

Chapter 3

The Research Approval Process

A. Human Subjects Research

CAMC Policy states that research involving human subjects can be undertaken when approval has been granted by the appropriate institutional bodies. Research studies may not begin until the Principal Investigator has received a letter of approval from the Chairperson of the CAMC/WVU Institutional Review Board and the necessary approvals from Research and Grants Administration.

B. Who Can Lead a Research Investigation

2003 JCAHO Standards (pages 83 and 93) require that an IRB Board approve the conduct of a research project *based upon the expertise and qualifications of the investigators and staff to be involved in the conduct of the study*. All approved research or grant funded projects must identify a responsible Principal Investigator (PI) who will be primarily responsible for the conduct of that study.

More Than Minimal Risk Studies:

1. Research studies that are designated as "More Than Minimal Risk" or "Significant Risk" by the IRB, and/or that are subject to FDA audit, require that the PI hold a doctoral level degree and/or licensed medical degree, as needed, in order to be appropriately qualified to conduct the study.

Employees:

2. Employees of the CAMC Health System who hold a Bachelor's degree or above are eligible to serve as Principal Investigator(s) of exempt and expedited research studies subject to qualifications, department head approval, IRB and Scientific Review Board approval, and other required institutional and administrative approvals.
Note: Departments may implement higher, but not lower standards and qualifications for the role of Principal Investigator.

Pursuit of Advanced Degrees:

3. Individuals (i.e. employees and non-employees) completing doctoral degree requirements by conducting their research dissertation at CAMC facilities may serve as the PI for that research study with appropriate on-site professional/faculty/clinical supervision by an individual who holds an appropriate doctoral degree. The supervisor is not required to serve as a co-PI or investigator on the doctoral research dissertation.

Student Research:

4. Students participating in medical, nursing and allied health programs, or employees who are enrolled in a degree-granting program who are required to conduct a research project as part of the program/curriculum requirements for completing the degree either at CAMC or outside of CAMC, may not serve as PI's of research studies that will be

conducted at CAMC or CAMC facilities. In order to conduct research at CAMC facilities, the student must align him/herself with an appropriately qualified professional at the Master's level or above, at the medical center who is interested in pursuing this research, qualified, and agrees to serve as Principal Investigator. The student may then serve as an Investigator on the approved study. The non-student PI will be responsible for continuing review and closure of research studies.

Non Employees:

5. Undergraduate students and students completing the Master's Degree requirements who are not employed by CAMC and who wish to conduct research at CAMC or CAMC facilities as part of their curriculum requirements must adhere to CAMC research policies and procedures and align him/herself with a qualified professional at the Master's level or above at the medical center who will agree to serve as the on-site Principal Investigator (PI). The student may then serve as an Investigator, as appropriate, on the approved study. The non-student PI will be responsible for continuing review and closure of research studies.

All students must submit a letter of approval from their thesis/dissertation Chairperson and/or committee, their affiliated university IRB, as indicated, and/or faculty advisor as needed. Students shall prepare appropriate written documentation and informed consent form for review by the IRB. With respect to student research, the consent form may be on either the departmental letterhead of the student's Principal Investigator or faculty advisor, or on the letterhead of the student's educational institution.

Note: If the study will involve CAMC inpatients, signature approval from the appropriate Medical Director of that unit is required. Medical records/data access or patient access on a unit is not permissible without prior written approval from each patient's attending physician.

If the above guidelines do not meet your particular circumstance, you will need to contact the Office of Research and Grants Administration (RESEARCH AND GRANTS ADMINISTRATION...) at 388-9970 for additional directives.

C. Research Team

A research study, or clinical trial may be composed of the following individuals depending upon the nature of the study:

1. **Principal Investigator (PI)/ Project Director (PD)** means an individual directing a research (grant)/study being conducted at CAMC or WVU-Charleston Division. Every research study or funded project must have a responsible Principal Investigator (PI) or Project Director (PD).

Responsibilities and accountabilities:

- accepts accountability for the study
- being aware of and adhering to CAMC's research and grant policies,
- representing the study or project within CAMC and serving as the principal contact,
- obtaining all required approvals,

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- ensuring a study is conducted as stated in the approved protocol,
- assuring that all personnel involved in the study or project adhere to policies regarding confidentiality, scientific integrity and conflict of interest.

2. **Co-Investigators/Sub-Investigators:** CAMC will permit the participation of Co-Investigators/Sub-Investigators who act as an agent of the Principal Investigator and who are actively conducting the research along with the PI. Investigational Drug Trials will require that each Investigator sign the FDA Form 1572. By signing FDA Form 1572 the Investigator assumes responsibility for the conduct of the Clinical Trial and adherence to all applicable laws, rules, regulations, and guidelines and this policy. The PI(s) and any Co-Investigator(s) shall assume responsibility for participation in the Clinical Trial and shall ensure compliance with all applicable laws, rules, regulations and guidelines and this policy. **Each Co-Investigator/Sub-investigator must be identified on FDA Form 1572.** Investigators may have additional offices where subjects will be evaluated for study inclusion. These locations must be listed on the FDA Form 1572. **Note: Only investigators listed on the IRB approved protocol and the Sponsored Projects Approval Form shall be considered "approved" investigators for that study. Note that NIH grants do not acknowledge the “Co-Principal Investigator” title.**

3. **Study Coordinator:** A PI may designate an appropriately trained individual to monitor the daily progress of a research study. Physician assistants, research assistants, and nurses are examples of acceptable Study Coordinators. Selection will depend on the type of study to be conducted. The Study Coordinator need not be a person qualified to diagnose and treat a disease or other condition for which the Investigational Product or Procedure is under investigation; however, qualifications must be reflective of the protocol requirements.

4. **Non-Investigator Nurses:** PI's will be required to facilitate the collaboration between investigators and the nursing staff in the patient care areas where patients will be recruited or located. The PI and/or Study Coordinator must notify the appropriate Nurse Manager(s) of nursing staff participation, and obtain the signature(s) of the Nurse Manager(s) (See Form 7 in the Research Approval Formset). The PI/study coordinator should discuss the approved protocol with the Nurse Manager and provide a planned inservice to the nursing staff of the unit(s) where the study will be conducted.

Obtaining informed consent from subjects is considered the responsibility of the investigators and/or his or her designee. (Jan 2000)