Overview

Created by the Michigan Institute for Clinical and Health Research (MICHR), the Research Basics workshop is designed for study coordinators, investigators and other members of research study teams who are new to research. This introductory program includes four modules that outline fundamental concepts and skills needed for the successful implementation of a clinical research study. Training materials include slides, lecture scripts, facilitator’s guides and instructions for hands-on skills activities done in small groups. Key information for program success as well as specialized information and tips for instructors is also included.

The Research Basics workshop is designed for research coordinators, investigators and other members of research study teams who are new to research. The program provides basic instruction in the roles and responsibilities of research study team members, implementation of research best practices, creating and maintaining source documents and study binders, necessary components of informed consent documents, and strategies to enhance communication during the informed consent process. The program consists of four modules that outline basic concepts needed for the successful implementation of a clinical research study. Information and activities in the program will engage participants and provide opportunities for hands-on skill building and learning. Each module includes learning goals and objectives, a complete list of materials needed, detailed instructions for each learning activity, and important resources. Key information for program success as well as specialized information and tips for instructors are also included. This program was developed by the Michigan Institute for Clinical & Health Research (MICHR) at the University of Michigan. The program materials are offered as a guide and can be adapted for a specific institution and local needs.

Research Basics Module Descriptions

Module 1: Roles of Clinical Research Professionals

Information and activities in this module provide participants with an overview of the life cycle of a clinical research project and the roles and responsibilities of members of a clinical research study team.

The goals of the session are to:

1) Increase participants’ understanding of the roles of study coordinators within a clinical research study team.

2) Provide strategies for effective communication between study team members.

Module 2: Good Clinical Practice and Understanding a Protocol

In module 2, participants are introduced to Good Clinical Practices (GCP) and provided with a review of the elements of a clinical research protocol.

From this module, participants will learn:

1) How GCP impacts the clinical research process.
2) How to identify and prevent ‘root causes’ of non-compliance.

3) How to evaluate a clinical research protocol for participant visits and other study activities.

4) How to properly complete source documents.

**Module 3: Regulatory Binder and Essential Documents**

Module 3 explains the concept and structure of a regulatory binder as well as the collection and maintenance of essential documents needed for conducting clinical research.

*Participants will:*

1) Learn how Good Clinical Practice (GCP) translates into the collection and maintenance of essential documents for clinical research

2) Increase skills needed to complete source documents properly

3) Learn strategies for maintaining a regulatory binder to reduce errors.

**Module 4: Obtaining Valid Informed Consent**

Information in this module will provide participants with an overview of best practices regarding informed consent and the process of communicating with potential study participants to obtain valid informed consent. In this session participants will have the opportunity to demonstrate the necessary language and communication skills needed when interacting with potential study participants and their families.

*Participants will learn:*

1) Necessary components of informed consent documents

2) Strategies to enhance communication between study coordinators or investigators and research participants during the informed consent process

3) How to practice obtaining informed consent