Module 1: Introduction

Introduction

Welcome to the Social and Behavioral Research Best Practices for Clinical Research course.

In this introductory module, we'll cover the importance of social and behavioral research best practices and introduce some common roles that people have within research teams.

The next seven modules will highlight elements of best practice, which often come into play at different times in the life-cycle of a well-planned research study.

In designing a study, you'll need to have a well-developed research protocol, including plans for participant recruitment and retention, the informed consent process, privacy and confidentiality, quality control and assurance, and study operations.

Once the study begins, you'll implement your plans in the research protocol. You'll need find and recruit participants, obtain informed consent from them, and ensure participant privacy and confidentiality. You'll also implement quality control and quality assurance plans from the protocol, including ensuring participant safety and reporting adverse events. Data will need to be appropriately reviewed, you'll learn to take corrective actions when necessary to ensure data integrity. Tracking protocol deviations and gathering feedback from study staff will signal the need to revise study operations from the original plans.

At the study close-out, use best practices recommendations, for sharing results. Throughout the entire life-cycle of a research study, research ethics have to be upheld. You'll hear about your role in upholding research ethics by reporting and preventing research misconduct.

During these modules, you'll hear about the experiences of multiple clinical researchers. Some of them embody the best practices highlighted during this course and others

could do with a little improvement. Make sure you take the time to learn from their experiences! We'll then wrap up the course with a Conclusion module to highlight some key points and takeaway from this course.

Let's get started!

Resources and Course Study Manual Check-In

The Resources section in the top right corner of your screen will contain useful documents and links for each individual topic. At the beginning of each module, you'll be reminded to explore this section. You'll also be asked to download and print a Course Study Manual for that specific topic. This document will follow along with the content, and can serve as a great note-taking guide and job aid for you. It is strongly recommended that you utilize this resource as you move through the course. You can download this module's course study manual at any time.

Throughout the course, you'll also be asked to locate your own institution's polices related to human subject research. Take a moment now to locate where these policies can be found and note them in your course study manual.

What is G.C.P.?

The foundation for social and behavioral research best practices stems from the concept of Good Clinical Practice, or G.C.P. G.C.P. is a set of 13 principles that help guide clinical researchers to ensure that quality research is being conducted and that participants in research are protected. The principles were established by the International Conference on Harmonization in 1990 to define the minimum standards expected for clinical trials involving human subjects. Although these principles were written with drug, device, and biological studies in mind, most of these principles are applicable to social and behavioral research, as well.

In the United States, the Food and Drug Administration, or F.D.A., has published guidance on the principles of G.C.P. for the development of drugs, devices, and biologics. Although social and behavioral research does not have an F.D.A. equivalent, new policies at the National Institutes of Health, or N.I.H., establish an expectation that

G.C.P. will be followed in all clinical research. The modules in this course will describe key G.C.P. principles and how to implement them in social and behavioral research.

Take a moment to pause this course and look at the G.C.P. principles listed in your Course Study Manual. How can these apply to your own social and behavioral research? Are there any specific actions or information you'd like to take away from this course?

A New Definition of Clinical Trials

You may be asking yourself: "If G.C.P. applies to clinical trials, why do I need to learn about them? I'm not conducting a clinical trial to test a drug, device, or biologic."

In 2014, the National Institutes of Health, or N.I.H., expanded the definition of a clinical trial to include "any research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

This broader definition signifies that many social or behavioral interventions are now defined as clinical trials and will therefore be more closely regulated than before. From studies addressing alcohol consumption in young adults; to school performance in children with learning disabilities; to controlled diets in obese adults, the spectrum of studies included under this definition is endless.

Social and behavioral research teams must provide the same assurances for participant safety and quality research that other clinical trials do when following G.C.P.

This course will provide clinical trial team members, like you, with great resources and instruction on social and behavioral research study best practices. Application of these best practices in your studies, in addition to satisfying the new regulatory requirements, will ensure that participants are protected and quality data is obtained.

Benefits of Using Best Practices

The big question is: Why should you implement what you'll learn during this course?

Studies that are designed and executed with best practices in mind often run more smoothly, help protect research participants, and help prevent situations of non-compliance during studies. Additionally, data collected and analyzed at the end of a well-run study are often more complete and accurate, resulting in high quality, reproducible study findings. Not surprisingly, having a well-planned, carefully run research study with high quality data may also increase the likelihood of publishing your findings in high impact journals with a larger audience.

Research Roles and Responsibilities

Now that we've addressed why these best practices are so important, let's take a look at who all is involved. Before you continue with the rest of the modules in this course, you'll want to be familiar with each of the roles and responsibilities within a research team.

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. Click each role on the left to learn a bit more about it. When you're done, click Next.

Sponsor

I work for a federal funding agency, industry or foundation. We review grant applications submitted by principal investigators, and select studies for funding. If a study is funded by us, we monitor the progress of the study to ensure study objectives are being met, and study findings are disseminated.

Institutional Review Board (I.R.B.)

As a long time researcher and member of the Institutional Review Board, I am responsible for reviewing and approving studies. I work in conjunction with the I.R.B. to protect participant safety, and ensure regulations are met. The I.R.B. is the go-to for all document approvals, open questions and general guidance.

Monitor/Auditor

My job is to ensure that proper study procedures are being followed and that the study protocol is being carried out consistently between study sites. I am usually involved in more complex studies, such as those with multiple sites or those that are higher risk.

Principal Investigator
As the principal investigator, I am the study lead and have responsibility for overseeing all aspects of the study. I generate ideas, write grant proposals to obtain funding, and manage all scientific aspects of the study.

Coordinator
I help everything run smoothly in the study by making sure the day-to-day tasks are completed, and that everyone on the study team is trained and doing their jobs correctly. I also communicate regularly with the P.I. about the study.

Research Assistant (R.A.)
As a Research Assistant I am responsible for recruiting participants and collecting data from participants.

Data Manager
As a data manager, I oversee all of the data that are collected for the study. This means I make sure that the data are recorded and managed as specified in the protocol document. I also clean and prepare data for analysis.

Statistician
As a statistician, I may be a co-investigator or consultant on a study team. I work with the principal investigator and co-investigator to help design the data analysis plan, analyze the data, and then interpret the study findings so that the study questions can be answered.

Co-Investigator
As a co-investigator, I partner with a principal investigator on studies where my scientific or methodological expertise can be put to use.

Research Nurse
As a research nurse, I work with researchers whose studies require a medical procedure that must be completed by a licensed practitioner.

Interventionist
I work as an interventionist. I have special expertise and training that qualifies me to administer the study intervention. For instance, I may be a clinical psychologist, therapist, or educator.

Office of Research Integrity

I'm a research integrity officer. I oversee investigations of misconduct for federally funded trials.

Your Turn

Now, let's take a moment to see what you learned. Match each of the responsibilities listed on the left with their corresponding role on the right. Responsibilities will only stick when they are correct!

Course Study Manual Check-In

By now you should have completed the Introduction section of your Course Study Manual. If you haven't, take some time to complete this job aid. And don't forget to check out the Resources section for additional information and links, as well. When you're ready, click Next to move to the final assessment for this module.