

The Importance of Standard Operating Procedures For Investigators

Janet F. Zimmerman, MS, RN, Clinical Research Training Consultant, Newtown, PA

ACCORDING TO THE 1996 International Conference on Harmonization (ICH) Tripartite Guideline for Good Clinical Practice (GCP), sponsors and institutional review boards (IRBs) are expected to have written policies and procedures for operational activities. It would seem logical that investigators, the third responsible party identified in the ICH GCP guideline, also would be expected to have policies and procedures for clinical research operations. Surprisingly, the ICH GCP guideline does not mention written policies and procedures for investigators. Was this an oversight or was it intentional? In either case, it was a mistake. Investigators need standard operating procedures (SOPs) for conducting clinical trials and here is why.

DEFINITION AND IMPORTANCE OF CLINICAL RESEARCH SOPs

The ICH GCP guideline defines SOPs as “detailed, written instructions to achieve uniformity of the performance of a specific function.”¹

In clinical research, an investigator is expected to vigilantly comply with the protocol to assure control and consistency in the conduct of the trial. In the same way, an investigator *also* needs to carefully prepare and follow written SOPs to help ensure that the investigator and his or her clinical research team are achieving maximum operational effectiveness and compliance.

An investigator who has well-

¹ ICH Harmonized Tripartite Guideline for Good Clinical Practice. (1.55). May 1, 1996.

written, comprehensive and practical clinical research specific-SOPs is an investigator who has a distinct

“ Clinical research SOPs help to ensure consistency, compliance, accountability, and efficiency...”

advantage over other investigators who do not. The advantage is that writing SOPs impels an investigator to take the critical steps of reading and interpreting GCP regulations and guidelines and then applying them to his or her particular clinical research operations.

Clinical research SOPs help to ensure consistency, compliance, accountability, and efficiency of the investigator and the investigator’s team when they are conducting clinical trials. Investigators who do not have clinical research specific-SOPs run a high risk of GCP noncompliance and poor productivity.

Will investigators actually write the SOPs? Probably not. An investigator may delegate the preparation of the SOPs to a team member who has

exceptional interviewing, writing and organizational skills, or the project may be outsourced. Another option is for the investigator to purchase customizable GCP SOP templates, which may be the most cost-effective method for an investigator to develop clinical research SOPs. In any case, investigators should be involved in the planning and review process because the investigator will ultimately approve and authorize each SOP with his or her signature.

SOPs AND GCP TRAINING

In the US, GCP training for investigators and their team typically includes Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) regulations, guidelines, and policy directives; ICH GCP guidelines; and applicable state and local requirements. Because these resource documents provide the regulatory basis for investigators conducting clinical trials with investigational medical products intended for human use, they are the foundation for GCP training.

“ SOPs include the
who, what, when,
where, how and why
of the investigator’s
clinical research
operations.”

In addition to these essential resources, the investigator’s clinical research specific-SOPs would also be referenced in GCP training. Because SOPs include the who, what, when, where, how, and why of the investigator’s clinical research operations, it is important for the GCP trainer to be familiar with the investigator’s SOPs and to integrate them into the training program. For example, applying and explaining GCP regulations and

guidelines with examples of the investigator’s clinical research specific-SOPs helps to ensure a more practical and meaningful interpretation of GCP documents and enhances learning for the investigator and his or her team. It also demonstrates to sponsors, auditors, and inspectors that the investigator is committed to implementing the clinical research specific-SOPs, and not have them languish on a shelf and go unused.

It is important to clarify that GCP training is not the same as SOP training and vice versa. They are two distinct training programs with unique goals and objectives. However, when trainers integrate and reference well-written, comprehensive, and practical clinical research specific-SOPs into GCP training, they will emphasize the importance and relevance of SOPs and they will help enhance investigator GCP compliance.

Copyright ©1999 Janet F. Zimmerman, MS, RN



Reprinted with permission from the November 1999 issue of SoCRA Source, a quarterly publication of the Society of Clinical Research Associates.



CONSULTING GROUP

Janet F. Zimmerman, MS, RN
President

Specializing in GCP Training for Investigators, Coordinators and Monitors

- ★ GCP Compliance
- ★ Team Development
- ★ Communication Skills
- ★ Medical Writing

One Geranium Court ★ PO Box 1364 ★ Newtown, PA 18940 USA ★ **215.579.7694**

Innovative Methods for Providing Advanced Clinical Training ★ www.impactcg.com