**GUIDANCE 14**

**GOOD CLINICAL PRACTICE GUIDANCE**

Good Clinical Practices (GCP) Good Clinical Practices or GCP are guidelines that cover the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of clinical studies.

FDA Guidance for Good Clinical Practice (GCP) is an international quality standard defined by the International Council for Harmonization (ICH) that governs ethical and scientific considerations for designing, conducting, recording and reporting trials involving human subjects.

Following links provide guidance to good clinical practice:

<https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/good-clinical-practice>.

NIH Guidelines for GCP: <https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm>.

GCP Integrated Addendum to ICH Guidelines: <https://www.fda.gov/media/93884/download>.

ICH Guidelines documents: <https://www.fda.gov/science-research/guidance-documents-including-information-sheets-and-notices/ich-guidance-documents>.