

Responsibilities of the Research Team

Responsibilities of the Research Team

A successful clinical trial program is typically comprised of a team of individuals who are committed to conducting high-quality clinical trials. All staff involved in clinical research must adhere to the regulations and understand the guidelines that govern clinical research. All research teams are led by a Principal Investigator (PI) and have research participants. Other key staff include, but are not limited to: Nurses, Study Coordinators, and Clinical Data Managers. This module will provide an overview of key roles of the research team. The module is divided into 3 required components (videos) and 3 recommended videos. Once you have completed all required parts, please link to the evaluation after which you will be directed to a certificate of completion for your education records.

Module Objectives

At the conclusion of this module, learners will be able to:

- Describe the role and responsibilities of the Investigator as described by OHRP, FDA, and ICH GCP.
- Describe the role and responsibilities of the Research Nurse.
- Describe the role and responsibilities of the Study Coordinator.
- Describe the role and responsibilities of the Clinical Data Manager.
- Describe the role and responsibilities of the pharmacist.

| Required | | | | |
|--|--|--------------------------------|---------------------------|----------------------------|
| Part 1 | Role and Responsibilities of the Principal Investigator (PI) (24½ minutes) | Part 1 Handout | Resources | Evaluation |
| Part 2 | Responsibilities of the Clinical Trials Team (15 minutes) | Part 2 Handout | | |
| Part 3 | Clinical Research Professional Organizations (7 minutes) | Part 3 Handout | | |
| Recommended | | | | |
| <u>Videos</u> <ul style="list-style-type: none">• You're in Charge: Principal Investigator Responsibilities (38 minutes focuses on PI role - NOTE: last 25 minutes is Q & A)• Clinical Trial: A Nursing Perspective (19 minutes)• The Role of the Research Nurse (10 minute) | | | | |