

## Chapter 2

# Governing Principles of the IRB

### A. Definition:

**Board or IRB** refers to members of the Institutional Review Board for the Protection of Human Research Subjects acting collectively.

"IRB" generally means any Board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct periodic review of research involving human subjects (21 CFR 56.102). For purposes of these guidelines, IRB means the CAMC/WVU Institutional Review Board.

Respect for individuals and their rights and welfare are the basic tenets underlying the IRB guidelines. Statements supporting the ethical principles and standards adopted by the Board can be found in the following major documents that are on file in the IRB office:

The Declaration of Geneva  
The Nuremburg Code  
The Helsinki Declaration  
The Belmont Report

### B. Ethical Principles

The IRB guidelines are based on the following general ethical principles:

1. *The rights and welfare of all subjects must be adequately protected.* This principle applies to the need for safeguarding the physical and psychological well being of a subject and to preservation of the rights of privacy and self-determination.
2. *Risks must be minimized* by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. Whenever appropriate, investigators should use procedures already being performed on the subjects for diagnosis or treatment.
3. *Risks must be reasonable* in relation to anticipated benefits to subjects or to importance of the knowledge that may be gained. The Board reviews research for scientific merit with respect to the risk or benefit to human subjects, including the anticipated benefits from the knowledge that may be expected to result.
4. *Recruitment and selection of subjects must be equitable* within the confines of the purposes and design of the study; subjects must not be arbitrarily excluded on the basis of gender, race, national origin, religion, creed, education, or socioeconomic status.
5. *If informed consent* is required, it must be obtained from each subject or the subject's authorized representative.

- a. The informed consent process must be documented by a written "consent form," a copy of which must be given to the subject and subject's family/representative (if applicable).
  - b. To the fullest extent possible, the subject's consent must be based upon an understanding of the research, the risks, possible discomfort, benefits, and alternative procedures.
  - c. The informed consent document must provide the subject's ability to refuse participation to discontinue participation at any time without prejudice.
  - d. The informed consent document must be written in the subject's language.
6. Provisions must be made to monitor data to ensure the safety of subjects.
7. Adequate provisions must be made to protect the *privacy* of subjects and the *confidentiality* of data. In addition, the Board must be satisfied that questionnaires and protocols involving sensitive issues (which could, if they became known outside the research, place the subject at various physical or social risks) are carefully designed to avoid gathering more personal data than is absolutely essential to the research.
8. Additional safeguards must be included in the study to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence or who belong to potentially vulnerable populations.

In addition, several professional organizations and societies have formulated their own guidelines for research involving human subjects. Such guidelines can supplement but do not supersede or diminish the protections and requirements outlined here.

### **C. Authority of the Board**

The Board has the authority and responsibility to approve and monitor for compliance with sound ethical principles and applicable regulations all research involving human subjects conducted by faculty, medical staff, CAMC and CAMC employees, residents and students.

1. Approve or disapprove a protocol or to require modifications to a protocol (including the consent form) as a condition for approval;
2. Oversee the conduct of a study and require progress reports;
3. Suspend or terminate a study, or impose restrictions or require modifications to a study as a condition for continuation.

An investigator whose protocol has been disapproved, modified, restricted, suspended or terminated by the IRB may request the Board to reconsider the protocol or request the Board to convene an advisory review panel. No administrator, faculty, or medical staff can override Board decisions.

## **D. Retroactive Approval**

The Board does not have the authority to grant retroactive approval once human subjects (including human subject data) has been involved.