Module 1: Introduction

After completing this module, you will understand the International Conference on Harmonization's (ICH) role in providing guidelines that are applied to social and behavioral research. You'll also be familiar with ICH's development of Good Clinical Practice (GCP) and how to interpret and apply it within the context of social and behavioral clinical trials.

Introduction

What are your institutional policies on human subject research?

The Foundations of Best Practices

The foundation for social and behavioral research best practices are based on ICH's Good Clinical Practice, or GCP. The 12 principles listed below have been adapted from the 13 principles created by ICH and are a great framework for high-quality research and participant safety.

Principle 1: Trials should be conducted with ethical principles that come from the Declaration of Helsinki.

Principle 2: Risks, benefits and alternative procedures need to be weighed prior to designing and beginning a trial. They should also be discussed in detail with the prospective research participant.

Principle 3: The rights, safety and welfare of the research participant override the interests of the study, society and science. The advancement of medicine is never the most important factor in research; therefore investigators must never sacrifice the interests and rights of study subjects to ensure completion of a trial.

Principle 4: The proposed study should be based on sound scientific data.

Principle 5: Trials should be described in a clear and detailed protocol.

Principle 6: Trials should be conducted in accordance with the protocol that has received prior approval by an Institutional Review Board or ethics committee.

Principle 7: Medical care within the context of a trial should be the responsibility of a qualified physician, dentist or other health care provider.

Principle 8: Each individual on the study team should be qualified by education, training and experience to perform their designated study responsibilities.

Principle 9: Freely given informed consent should be obtained from every participant prior to their participation.

Principle 10: All trial information should be recorded, handled, and stored in a way that allows accurate reporting, interpretation and verification.

Principle 11: The confidentiality of participants records and their privacy should be protected in accordance with all applicable federal and local regulation.

Principle 12: Systems with procedures that assure quality of every aspect of the trial should be considered and implemented.

How can these GCP principles apply to your own social and behavioral research?

Are there any specific actions or information you'd like to take away from this course?

Roles and Responsibilities

Tasks within a study team are often assigned based on experience, education and study logistics. Often times a single person may take on several different roles, based on the study scope and budget. Regardless of the size of your team, these roles and responsibilities represent actions that need to be accomplished.

Sponsor: Reviews grant applications, selects studies for funding, and monitors study progress

Institutional Review Board: Reviews and approves research studies, works to protect participant safety, ensures study meets regulations

Monitor/Auditor: Ensures proper study procedures are followed and that the protocol is carried out consistently

Principal Investigator: Leads study and is responsible for overseeing all aspects; generates ideas, writes grant proposals, manages scientific aspects of study

Coordinator: Ensures day-to-day tasks are completed and that everyone on study team is trained and doing jobs correctly; communicates regularly with PI

Research Assistant: Responsible for recruiting participants and collecting data

Data Manager: Oversees all data; ensures data is recorded and managed per protocol document; cleans and prepares data for analysis

Statistician: Consults with PI and Co-Investigator to analyze data and interpret study findings

Interventionist: Administers study intervention (background and training vary widely)

Co-Investigator: Partners with PI on studies where scientific methodological expertise is put to use

Research Nurse: Works on studies requiring medical procedures completed by a licensed practitioner

Office of Research Integrity: Oversees the investigation of any misconduct allegations arising during social and behavioral research studies

What role(s) do you play on your study team? What roles do your other team members play?

Other Notes

Resources

International Conference on Harmonization Guideline on Good Clinical Practice
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf