

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

### **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 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.
- 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
  - 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.