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Informed consent process, the bane of unethical clinical research

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The current regulations for clinical research are based on a combination of ethical thought and history. Ethics is different from law and regulation, both of which mandate a certain way of acting. The United States regulations for the protection of human subjects provide minimum baseline with which everyone must comply in operating an institutional review board (IRB), obtaining informed consent from research subjects, and conducting research in an ethical manner. Ethical thought has helped shape the regulations. But ethics goes beyond what the regulations require to include what we ought to do. Ethics asks, "What ought I to do?" and "What is the right thing to do?" Throughout the 4,000 years history of ethics, there have been many interesting theories about what ethics ought to be and what principles should be at the forefront of our thinking. The challenge, especially in a practical environment such as clinical research, is to translate the theoretical concepts from ethics into action. Many years after the document governing ethical principles of clinical research was produced and addressing three major areas: respect for persons, beneficence and justice, abuse of informed consent process has been a major ethical problem in most clinical research conducted across the globe and especially those conducted in Africa. Is there a better way of administering informed consent to achieve a better research outcome that will benefit all? This presentation shall focus on recalling history of abuses of informed consent process and ways to correct the unethical practice shall be discussed.

Biography

Onyeaghala Augustine is a Biomedical Scientist, Clinical Research Scientist, Quality Assurance Expert, GMP, GCP and Regulatory Affairs Specialist. He holds a Masters Degree in Clinical Biochemistry, Post Graduate Diploma in GCP, GMP, GLP, Quality Assurance and Regulatory Affairs from Kriger Research International, Canada. He is currently a doctorate student in Clinical and Translational Research. He is a regular speaker and presenter at international and local conferences and meetings discussing clinical research, quality assurance, biomedical science and good clinical practice regulations. He has published a sizeable number of research papers in local and international journals and is also an author of a book in total quality management.

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