

# Integrating Ethics Into GCP Training

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**I**F I ASK INVESTIGATORS, COORDINATORS OR MONITORS *what Good Clinical Practice (GCP) training is all about, they would probably respond by saying, “the regs.” They would be correct...partially. GCP training for these individuals typically provides interpretation and application of regulatory requirements. It also includes instruction on protocol implementation and adherence. These two topics — regulatory and protocol compliance — complement each other, and most investigators, coordinators and monitors would say that their GCP training primarily focuses on these two components. There is, however, a third component of training for GCP compliance that often is overlooked — the application of ethics in clinical research.*

## TRADITIONAL GCP TRAINING

Investigators are responsible for complying with the regulations and the protocol. Monitors are responsible for ensuring that the investigator, the investigator’s study coordinator and other members of the investigator’s team vigilantly adhere to regulatory and protocol requirements. Consequently, GCP training for these individuals has traditionally included a strong emphasis on how to interpret and apply the regulations and the protocol commensurate with their particular responsibilities and duties.

GCP training topics often correspond to regulatory documents. For example, in the United States, GCP topics would be similar to titles found in the Food and Drug Administration (FDA) and the Department of

Health and Human Services (HHS) regulations, guidance documents and policy directives. Trainers who use this approach to GCP training may

have greater confidence that their selection of topics at least is consistent with FDA and HHS regulations and guidelines.

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## NEED FOR ETHICS IN GCP TRAINING

Investigators, coordinators and monitors are different from others who are involved in the clinical research process in that they perform their responsibilities in close proximity to the human subjects, where regulatory and protocol compliance will be put to the greatest test. These individuals form a unique working triad that relies on mutual trust, cooperation and oversight to ensure GCP compliance.

Proximity to the research subjects and this close working relationship may cause investigators, coordinators and monitors to encounter more

ethical dilemmas in the pursuit of regulatory and protocol compliance than others who are involved in bringing a new human medical product to market. For many investigators, coordinators and monitors, a major source of ethical dilemmas is noncompliance by a member of this working triad. These individuals often witness, or are aware of, regulatory and protocol noncompliance before anyone else.

Recognizing and dealing with noncompliance, whether it was intentional or not, may cause tremendous anguish and uncertainty for investigators, coordinators and monitors. Overlooking ethics in their GCP training may leave these individuals ill-prepared to deal with the ethical dilemmas they will encounter as they carry out their responsibilities and duties for GCP compliance.

#### ADDING ETHICS TO GCP TRAINING

What can trainers do to help investigators, coordinators and monitors better recognize and deal with ethical dilemmas in clinical research? The answer is found in GCP.

The introduction of the 1996 International Conference on

“ ICH places primary importance on the *ethics* of clinical research, which has been overlooked or under emphasized in traditional GCP training.”

Harmonization Guideline for GCP (ICH GCP) defines GCP as “an international *ethical* [author’s emphasis] and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.”<sup>1</sup> Good Clinical Practice is not just about regulatory and protocol compliance. ICH places primary importance on the *ethics* of clinical research, which has

been overlooked or under emphasized in traditional GCP training.

The ICH GCP guideline includes 13 principles for conducting research with human subjects.<sup>2</sup> These standards, as well as principles from other documents, such as The Nuremberg Code, Declaration of Helsinki and The Belmont Report, can provide the basis for training on the third essential component of GCP compliance — the application of ethics in clinical research. By integrating ethics into GCP training, we can help investigators, coordinators and monitors better understand their responsibilities and duties for ensuring GCP compliance at the investigative site.

<sup>1</sup> International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. Good Clinical Practice: Consolidated Guideline. May 1, 1996.

<sup>2</sup> Ibid., Section 2.

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