

# Roles and Responsibilities of the Investigator and the Study Process

**At the conclusion of this chapter, readers will be able to:**

- Describe the roles and responsibilities of the investigator and research team.
- List the items that should be included in a protocol (study design).
- List the required elements of a consent form.
- Describe the issues to consider in patient recruitment for a study.

## Introduction

The complex responsibilities of conducting research can make the investigator's role difficult and challenging. On the other hand, once the investigator understands the responsibilities involved, research can be rewarding for both the investigator and for the patients who participate. The study process begins before the first patient is entered and continues after the last patient has completed his or her study involvement. This chapter provides an overview of the responsibilities of investigators, the roles of the research team members and the steps involved in the process of conducting a successful research study.

## Investigator's roles and responsibilities

Investigators share with research institutions and sponsors the responsibility for ensuring that study volunteers are adequately protected. They are required to assure that the Institutional Review Board (IRB) reviewing the study is in compliance with federal regulations. Studies must be properly designed so that they are scientifically sound and likely to yield valid results. Investigators must be appropriately qualified to conduct the research. The investigator is responsible for ensuring that the research is conducted according to the research design as approved by the IRB. Respect for study volunteers' rights and dignity requires that informed consent be obtained before a person participates in a study.

**The safety and welfare of research volunteers ultimately rests with the investigator.**

### **Professional Judgment**

The ultimate responsibility for the acceptable conduct of research with human volunteers rests with the investigator. Only sound professional judgment can ensure the protection of study volunteers. It is up to the investigator to see that:

- The personal dignity and autonomy of the research volunteer are respected.
- Volunteers are protected from harm by maximizing anticipated benefits and minimizing possible risks.
- The benefits and burdens of research are shared fairly.

The challenge arises in deciding how to protect the study volunteers while also achieving progress in science. Although the two objectives are not mutually exclusive, they also are not without conflict. Understanding the distinction between research and regular practice is fundamental to resolving any conflict that may arise. It is also essential to recognize the potential for confusion on the part of the volunteer (e.g., patient, client, student) about his/her relationship to the investigator, who may also be his/her physician, social worker, mentor or teacher.

The purpose of medical or behavioral practice is to provide diagnosis, preventative treatment or therapy. "Practice" involves interventions designed solely to enhance the well-being of the patient or client. These interventions are undertaken because there is a reasonable expectation of a successful outcome. "Research" constitutes activities designed to contribute to generalizable knowledge. Typically, in research, a set of activities is consistently applied to groups of individuals in order to test a hypothesis and draw conclusions. The activities do not necessarily provide direct benefit.

The line between practice and research is often blurred. Novel procedures do not necessarily constitute research and often, research and practice occur simultaneously. The investigator's professional judgment is essential to maintain the integrity of the research process and to keep the study volunteer informed of his/her role in the process and relationship with the investigator(s). People who are used as research subjects without their consent may be wronged, even if they are not harmed.

Good judgment is required throughout the research process to provide the necessary checks and balances. No balance of research/therapy is acceptable if it is likely to result in less than adequate care for the patient. It can be tempting to value knowledge more highly than basic human rights when excited by the prospect of a new scientific method or new understanding of

behavioral processes. To avoid this, consider the following questions before undertaking a new study.

- What types of people will be enrolled? Address this from an ethical perspective as well as on the basis of entry criteria.
  - What alternatives are available?
  - Would some potential patients incur more risks than others? Accrue more benefits?
  - Are all patients capable of understanding the consent process?
- What is your relationship to the patient?
  - Are you also his or her caregiver, teacher, employer or in any other position of authority?
  - Does the patient delegate his or her decisions for participating in research to you?
  - Is the patient comfortable asking you questions? Are you comfortable asking probing questions to ensure he or she understands the study?
- How do you treat someone with an intervention that has not been proven to be safe or effective?
- Are you so involved with the “science,” publishing, presenting or grant review that there is significant potential for conflict?

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These are among the many questions that investigators must ask themselves regularly.

There is no standard operating procedure to address the potential issues that can arise when human patients are involved in research. Because the future of science depends on the goodwill and trust of the public, investigators must understand and meet their duty to human volunteers.

### **Study Conduct**

The investigator is personally responsible for the conduct of the research project and for the actions of personnel under his/her supervision. Many studies are conducted by one investigator, commonly referred to as the principal investigator (PI) or, to use the FDA term, clinical investigator (CI). The investigator of a study is required to conduct the study according to the:

- Investigational plan (including the protocol and IRB stipulations)
- Institutional policies