OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Summit on
GMP, GCP & Quality Control

November 12-14, 2013 DoubleTree by Hilton Hotel Chicago-North Shore, USA

The informed consent form process: A basic contemporary standpoint for medical research professionals

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Abstract

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. (Guidance for industry)[62 FR 25692]

The Informed Consent Form Process is kind of synonymous to the fundamental principles of the practice of medicine in terms of the Hippocrates oath which summarily burdened the professional with the enviable commitment to protect subjects and or patients from deliberate harm and unjust treatment during the dispensing of his or her duty as a medical or healthcare professional. For an Informed Consent Process to meet stipulated regulations especially as contained in the Code of Federal Regulations 21 CFR 50 (The protection of Human Subjects in Research Study) it must be able to prove within the scope of existing scientific evidences and sound doctrines that the study will protect human subjects from knowingly subjecting them to either harm, or have their the rights taken away.

A basic contemporary standpoint of the Informed Consent Form Process (ICFP) therefore attempts to surmise the essentialities of the ICFP with the hope of making it very easy to identify the necessities, sustenance and propagation of GCP and thereby help prevent the breach of basic ethical principles such as respect for persons, beneficence and justice.

Biography

Peter Odeh, BS, MLS (ASCP), MT (AMT), CLS (NCA), AIMLS (NIG) is a Research Medical Laboratory Scientist/ Medical Technologist and Clinical Laboratory Scientist with SNBL Clinical Pharmacology Center in Baltimore Maryland. In the year 2002, Mr. Odeh received the International Travel Grant Award and the Gallwas Membership Grant Award of the American Association for Clinical Chemistry in Orlando Florida during the AACC scientific meeting. In addition he received several other awards such as the McAuley Silver Award for outstanding leadership and quality of work at Mercy Medical Center in Baltimore and Continuing Education Certificate of Excellence by the American Medical Technologists Institute for Education. He has vast experience in working both in the hospital and research environment, has written series of articles and is the oversea consult director of technical services for ROPAN DIAGNOSTIC (NIG) LTD.