

Human Research Protections Program (HRPP)

What is an Institutional Review Board (IRB)?

An IRB is any group or committee formally appointed by an institution to conduct initial or continuing review of a research protocol, to require modifications, to observe the consent process and protect the rights and welfare of human subjects and/or human derived materials in compliance with the federal regulations, state law as well as the ethical principles and regulations. An IRB is an independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

An IRB may also be referred to as Ethical Review Board (ERB) or an Independent Ethics Committee (IEC).

How Many IRBs Does the Institution Have?

The institution has two IRBs: Human Assurance Committee (HAC) and Chesapeake Research Review, Inc. (CRRI). Some protocols may be eligible for review by the commercial IRB, Chesapeake Research Review, Inc. (CRRI). There is a comparison page on the OHRP web site for your convenience. For additional information and to determine if your protocol meets the eligibility requirements, call (706) 721-1478. All other protocols must use the HAC. All students, faculty and staff that are involved in the conduct of research, regardless of its location, must comply with this institutional requirement.

What is a Privacy Board?

A Privacy Board is a review body that may be established to act upon requests for a waiver or an alteration of the Authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research study. A Privacy Board may waive or alter all or part of the Authorization requirements for a specified research project or protocol. A covered entity may use and disclose PHI, without an Authorization, or with an altered Authorization, if it receives the proper documentation of approval of such alteration or waiver from a Privacy Board. An IRB can also serve as the Privacy Board if asked by the institution.

Who Serves as the Privacy Board for Research Matters?

The HAC and CRRI are the Privacy Boards.

What Web Resources are Available?

Access to current forms, guidance documents, training opportunities, IRB Rosters and the Federalwide Assurance (FWA) numbers are available on the MCG OHRP web site. Updates and other information related to deadlines, new forms or policies, etc., are posted on the web site as relevant. "Need to Know" postings in the MyMCG portal and direct emails are also sent and updates are posted in the MCG OHRP office. Public announcements are made at the Research Coordinators United in Excellence (RESCUE) meetings. Direct emails are also sent from the Vice President for Research.

The MCG OHRP has posted a decision tree from the Department of Health and Human Services

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(DHHS) Office for Human Research Protections (OHRP) to assist in determining if an activity is research. The decision tree is posted at <http://www.mcg.edu/research/ohrp/hac/decchart.pdf>

Are Other Approvals Required in Addition to the IRB Approval?

Approvals by other committees and/or services as listed below may be required prior to HAC approval release or MCG OHRP release for CRRRI approval. Please note that the HAC and MCG OHRP serve as gatekeepers for these approvals and cannot release IRB approval until these are met (as applicable):

- Institutional Biosafety Committee (<http://www.mcg.edu/research/ibc/>)
- Institutional Chemical Committee (<http://www.mcg.edu/services/ehs/chemsafe/chemsafe.htm>)
- Radiation Safety Committee, Human Use Sub-Committee (<http://www.mcg.edu/services/ehs/radsafe/RadSafe.htm>)
- Information Technology Support Services (<http://www.mcg.edu/itss/>)
- Graphics Standards Committee (<http://www.mcg.edu/research/ohrp/irb/hac/templates.asp>)
- MCG Health, Inc (MCGHI) Office of Clinical Investigative Services (OCIS) Health System Review Office (HSRO) (<http://www.mcg.edu/OCIS/review.htm>)
- For Charlie Norwood VA Medical Center studies, all appropriate approvals from sub-committees such as Radiation Safety or Biosafety must be met prior to releasing any HAC approval.

What are the Roles and Responsibilities of Research Team Members?

There are multiple roles that may be assigned to an individual during the life cycle of a research protocol. Most of these roles may be easily defined as Principal Investigator (PI) or Project Director (PD), Sub-Investigator (SubI), Faculty Sponsor (FS), Study Coordinator (SC), Administrative Contact or other key personnel. There are other roles that may not be as easily defined.

Each role is required to protect the rights and welfare of human subjects and/or human derived materials. These protections may be tangible protections such as locks on doors to prevent unauthorized physical access or they may be as intangible as maintaining the highest level of confidentiality.

Investigator Responsibilities

Refer to the Office of Human Research Protection (OHRP) Standard Operating Procedure (SOP) for information regarding the Principal Investigator.

What is a Principal Investigator?

The term Principal Investigator (PI) defined as the individual under whose immediate direction the research activities (i.e., focus group, survey, and drug or device trial) occur. It is the current policy of the Medical College of Georgia (MCG) to allow only one PI. The term Co-PI is currently not recognized at this institution. The term Project Director is synonymous with PI.

What are my Responsibilities as a Principal Investigator (PI)?

The protection of human research subjects is a shared responsibility between the PI, the institutional review boards [Human Assurance Committee (HAC) or Chesapeake Research

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Review, Inc (CRRI), as applicable] and the sponsor (as applicable). The PI must acknowledge that regulations governing human subjects' research are an additional area of expertise and that the OHRP staff, members of the HAC and CRRI staff are available to provide guidance as needed.

The PI is ultimately responsible for:

- Submitting their proposed research for approval by the IRB (either HAC or CRRI, as appropriate). All research involving human subjects (including records, surveys, tissues or other human-derived materials) conducted at MCG, MCG Health, Inc. (MCGHI), or by MCG or MCGHI faculty, staff or students must be reviewed and approved in writing by the IRB (either HAC or CRRI, as appropriate). The Human Assurance Committee (HAC) must approve all research conducted at the Charlie Norwood VA Medical Center (VAMC) or by the Charlie Norwood VA Medical Center investigators (including students). The PI is also responsible for submitting the protocol to the VAMC Research and Development Committee if the protocol will be conducted at the Charlie Norwood VA Medical Center. Additional review by other IRBs, other approval bodies or committees may be required in some cases.
- All actions that take place during a clinical study to ensure patient/subject safety at all times by abiding by and promoting Good Clinical Practices (GCP) guidelines. The PI may delegate some tasks and responsibilities but retains ultimate responsibility for the ethical conduct of the research. It is strongly encouraged that all delegations be made in writing.
- Training and communicating with research team members in an interactive conversation and dialogue regarding the conduct of the research protocol.
- Requesting continuing review of the research and ensuring the IRB (either HAC or CRRI, as appropriate) that the research is proceeding according to all applicable regulations.
- Notifying the IRB (either HAC or CRRI, as appropriate) of any upcoming audits (sponsor, FDA, OHRP, etc.) and then providing the IRB (either HAC or CRRI, as appropriate) with a copy of the audit report. Notification of a routine monitoring visit is not required.
- Reporting to the IRB any findings and allegations of non-compliance.
- Notifying the IRB (either HAC or CRRI, as appropriate) in writing prior to leaving MCG, MCGHI or the Charlie Norwood VA Medical Center. Prior to the PI leaving the institution, a list of all active studies, by title and IRB file number, must be submitted to the IRB of record with a request to terminate the study or with designation of a new PI. In the latter case, revised written Informed Consent Document(s) (ICD) and/or Children's Assent Document(s) (CAD) must be approved by the IRB before transfer of the study. IRB approval of the study will be terminated if the PI does not take these steps before leaving the institution. HAC must also be officially notified of all Sub-I and/or SC changes.

All investigators (PI and Sub-I) are responsible for:

- Communicating with all members of the research team regarding the study, the research subjects or any items related to the conduct of the research study.

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- Serving as the ultimate protector of the subject's rights and safety. Each investigator is obligated to be personally certain that each research subject is adequately informed and freely consents to participate in the investigator's research.
- Personally assuring that every reasonable precaution is taken to reduce to a minimum any risk to the subject.
- Ensuring that all research subjects are fairly and equitably chosen.
- Compliance with all federal, state, and institutional rules and regulations related to research involving human subjects and human subject-derived information and materials.
- Understanding the implications of his/her evolving role from health care provider to research investigator, as applicable. A patient is no longer just a patient when they are a research subject. The protocol will determine the care of the subject while a physician may determine the care of his/her patient.
- Assuring that only licensed and/or otherwise qualified individuals perform study related procedures with the appropriate level of supervision under the laws of the state of Georgia and the policies of MCG, MCGHI, and/or the Charlie Norwood VA Medical Center. The investigator will not deviate in any way from the IRB (either HAC or CRRI, as appropriate) approved protocol unless the Committee has provided written notice of approval to the investigator's written request unless such a change is immediately required to reduce risk to the subjects. This includes such changes that may be part of the routine standard of care for patients unless it reduces risks.
- Providing the subject's health care provider with any important information regarding the subject's health that may occur during the course of the research.
- Properly obtaining informed consent and documenting the informed consent process in the source documents which includes the hospital medical record and/or research record. Documentation of the subject's willingness to participate and the volunteering of informed consent prior to any study related procedures should also occur as this is required by federal regulations. This process is required for all studies including behavioral type studies. The continuing informed consent must also be noted. The documentation of informed consent must be maintained in compliance with institutional policies, FDA regulations, DHHS OHRP regulations, VHA regulations, ICH regulations or contractual obligations, as applicable.
- Becoming familiar with the appropriate sections of the federal regulations for human subject and/or human materials research including the Code of Federal Regulations (CFR) and the Internet at GPO Access (<http://www.access.gpo.gov>):
 - 45 CFR Part 46 for the Department of Health and Human Services (DHHS)
 - 21 CFR Part 50 for the Food and Drug Administration (FDA)
 - 21 CFR Part 56 for the FDA
 - 21 CFR Part 310 for the FDA
 - 38 CFR Part 16 for the Veterans Health Administration (VHA)
 - VHA Handbook 1200.5
 - HIPAA regulations related to research

In order to fulfill these responsibilities, the PI should:

- Be aware that not all responsibilities or scenarios can be foreseen or covered in a manual.
- Be aware of resources available, including, but not limited to the:
 - MCG Human Assurance Committee (HAC), as applicable

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- Chesapeake Research Review, Inc. (CRRI), as applicable
- MCG Office of Human Research Protection (OHRP)
- MCG Division of Sponsored Programs Administration (DSPA)
- MCGHI Clinical Research Pharmacy (CRP)
- Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP)
- Food and Drug Administration (FDA)
- Have realistic expectations of research team members and understanding of their positions and time commitments.
- Have access to the Internet.
- Understand and follow institutional policies, standard operating procedures and guidance concerning human subject research.
- Understand and follow FDA rules and regulations concerning human subject research.
- Understand and follow DHHS OHRP rules and regulations for human subject research.
- Understand and follow International Conference on Harmonization (ICH) guidelines, if appropriate.
- Have access to and read/respond to email.
- Have access to the electronic medical records, if appropriate.
- Have access to the electronic scheduling system for patient/subject information, if appropriate.
- Attend and participate in the training classes offered by the OHRP. The PI is also responsible for ensuring that all members of the research team are current with their training requirements.
- Obtain informed consent and continuing consent from subjects.
- Carefully review lab reports and subjects history/physical findings noting any abnormalities while reviewing in the context of known effects of drug/device under study.
- Delegate duties of research team in writing.
- Understand and abide by the investigator's responsibilities as outlined in the current IRB (either HAC or CRRI, as appropriate) policies and procedures including those as outlined on the Form FDA 1572 (as applicable).
- Encourage research team and provide financial support for professional growth.
- Complete required education for human subjects' protections per MCG administrative policies and procedures.
- Ask questions when needed and encourage other research team members to do the same.
- Report to the IRB any findings and allegations of non-compliance.

What if I Conduct Research Here and at Other Institutions?

Any study involving another institution that wishes to use an investigator at MCG, MCGHI, or the Charlie Norwood VA Medical Center must be approved by the appropriate Institutional Review Board (IRB) of record for MCG. Other IRB approvals for different sites (if granted) or the submission date to the other IRB must accompany the application. Information regarding protocol disapprovals must also be included.

What is a Faculty Sponsor (FS)?

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A Faculty Sponsor (FS) is a faculty member who serves as a guiding mentor for an undergraduate or graduate student research project.

What Are My Responsibilities as A Faculty Sponsor (FS)?

The responsibilities for a FS are those for a PI and should not be accepted lightly. The FS must be actively involved in the research, from the protocol design to the data analysis and report preparation. The FS will be responsible for the protocol if a student leaves the institution prior to completing the research protocol. The FS must fully understand and commit themselves to these responsibilities before assuming this role.

What is a Sub-Investigator?

The term Sub-Investigator (Sub-I) may include any other individual member of the research team. [21CFR 312.3] and is generally understood to mean those individuals engaged in the informed consent process or who will have a significant role in the design or conduct of the research. However, all individuals who may obtain informed consent must be approved by the IRB (either HAC or CRRI, as appropriate).

What are My Responsibilities as a Sub-Investigator (Sub-I)?

The responsibilities are the same as those for the PIs and are outlined in the PI section.

What is a Study Coordinator (SC)?

Many investigators delegate the day-to-day administrative requirements of a protocol to the clinical and non-clinical research study coordinator (SC). The link between the subject, the investigator and the sponsor is important to the safe and ethical conduct of any clinical research trial. The duties and responsibilities of a SC may vary across different infrastructures. Broadly speaking, the coordinator generally manages the administrative responsibilities of the trial including research subject participation and acts as a liaison between the trial site, sponsor, and research subject.

The coordinator must make every effort to:

- Ensure subject safety by providing information regarding adverse events and any pertinent information to subjects and investigators in a prompt manner.
- Serve as an advocate for the research subject.
- Facilitate information exchange among sponsor/Contract Research Organization (CRO), investigators, faculty, staff, research subjects, the subject's representatives and/or families or other support system.
- Work directly with prospective and enrolled subjects and their families or caregivers, as applicable.
- Provide safety and protection to all subjects while collecting and managing data obtained from the subject for the study.
- For some studies, the SC may promote, advertise, and conduct telephone and face-to-face screenings to recruit potential subjects.
- May assess and coordinate the research subject's clinical/laboratory testing and physical exams, if licensed and trained appropriately.
- May obtain vital signs such as height, weight, blood pressure, respiration rate, and pulse.
- May withdraw blood and/or obtain, process and ship blood/urine specimens.

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- May follow up with subjects after the study activity ends.
- Manage a great deal of paperwork, electronic correspondence and data.
- May also be listed as a Sub-I at the discretion of the PI.
- Reporting to the IRB any findings and allegations of non-compliance.

What are My Responsibilities as a Study Coordinator?

The responsibilities of a SC may vary from study to study but generally include the following broad guidelines:

- Communicate with all members of the research team regarding the study, the research subjects or any items related to the conduct of the research study.
- Personally assure that every reasonable precaution is taken to reduce to a minimum any risk to the subject.
- Ensure that all subjects are fairly and equitably chosen.
- Compliance with all federal, state, and institutional rules and regulations related to research involving human subjects and human subject-derived information and materials.
- Understand the implications of his/her evolving role from health care provider to research team member, as applicable. A patient is no longer just a patient when they become a research subject. The protocol will determine the care of the subject while a physician may determine the care of his patient.
- Assist the principal investigator to assure that only licensed and/or otherwise qualified individuals perform study related procedures with the appropriate level of supervision under the laws of the state of Georgia and the policies of MCG, MCGHI, and/or the Charlie Norwood VA Medical Center.
- The SC will not deviate in any way from the IRB (either HAC or CRRI, as appropriate) approved protocol unless the Committee has provided written notice of approval to the investigator's written request unless such a change is immediately required to reduce risk to the subjects. This includes such changes that may be part of the routine standard of care for patients unless it reduces risks.
- Provide the subject's health care provider with any important information regarding the subject's health that may occur during the course of the research.
- Report to the IRB any findings and allegations of non-compliance.

Is There a Checklist to Help Me Understand My Responsibilities as a Study Coordinator?

Please be aware that not all responsibilities or scenarios can be covered. The following checklist is a brief listing of items and systems that will aid the clinical and non-clinical SC in assisting the investigator in meeting the requirements of a protocol:

- Be aware of and utilize resources available, including, but not limited to:
 - Human Assurance Committee (HAC) and web page, as applicable
 - Chesapeake Research Review, Inc. (CRRI), as applicable
 - Office of Human Research Protection (OHRP) web page
 - Division of Sponsored Programs Administration (DSPA) and web page
 - Clinical Research Pharmacy (CRP)
 - Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP) web page
 - Food and Drug Administration (FDA) web page
 - MCG Home Page

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- Notify investigators of changes, updates, etc. when appropriate.
- Have access to the internet, specifically the MCG home page (www.mcg.edu), the FDA home page (www.fda.gov), Center for Drug Evaluation and Research (CDER) home page, etc.
- Understand and follow institutional policies and procedures concerning human subject research. Notify investigators of changes, updates, etc. when appropriate.
- Understand and follow FDA rules and regulations concerning human subjects. Notify investigators of changes, updates, etc. when appropriate.
- Understand and follow DHHS OHRP rules and regulations for human subject research. Notify investigators of changes, updates, etc. when appropriate.
- Understand ICH guidelines, if applicable. Notify investigators of changes, updates, etc., when appropriate.
- Have access and read/respond to email.
- Have access to the electronic medical records system, if appropriate.
- Have access to the electronic scheduling system for patient/subject information, if appropriate.
- Attend and participate in the training classes offered by the OHRP.
- Accurately and promptly complete case report forms (CRF) or data collection tools (DCT).
- Assume personal responsibility for professional growth through such avenues as certification, education, etc.
- Attend and participate in the bi-monthly **RESCUE** meetings.
- Facilitate information among sponsor/CRO, investigators, faculty, staff, research subjects, subjects' representatives and/or families.
- Understand and abide by responsibilities as outlined by MCG Health, Inc. (MCGHI), if appropriate.
- Complete required education for human subjects' protections per MCG administrative policies and procedures.
- Ask questions when needed and encourage other research team members to do the same.

Who Are Research Team Members?

Research team members are all persons who will have a significant role in the design or conduct of the research. At a minimum, the team consists of the Principal Investigator (PI), Sub-Investigators (Sub-I), Study Coordinators and other individuals or personnel who may be named on a grant or contract application, who may be listed on the Form FDA 1572, who are named as contact persons in the informed consent document (ICD) or any recruitment materials, or who provide supervision of the persons conducting the research. For additional information on the roles and responsibilities of these individuals please refer to the section on Investigators and Research Team Members.

Research Conducted with Investigators That Do Not Have an Affiliation with MCG, MCGHI or the Charlie Norwood VA Medical Center

Research protocols may include investigators who do not have an affiliation with MCG, MCGHI or the Charlie Norwood VA Medical Center to conduct the research. Each investigator must complete an "Individual Investigator Agreement (IIA)" prior to IRB approval. The IIA

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documents the roles and responsibilities of each investigator and replaces the CPRP agreement. The IIA is available on the web site.

Investigators with an MCG appointment and are not required to complete the IIA. If a performance site includes multiple investigators (e.g., a private practice with five clinicians, etc.), then each individual member of the practice must complete the IIA. In addition, the performance site itself must complete a Memorandum of Understanding (MOU) to fully document the overall site support of the research arrangement.

Research Conducted with Other Institutions or Performance Sites

The relationship and duties for each site should be documented in a Memorandum of Understanding (MOU) or other written agreement. The IRB (either HAC or CRRI) may require a copy of the IRB approval letter from that institution or other performance site. The IRB (either HAC or CRRI, as appropriate) may serve as the IRB of record with a properly executed IRB Authorization Agreement. Please note that the IRB does not approve these agreements. The MCG OHRP staff will route these agreements for the approval of the FWA institutional official. If the other institution or performance site has a federalwide assurance (FWA), then the appropriate FWA for MCG, MCGHI or the Charlie Norwood VA Medical Center FWA must be revised to include this site.

Research Conducted in an International Setting

Research conducted outside the United States by MCG, MCGHI or Charlie Norwood VA Medical Center investigators also falls under the appropriate FWA for each institution. While each culture is respected for its differences, the human subjects' protections must be equally applied and the research must be approved by their local equivalent of an institutional review board. The IRB (either HAC or CRRI, as appropriate) must be provided with this documentation. Ad hoc members may be added to the IRB (either HAC or CRRI, as appropriate) to meet the requirement for knowledge of local context.

All international sites conducting federally funded research must obtain an Assurance for International Institutions. For additional guidance please contact the MCG OHRP.