

# Something is Missing From GCP Training

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**M**OST INVESTIGATORS, COORDINATORS AND MONITORS *would agree that Good Clinical Practice (GCP) training primarily focuses on two areas: regulatory and protocol compliance. Public workshops, conferences and professional meetings abound in presentations on the interpretation and implementation of federal regulations for conducting trials with human subjects. Sponsors also provide investigator meetings to explain the regulatory, scientific and procedural aspects of a specific protocol. Unfortunately, this emphasis on regulatory and protocol requirements frequently results in the oversight of a third essential component of GCP training — the application of ethics in clinical research.*

## DEFINING ETHICAL STANDARDS

Ethics may be defined as a set of standards by which human behaviors and actions are measured. Ethical standards are dynamic and evolve over time. Any group of individuals with a common interest, for example, cultural or religious communities and professional organizations, may establish ethical standards for its members to follow. These standards may be informal and unwritten or they may be official documented codes of conduct. Compliance with these standards is voluntary although sanctions may exist for violations. National, state, and local laws and regulations are often based on the ethical standards of its citizenry.

The introduction to the 1996 International Conference on Harmo-

nization Guideline for GCP (ICH GCP) defines GCP as “an international *ethical* [author's emphasis] and scientific quality standard for

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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 emphasis on the *ethics* of clinical trials. At the beginning of the 21st century, the international standard is that good science is based on good ethics.

## NEED FOR ETHICS TRAINING

Everyone who contributes to bringing a new human medical product to market needs ethics training. There are, however, three contributors who have a more critical need for ethics training: investigators, coordinators and monitors. Why? These individuals perform their GCP responsibilities and duties in closest

proximity to the human subjects where regulatory and protocol compliance will be put to the greatest test.

Because of their direct contact with human subjects, investigators and their coordinators are more likely to experience ethical dilemmas in the pursuit of regulatory and protocol compliance. For many reasons, regulatory and protocol compliance is inherently difficult with human subjects. Yet, investigator adherence to regulatory and protocol requirements is a prerequisite for conducting clinical trials. By including ethics in their GCP training, we can help investigators and coordinators better deal with the inescapable issues of regulatory and protocol compliance.

Monitors also need ethics training. As the field liaison for the sponsor, monitors have direct contact with investigators and their coordinators. Monitors are the first to observe and evaluate the investigator's conduct of the study, which is based on regulatory and protocol compliance. Noncompliance by an investigator or a coordinator may be overt or hidden, deliberate or unintentional. In any case, in addition to regulatory and protocol knowledge, monitors need a third knowledge

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domain to meet their GCP responsibilities for ensuring investigators' compliance — and ethics training can help.

### **ADDING ETHICS TO GCP TRAINING**

An ethics-based GCP training program enhances regulatory and protocol compliance because ethical discussions help to explain the "why" behind the requirements. Several documents with fundamental research and ethical principles are available as references for discussing the evolution and importance of regulatory and protocol compliance. These include

The Nuremberg Code, Declaration of Helsinki, The Belmont Report and the aforementioned ICH GCP guideline. These documents should be required reading for investigators, coordinators and monitors. Ethical discussions are most effective when they are based on case studies.

Regulatory and protocol compliance are the two traditional components of GCP training. By adding a third component — the application of ethics in clinical research — we can help investigators, coordinators and monitors better understand the "why" behind the requirements and provide them with a stronger foundation for performing their responsibilities and duties for GCP compliance. At the beginning of the 21st century, the international GCP standard is that good science is based on good ethics.

<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.

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