

Chapter 8

THE COMPONENTS OF INSTITUTIONAL RESEARCH APPROVAL

A. Components of the Institutional Research Review and Approval Process

There are six overall components of the Research Approval Process at Charleston Area Medical Center and WVU-Charleston Division:

1. **Determination of Research Review/Protocol Application Development**
2. **Completion of IRB Application and Informed Consent**
3. **Special Clearance Forms**
4. **Submission of Materials**
5. **Pre-screening of Materials**
6. **Institutional Approval**

Principal Investigators or other interested persons should contact the **Office of Research and Grants Administration** as soon as possible to discuss potential protocols. The Institutional Review Board for the Protection of Human Subjects (IRB) is located within the Office of Research and Grants Administration. The Investigator is responsible for obtaining a copy of the Research Policy Handbook and a Research Approval Formset from the Office Research and Grants Administration. The IRB Coordinator will verify whether the potential study involves human subjects.

B. Special Clearance Forms

Special departmental approvals and/or clearances may be required based upon the nature of a particular study. These clearance forms are identified on the IRB applications and are included in the Research Approval Formset. Depending on the study being proposed, any or all of the following forms may need to be completed:

Form 5 - Drug Data Form

If the research study involves medications, whether these are FDA-approved or investigational drugs, the investigator is required to meet with the Investigational Drug Pharmacist to discuss the services needed and to develop a budget.

Form 6 - New Technologies (Device) Data Form

Research that involves the use of a non-FDA approved (investigational) device or the testing for safety and efficacy of the "off label" use of an existing FDA approved device, will require approval by the Director of Safety and physician credentialing approval by the Vice President for Medical Affairs.

Form 7 - Laboratory and Pathology Data Form

If the research study will require the use of CAMC's laboratories and/or department of pathology, the investigator is required to submit the protocol to the Director of Laboratories and Pathology in order to obtain approval.

Form 8 - Research Patient Charges Identification Form

Research that involves tests or procedures that will be administered to CAMC patients, and that will be covered by a grant or sponsoring company and not billed directly to the patient, requires the Investigator to obtain a special billing number from the Department of Patient Accounts prior to the start of the study.

Form 9 - Notification/Information of Nursing Participation on a Research Protocol

The Investigator will be responsible for notifying the appropriate Nurse Manager that patients on his/her floor will be involved in a research study, and for any education necessary on that unit as it relates to the study protocol. Approval of the Nurse Manager is necessary for all inpatient research studies.

Form 10 - Sponsored Projects Approval Form

If your research study is requesting resource support, i.e., financial, drugs, devices, supplies or equipment, from a source other than CAMC/CAMC Institute, or an internal funding source, it qualifies as "sponsored" research and must receive the appropriate institutional approvals prior to study implementation.

Form 11 - Radiation Safety Office Proposed Use of Radioactive Materials

Investigators who propose to use radioactive materials in a research study are required to contact the CAMC Health Physicist to discuss the development of the protocol and to obtain the approval of the CAMC Radiation Safety Committee.

Form 12 - Administrative Signature Approval for Research

Required for all research. Approval of the appropriate Vice-President is required for all projects that will involve CAMC or the CAMC Institute, and WVU-Charleston Division. The Office of Research AND Grants Administration will obtain administrative approval for Expedited and Full-Board research. Vice Presidents/Presidents will serve as primary signatory approval and will have a maximum of one week to review, sign and return the form(s) to the Office of Research and Grants Administration.

Form 13. Administrative Signature Approval for Sponsored Projects

Required for all research. Approval by the appropriate Vice-President/President is required for all projects that will involve CAMC or the CAMC Institute, and WVU-Charleston Division. The investigator(s) are responsible for obtaining the administrative approvals prior to submission of the Sponsored Projects Approval Form to the Office of Research and Grants Administration. Failure to do so may delay the submission of your grant proposal.

All special clearances must be completed and signed by the designated department Director and attached to the application at the time of submission. Failure to obtain Director approval may delay review of the study by the IRB.

C. Institutional Scientific Review

An *Institutional Scientific Review Board* (ISRB) is established as an institutional research review body to formally review all proposed "Investigator-initiated" (original) research studies for scientific validity. This Board is separate and distinct from the Institutional Review Board for the Protection of Human Subjects and is established to assist in the strengthening of the merit of the proposed research.

This review process provides an opportunity for comments and an objective and interdisciplinary perspective to the study investigators regarding the scientific and methodological aspects of their study. This process is intended to be helpful to the investigators as the institution continues to promote a higher level of quality in research. The Board will make every effort in this process to support the investigator without causing unnecessary delay in the research approval process.

Procedures:

The scientific review process will be applied to all expedited and full-board types of research.

Note: Individuals attempting to complete a master's program that requires review of their proposed research studies by a review committee will not require ISRB review.

All non-Exempt investigator-initiated research study protocols/IRB applications are due to the Office of Research and Grants Administration on the **first working day of the month**. Investigators should submit the **original only** to the Office of Research and Grants Administration at that time.

If your study protocol is a federal grant application, your completed/submitted grant application may be substituted for the **DISCUSSION** Section of the IRB application.

The Board will meet routinely the **second Monday** of each month to review all investigator-initiated proposed research studies. The Board will carefully review the protocol for methodological completeness and relationship to the research objectives. The statistical analysis and relationship to variables will also be assessed.

The Principal Investigator will be notified by fax on the **second Tuesday** of each month of the ISRB's comments and recommendations and be asked to respond to any concerns from the ISRB as they relate to study design, methodology and clinical application. Investigators will be asked to respond in writing to required elements/significant concerns prior to the IRB meeting or to notify the research office if changes will be made based on the suggestions noted in the response letter.

The Investigator will then have the opportunity to revise the protocol, as needed. The revised original protocol will be submitted along with 25 copies to the Office Research and Grants Administration. Office which will then make the protocol available to the IRB.

All Investigator-initiated protocols will be routed for administrative approval by the Office of Research and Grants Administration Coordinator. **Administrative approvals for all research protocols must be received in the Office of Research AND Grants Administration before research approval can occur.**

Appeal Process: If an Investigator strongly disagrees with the Institutional Scientific Review Board's comments and recommendations, the Investigator should notify the ISRB Chairperson in writing immediately to this effect to the attention of the ISRB Coordinator, WVU Building, Room 3273, Memorial Division, FAX 388-9976. A separate subcommittee of three members will be appointed to serve as the Appeals Committee. One member each will be appointed by the ISRB and the Director of Research and Grants Administration on behalf of the President of the CAMC Health, Education and Research Institute, and the Investigator(s).