

## Chapter 1

# RESEARCH POLICY OVERVIEW

### A. Purpose

In 1966 the Surgeon General of the United States issued a formal policy statement on protecting human subjects in research sponsored by the Public Health Service. In response to that statement, West Virginia University formed its first Institutional Review Board (IRB) for the protection of human research subjects.

The Charleston Area Medical Center and West Virginia University/Charleston Division IRB was established at the Charleston Division Health Sciences Center in 1985 to protect human subjects in research sponsored by both federal and nonfederal sponsors. The purpose of the IRB is to protect the rights and welfare of individuals who serve as subjects of research conducted by medical staff, faculty, allied health professionals, staff and students, and to ensure institutional compliance with those ethical considerations contained in the Code of Federal Regulations (45 CFR 46). To meet these obligations, the IRB

- maintains guiding principles and operating policies (as contained in this document) demanding the highest professional standards in dealing with human subjects
- and
- reviews all research projects involving human subjects to ensure that appropriate standards are met and the research procedures do not infringe upon the safety, health, welfare, or life of those subjects.

### B. Institutional Policy

CAMC encourages investigators to conduct research that will contribute to the body of scientific knowledge and that will provide information and supportive programs that relate to the improvement of patient care and patient quality of life. Charleston Area Medical Center, Inc. (CAMC), recognizes the value of the clinical investigation of new devices, drugs, and other health products and procedures and their benefit to the applicable patient population.

As a site for the conduct of clinical trials for investigational drugs, devices, and other health products and procedures, CAMC is responsible for providing internal scientific and business standards and policies that will allow for a safe and compliant environment for the research and application of investigational devices, drugs and other health products and procedures. Accordingly, CAMC has adopted policies with respect to clinical trials conducted, in whole or in part, at CAMC facilities. The Department of Research and Grants Administration and appropriate related bodies and departments as required by federal regulations will oversee the implementation of the procedures and guidelines set forth.

CAMC Policy states that no research involving human subjects should be undertaken until the research project and/or grant application has been processed through the established policies, procedures and guidelines that follow. **Failure to comply with institutional research and grant policies may jeopardize the acceptance of a grant award, delay access to grant funds and jeopardize implementation of your research study.**

**COMPLIANCE WITH LAWS.** All research conducted with Investigational Products at CAMC shall comply with the Research Policy Handbook and with all applicable state and federal laws, rules regulations, guidelines and orders, including but not limited to:

1. Federal Policy for the Protection of Human Subjects;
2. The Food, Drug and Cosmetic Act;
3. The Medical Device Amendments of 1976;
4. The Safe Medical Devices Act of 1990;
5. The Medicare Manual;
6. FDA Investigational Device Exemptions Manual;
7. American Society of Hospital Pharmacists, Inc. Guidelines for the Use of Investigational Drugs in Organized Health Care Settings;
8. 21 CFR 50 [FDA: Informed Consent];
9. 21 CFR 56 [FDA: IRB Review and Approval];
10. 21 CFR 812 [FDA: Investigational Device Exemptions]; and
11. 21 CFR 813 [FDA: Investigational Intraocular Lenses],

as each may hereafter be modified, amended, supplemented, superseded or replaced.

## **C. JCAHO Standards**

The CAMC/WVU Institutional Review Board adheres to the JCAHO Standards of 2003 related to the protection of patients and their rights during research, investigation and clinical trials involving human subjects (JCAHO Standards RI.3).

The 2003 JCAHO Standards maintain, "a hospital that conducts research, investigations, or clinical trials involving human subjects knows that its first responsibility is to the health and well-being of the individual patient. To protect and respect patients' rights, CAMC

- Reviews all research protocols in relation to the hospital's mission statement, values, and other guidelines;
- Weighs the relative risks and benefits to the subjects;
- Obtains the subject's consent."

## **Standards**

RI.1.2.1.1 All patients asked to participate in a research project are given a description of the expected benefits.

RI.1.2.1.2 All patients asked to participate in a research project are given a description of the potential discomforts and risks.

RI.1.2.1.3 All patients asked to participate in a research project are given a description of alternative services that might also prove advantageous to them.

RI.1.2.1.4 All patients asked to participate in a research project are given a full explanation of the procedures to be followed, especially those that are experimental in nature.

RI.1.2.1.5 All patient asked to participate in a research project are told that they may refuse to participate, and that their refusal will not compromise their access to services.

RI.3 The Hospital protects patients and respects their rights during research, investigation, and clinical trials involving human subjects.

RI.3.1 All consent forms address the information specified in RI.1.2.1.1 through RI.1.2.1.5; indicate the name of the person who provided the information and the date the form was signed; and address the participant's right to privacy, confidentiality and safety.

TX.3.8 Investigational medications are safely controlled, administered and destroyed

JCAHO Patient Data Audits. All investigators should appropriately maintain all patient data materials and documentation and be prepared for any planned or unplanned JCAHO visit to the medical center setting.

Affirmation of the hospital's compliance and performance of these standards may be accomplished by any or all of those methods identified below:

- ◆ Reviewing the hospital's formal research policies and procedures
- ◆ Reading minutes of the IRB meetings
- ◆ Asking to see actual clinical trial protocols
- ◆ Interviewing staff, patients and families
- ◆ Conducting joint interviews with pharmacy, administrative staff, medical and nursing staff
- ◆ By inspecting research patient records

### **Requirements and Procedures for meeting JCAHO Standards**

#### **Hospital Responsibilities**

- Through the informed consent form, potential research patients are informed about potential risks, benefits, alternative treatments and therapies when available, additional costs to patients enrolled in research, if any, possible safety issues, drug interactions, diet restrictions, and the date of IRB approval. Consent documents also inform patients about their right to privacy and confidentiality.
- Forms are used as evidence of disclosure. The hospital is required to document evidence which protects patients and respects their rights during research investigations and clinical trials
- Hospital must safely control the administration of investigational medications when clinical trials are underway. Policies and procedures must be established as to who is authorized to administer investigational drugs or medications in a clinical trial. Pharmacy department will establish investigational drug service policies and procedures for staff and investigators.

#### **IRB Responsibilities**

The IRB, on behalf of the hospital, oversees these requirements:

- Reviews all research protocols in relation to the hospital's mission. Senior management verifies the project's compatibility with the hospital's mission.

- Weighs the relative risks and benefits
- Receipt of subject's consent
  - The consent form must be written in the patients' primary language, and contain understandable explanations. The forms must document the name of the person who administered the consent form and the date the informed consent was signed by the approved investigator and the patient.

### **Principal Investigator Responsibilities**

1. Patient charts should be clearly identified and labeled as research.
2. A copy of the research informed consent should be in the front of the charts.
3. If it is an investigational drug study or clinical trial, the drug information sheet should be in the front of the charts.
4. There must be a note from the PI or designated research nurse before treatment begins which includes:
  - a. Protocol name and number
  - b. Note that the consent form was explained thoroughly and all questions answered. Counseling sessions must be documented in medical records according to hospital policy.
  - c. Note that a copy of the consent form was provided to patients and their families
  - d. Time of randomization, if applicable
  - e. Documentation of patient education
5. PI's must enter progress notes on the patient chart every three days.

## **D. General Research Definitions**

**1. Research** is defined in the Code of Federal Regulations as "a systematic investigation designed to develop and contribute to generalizable knowledge." The FDA defines "research" as an activity "designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge".

Research is undertaken principally to provide a new understanding of diseases, treatments, methods of delivering treatments, enhancing compliance with treatments, or of the outcomes of treatments. For the purposes of this handbook, the term "study" will be used to identify research that has been approved by the IRB. The term "clinical trial" will denote research that involves investigational products.

- a. Examples of activities that constitute research include
  - Any organized collection of data intended to result in publication or public presentation
  - Any activity resulting in publication or public presentation, even though it involves only review of existing data that was collected with no intent to publish,
  - Any use of an investigational drug or device, or investigational use of approved devices for non-approved purposes.
  - Non-routine clinical care, including diagnostic tests.
- b. An example of activities that are not research would be:
  - Any evaluation of an employee, course, program or service where such evaluation is not designed to lead to generalizable knowledge,

- Quality Improvement/Utilization/Outcomes reports that are designed, without manipulation of data, for intra-institutional distribution or evaluation and that are not designed to lead to generalizable knowledge external to CAMC (i.e., professional presentation or publication on behalf of CAMC).
- Routine management initiatives.
- Descriptions of the impact of such initiatives.
- Individual clinical case reports of a provider's own patients.

**2. Human subjects** are defined not only as living persons, but also human tissue, blood samples, pathological or diagnostic specimens, study of medical records, observation of public behavior, and all questionnaires.

**3. Clinical Trial** means any systematic study on investigational drugs, devices, or other health products or procedures involving human subjects in order to discover or verify the effects of and/or verify any adverse reaction to the product or procedure, and/or to study their absorption, distribution, metabolism and excretion in order to ascertain the efficacy and safety of the investigational product for human use.

**4. Sponsored Research** means any study that receives assistance/support from an external organization in the name of the P.I. to assist the organization in the conduct of research or other activity. The support can be in the form of:

- Financial support
- Drugs
- Devices
- Supplies/equipment

**5. Research vs practice:** Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. "Practice" refers to interventions that are designed solely to enhance the well-being of an individual patient and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventative treatment or therapy to particular individuals.