



Standard Operating Procedures: For Good Clinical Practice

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Good Clinical Research Practice (GCP) is a process that incorporates established ethical and scientific quality standards for the design, conduct, recording and reporting of clinical research involving the participation of human subjects. Compliance with GCP provides public assurance that the rights, safety, and well-being of research subjects are protected and respected, consistent with the principles enunciated in the Declaration of Helsinki and other internationally recognized ethical guidelines, and ensures the integrity of clinical research data. The conduct of clinical research is complex and this complexity is compounded by the need to involve a number of different individuals with a variety of expertise, all of who must perform their tasks skillfully and efficiently. The responsibility for GCP is shared by all of the parties involved, including sponsors, investigators and site staff, contract research organizations (CROs), ethics committees, regulatory authorities and research subjects.

A general definition of human research is: "Any proposal relating to human subjects including healthy volunteers that cannot be considered as an element of accepted clinical management or public health practice and that involves either (i) physical or psychological intervention or observation, or (ii) collection, storage and dissemination of information relating to individuals. This definition relates not only to planned trials involving human subjects but to research in which environmental factors are manipulated in a way that could incidentally expose individuals to undue risks." (World Health Organization, *Governance, rules and procedures*, WHO Manual XVII).

Handbook for good clinical research practice (GCP): guidance for implementation. (2005). Geneva, Switzerland: World Health Organization.

Vice President Research and Technology Transfer Signature:

Approved: _____ Date: _____