Gizelle Baker, J Bioequiv Availab 2011, 3:7
doi: http://dx.doi.org/10.4172/0975-0851.1000107

OMICS Group Conferences
Accelerating Scientific Discovery

International Conference & Exhibition on
Pharmaceutical Regulatory Affairs
6-7 September 2011 Baltimore, USA

The importance of investigative site clinical research standard operating procedures (SOPs)

Gizelle Baker
Medical University of South Carolina, USA

Why are Investigative Site Clinical Research SOPs so important? They establish standards for responsibilities that regulatory authorities have attributed to the Investigator. Well-written and well-managed GCP SOPs provide an official and standard way to consistently execute required research-related activities. In addition, they can improve communication among staff, reduce dependence on individuals with institutional knowledge, and improve efficiency of staff training.

Are Clinical Research Investigator Site SOPs required by law/regulations?

- ICH GCP 2.13 states that "Systems with procedures that assure the quality of every aspect of the trial should be implemented."
- 21 CFR 312.53 states that the Investigator will "ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed of their obligations in meeting the above commitments."
- FDA guidances and regulations infer Investigator responsibility.
- ISO 14155:2011 (6.8.1) states that "the Investigator shall assure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor..."
- ISO 14155:2011 (6.11) states that "Audits...may be conducted...to evaluate compliance with the CIP, written procedures, the International Standard and the applicable regulatory requirements."
- PhRMA Principle on Conduct of Clinical Trials (2009:2.i.) Quality Assurance. Procedures are followed to ensure that trials are conducted in accordance with GCPs and that data are generated, documented and reported accurately and in compliance with all applicable requirements.

The investigative clinical research site that operates under Clinical Research SOPs demonstrates it has a commitment to research and that consistent processes for research activities are in place.

Biography

Dr. Gizelle Baker and Dr. Wilkerson have complementary and integrated expertise, forming an extremely powerful and knowledgeable research leadership team. Both have extensive experience in US and global product development for drugs, biologics and devices. Additionally, both have led clinical project/programs and/or departments and served as project advisors on numerous project teams, and have been responsible for the strategic planning of development programs for drugs, biologics, and devices in a variety of therapeutic areas. They have published more than 20 articles in reputed journals. Dr. Wilkerson holds her PhD in Biochemistry from the Stanford University School of Medicine, where she was a National Science Foundation Pre-Doctoral Fellow. Dr. Baker holds her PhD in Biometry and Epidemiology from the Medical University of South Carolina.