

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

### **Institutional Review Boards**

The institution maintains an internal Institutional Review Board (IRB) known as the Human Assurance Committee (HAC) and an external Institutional Review Board known as Chesapeake Research Review, Inc. (CRRRI). These IRBs serve to review research protocols involving human subjects and to evaluate both risk and protection against risk for those subjects. It is the function of these IRBs to 1) determine and certify that all projects reviewed by the IRB conform to the policies and procedures in this document and all applicable regulations regarding the health, welfare, safety, rights, and privileges of human subjects; and 2) assist the investigator in complying with federal and State regulations and institutional policies and procedures.

The Medical College of Georgia and Medical College of Georgia Health, Inc., has granted the authorities to the Human Assurance Committee and the Chesapeake Research Review, Incorporated to:

- Approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the organizations of MCG, MCGHI and the Charlie Norwood VA Medical Center
- Suspend or terminate approval of research
- Observe, or have a third party observe, the consent process and the conduct of the research. This authority was granted to the Office of Human Research Protection.

The Charlie Norwood VA Medical Center has granted the authorities to the Human Assurance Committee to:

- Approve, require modifications to secure approval, and disapprove all research activities overseen and conducted by the organizations of MCG, MCGHI and the Charlie Norwood VA Medical Center
- Suspend or terminate approval of research
- Observe, or have a third party observe, the consent process and the conduct of the research. This authority was granted to the Office of Human Research Protection.

### **Human Assurance Committee**

The MCG IRB known as the Human Assurance Committee (HAC) meets the membership requirements of the U.S. Food and Drug Administration (FDA) regulations, 21 CFR Parts 50 and 56 and the DHHS OHRP 45 CFR Part 46. Where applicable, the HAC meets the requirements of the International Conference for Harmonization (ICH), in so far as they are consistent with FDA regulations. The HAC is directly supported by the MCG Vice President for Research. The HAC members not only have direct access to the Vice President for Research, on matters concerning the HAC and the HRPP, but the HAC Chairperson also has direct access to the President as the designated Institutional Official.

The HAC is responsible for determining whether an activity is research involving human participants based on the information provided by the investigator via the HAC Form 100 “Determining Whether a Proposed Activity is Human Research According to DHHS or FDA Regulatory Definitions Screening Tool and Cover Sheet”. The criteria used to make these determinations are:

- Activity is “Human Research” according to DHHS<sup>1</sup> regulations:**

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- I.  The activity involves research because all of the following are true:
- The activity is a systematic investigation, including research development, testing and evaluation
  - The activity is designed to develop or contribute to generalizable knowledge
- II.  The activity involves human subjects because all of the following are true:
- The investigator will obtain data about living individuals
  - Either or all of the following is true:
    - The investigator will obtain that data through intervention (physical procedures by which data are gathered and manipulations of the participant or the participant's environment for research purposes) with those individuals
    - The investigator will obtain that data through interaction (communication or interpersonal contact between investigator and subject) with those individuals
    - The information obtained is:
      - Private because the information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place OR the individual has provided the information for specific purposes and can reasonably expect that the information will not be made public (for example, a medical record)
      - Individually identifiable, because the identity of the participant is or may readily be ascertained by the investigator or associated with the information
- Activity is "Human Research" according to FDA regulations (Both of the following are true):**
- I.  The activity involves an FDA regulated test article because one or more of the following is true:
- The activity involves the use of a drug that is being used in the study for obtaining FDA approval for:
    - A new drug
    - An additional, or new, indication than what it was approved by the FDA for previously
  - The activity involves the use of a device to evaluate safety or effectiveness of that device;
  - Data from the activity will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product.

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- II.  The activity involves human subjects because one or more of the following is true:
- The test article will be used on one or more humans
  - Data obtained from controls will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product;
  - Data from the use of a device on tissue specimens will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product.

The process used to communicate these decisions from the HAC is an email from the HAC administrative office to the individual submitting the information for a decision.

### What Do You Need to Know Before Submitting a Protocol for Review to the IRBs?

Because MCG is an academic medical center, there may be several areas including departments, sections and approval committees that may impact your proposed research. The following information should assist in the facilitation of your research by identifying those areas.

Your first step will be to determine the type of research you plan to conduct. You may conduct multiple protocols and, as each protocol evolves; different types of reviews and approvals may be required. Although, the use of human subjects or human derived materials may differ for each protocol, the protections of human subjects or human derived materials remains equal.

If the protocol will utilize MCG Health, Inc. (MCGHI) resources (e.g., patients, personnel, equipment, space, supplies or records) and/or will be conducted by a faculty or staff member of the MCG School of Medicine (SOM), then the protocol must have MCGHI approval prior to the Institutional Review Board (IRB) (either HAC or CRRI, as appropriate) approval. Please contact the Medical College of Georgia (MCG) Office of Clinical Investigative Services (OCIS) Health System Review Office (HSRO) at (706) 721-6247 or visit their web page at <http://www.mcg.edu/OCIS/review.htm> for complete information on the MCGHI submission and approval process.

### Planned Emergency Research

The Medical College of Georgia does not review planned emergency research.

### How Do You Determine If The Planned Project Is Research Or Quality Assurance?

Yes	No	Research	Yes	No	Quality Assurance
		The goal of the project is to test an hypothesis			The goal of the project is to improve service delivery or administrative support at MCG/MCGHI or the Charlie Norwood VA Medical Center
		You are using scientific methods (e.g., controls, blinding, randomization) and the outcome of the project is uncertain			The project has a reasonable expectation of success

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Yes	No	Research	Yes	No	Quality Assurance
		The planned treatment/procedures deviate from normal clinical care			There is no change in normal clinical care or administrative support
		You expect to draw generalizable conclusions			The findings will be used to improve MCG, MCG Health, Inc. (MCGHI) or Charlie Norwood VA Medical Center patient service delivery or administrative service delivery only
		You expect to publish your findings ( <u>NOTE: Research can be conducted without the dissemination of the data</u> )			Publication is not intended, now or at any time in the future. <u>NOTE: Data can be disseminated regarding activities that do not meet the DHHS or FDA definition of “research” as stated in this policy and procedure.</u>
		Data will be submitted to an external group or program [such as the University Hospital Consortium (UHC) or another benchmarking organization] with a goal of drawing conclusions does constitute research			You are using tissues or samples without any identifiers.
		You are using human subjects			
		You are using tissues or samples with identifiers			

If your answers are yes to any of the questions on the left then submit a protocol to the HAC for review. (NOTE: These protocols are not eligible for review by Chesapeake Research Review, Inc.)

### **HAC Reporting Structure**

The HAC is autonomous in their review and determinations about research protocols. The HAC’s decision to disapprove a research protocol cannot be overruled. Officials of MCG, MCGHI and the Charlie Norwood VA Medical Center are prohibited from approving research that has not been approved by the HAC or CRRI.

### **Undue Influence**

If the HAC chairperson, member, faculty member, student or staff person feels that the HAC has been unduly influenced by any party, they shall make a confidential report to the must be reported to the OHRP Director, Vice President for Research and/or Provost and/or President, depending on the circumstances. The institution will conduct a thorough investigation and, if

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warranted, corrective action will be taken to prevent additional occurrences. Upon notification, the OHRP Director will initiate an investigation within one week. The findings of the investigation will be reported to the institutional officials and recommendations for further actions will be made. In the event that the undue influence prohibits the protection of human research subjects at the institution, the OHRP Director will contact the Department of Health and Human Services for guidance.

### **HAC Jurisdiction**

The HAC has review jurisdiction over all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that has adopted the human subjects' regulations.

### **OHRP Support to the HAC**

The OHRP supports the HRPP by providing educational programming for the HAC and investigators (including faculty, staff or students), providing regulatory guidance to the HAC and investigators (including faculty, staff or students), and providing administrative support to the both IRBs for the review process and record keeping. The Director and Assistant Director work closely with the Chairperson of the HAC in the development of policy and procedures and forms. The OHRP Director and Assistant Director are not voting members of the HAC.

### **HAC Administrative Office**

The MCG HAC Administrative Office reports directly to the Assistant Director of the Office of Human Research Protection (OHRP). Indirect supervision is provided by the Chairperson and Vice-Chairperson of the HAC. All of these individuals have expert knowledge in the field of federal regulatory compliance, state law and institutional policies and procedures related to human subject protections in research. This includes responding to faculty, student, and staff questions about human subjects' research as well as organizing and documenting the review process.

### **Certification of HAC Approval**

The HAC approval letter issued by OHRP staff, on the behalf of the HAC, serves as certification of HAC approval for each application or proposal of research covered under MCG's FWA. For research involving the Charlie Norwood VA Medical Center, an additional certification of HAC approval, Report of Subcommittee on Human Studies, VA Form 10-1223 will be provided to the Charlie Norwood VA Medical Center Research and Development (R&D) Office and the investigator upon receipt. All of these certifications are provided by OHRP on behalf of the HAC and the institution.

An Exemption letter will be issued by OHRP staff for each application or proposal determined to involve human subjects that is limited to one or more of the six exempt categories listed in the regulations [45 CFR 46.101(b)] or if the research is determined to be exempt by virtue of it not meeting the definition of research involving human subjects. The HAC Chairperson or his designee reviews and grants exemptions for the individual research protocol and provides certifications of the exemption determination via an approval letter.

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In addition, an Expedited Category approval letter will be issued by OHRP staff for each application or proposal determined to involve human subjects that is limited to one or more of the seven expedited categories listed in the regulations [45 CFR 46.101(b)]. Certifications of an expedited determination are provided by the HAC Chairperson or his designee has reviewed and granted an approval for the individual research protocol.

### **HAC Relationships**

The HAC functions independently of but in coordination with, other institutional regulatory committees. The HAC however, makes its independent determination whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected.

### **Chesapeake Research Review, Inc**

Chesapeake Research Review, Inc. (CRRI) was added to the FWA (MCG, MCGHI and MCGRI) in July 2005 for industry-sponsored, industry-initiated, multi-center clinical trials that will not be conducted at the Charlie Norwood VA Medical Center. CRRI has registered with the DHHS under registration number IRB00000790. They are an accredited HRPP with AAHRPP.

### **CRRI Jurisdiction**

The CRRI has review jurisdiction only over research that is industry-sponsored, industry initiated, multi-center clinical trials that will not be conducted at the Charlie Norwood VA Medical Center.

### **OHRP Support to CRRI**

The OHRP supports the HRPP by providing information on the potential subject and research community for CRRI, providing institutional guidance for CRRI education to the research team members, and providing auditing and compliance monitoring and support to CRRI.

### **CRRI Relationships**

The relationship between MCG and CRRI is evaluated on an annual basis and is documented in a written workflow agreement. The CRRI functions independently of but in coordination with, other institutional regulatory committees. The CRRI, however, makes its independent determination whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. Officials of MCG, MCGHI and the Charlie Norwood VA Medical Center are prohibited from approving research that has not been approved by the HAC or CRRI. Officials of MCG, MCGHI and the Charlie Norwood VA Medical Center are prohibited from approving research that has not been approved by the HAC or CRRI. Any undue influence must be reported to the OHRP Director. Upon notification, the OHRP Director will initiate an investigation within one week. The findings of the investigation will be reported to the institutional officials and recommendations for further actions will be made. In the event that the undue influence prohibits the protection of human research subjects the OHRP Director will contact the Department of Health and Human Services.