

Definitions

For the purposes of this policy, unless otherwise stated, the following definitions shall apply:

Standard Operating Procedures (SOP): are a detailed set of written instructions regarding how clinical research is to be conducted in order to achieve uniformity in the clinical research operations to ensure maximum safety and efficiency.

Good Clinical Practice Guidelines (GCP): are an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with these standards provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principals that have their origin in the Declaration of Helsinki, and that clinical trials being conducted are credible.

Declaration of Helsinki: is a set of ethical principals developed by the World Medical Association (WMA) for conducting research using human subjects. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in clinical research involving human subjects to adopt these principles.