrative office serves as gatekeeper for this review for all studies that meet these criteria for studies that the HAC reviews.

RSC review is communicated to the OHRP via an email to the [OHRP@mcg.edu](mailto:OHRP@mcg.edu) address. The OHRP serves as gatekeeper for this review for all studies that meet these criteria for studies that CRRI reviews.

### **Graphics Standards Committee (GSC)**

The GSC was formed in 1988 to ensure that all material representing MCG conforms to the institution's standards. The GSC must approve any material representing MCG for an external audience or mass MCG audience before it can be printed or broadcast.

GSC review is communicated to the HAC administrative office via a faxed document to the OHRP fax number. The HAC administrative office serves as gatekeeper for this review for all studies that meet these criteria for studies that the HAC reviews.

GSC review is communicated to the OHRP via a faxed document to the OHRP fax number. The OHRP serves as gatekeeper for this review for all studies that meet these criteria for studies that CRRI reviews.

### **Information Technology Security (ITS) Review**

The ITS review objective is to support the goals of the MCG enterprise by assuring the availability, integrity and confidentiality of information; and to provide a flexible, but secure computing environment that facilitates the research and academic mission, while increasing information security awareness at MCG.

ITS review is communicated to the HAC administrative office via a shared document in the email system. The HAC administrative office serves as gatekeeper for this review for all studies that meet these criteria for studies that the HAC reviews.

ITS review is communicated to the OHRP via a shared document in the email system. The OHRP serves as gatekeeper for this review for all studies that meet these criteria for studies that CRRI reviews.

### **Clinical Research Pharmacy**

The Medical College of Georgia Health System, Department of Pharmacy, Investigational Drug

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Service/Clinical Research Pharmacy is responsible for the receipt, dispensing, accountability and record keeping for all investigational drugs used in research studies involving humans on the MCG campus.

All medications provided to patients at the Veterans Affairs Medical Center (VAMC) Hospital will be dispensed through the VA Hospital Pharmacy.

### **Schools, Departments, and Sections of MCG Approval Process and Communication**

Each individual listed as a research team member on the HAC Form 101 or OHRP CRRI Form must sign the applicable form to document their commitment in regards to ethical consideration, scientific merit, departmental obligations and financial support. Department chairs, section chiefs, and when applicable, deans, must also sign the forms to indicate their commitment.

### **Scientific Review and Merit**

The OHRP Director or Assistant Director verifies that the appropriate scientific oversight individual (department chair, section chiefs, deans or the service line executive) has signed the IRB submission form.

### **MCGHI Approval Process and Communication**

Each individual listed as a research team member on the HAC Form 101 or OHRP CRRI Form must sign the applicable form to document their commitment in regards to ethical consideration, scientific merit, departmental obligations and financial support. Department chairs, section chiefs, and when applicable, deans, must also sign the forms to indicate their commitment. In addition, the Extramural Grant/Contract Routing Form must be signed by the CEO of MCGHI to indicate their approval of the project. A copy of the signed document is sent to the OHRP email address for distribution to the HAC or CRRI, as appropriate.

### **Service Lines of the Charlie Norwood VA Medical Center Approval Process and Communication**

Each individual listed as a research team member on the HAC Form 101 must sign the applicable form to document their commitment in regards to ethical consideration, scientific merit, departmental obligations and financial support. Department chairs, section chiefs, and when applicable, deans, must also sign the forms to indicate their commitment. In addition, for research conducted at the Charlie Norwood VA Medical Center, the Service Line Executive must sign the HAC Form 101 and a representative of the R&D Committee must also indicate their awareness of the proposed research study.

### **Adherence to Georgia State Laws**

The institution has the responsibility to inform investigators of the state laws governing human subjects' research and to aid the investigators in complying with these laws by maintaining policies and procedures that reflect current Georgia State law. Legal counsel from the Medical College of Georgia, Office of Legal Affairs, as well as outside legal consults have provided the HRPP with specific guidance on state and local laws as they apply to research. They are available as needed to assist the HRPP with guidance on state law outside of Georgia. This guidance has been incorporated throughout MCG policy where applicable.

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Where Georgia law is silent regarding particular research activities, the institution will provide guidance to investigators basing such guidance on the Federal regulations and guidance and other currently recognized ethical standards for human subjects' research. The HRPP relies on the counsel of the General Counsel of the institution for the interpretation and application of Georgia State law and the laws of any other state or other jurisdiction where research is conducted as they apply to human subjects' research. Guidance from these individuals is available at any time and specifically incorporated into regular policy reviews.