

SCHEDULE 1

CONDITIONS AND PRINCIPLES OF GOOD CLINICAL PRACTICE AND FOR THE PROTECTION OF CLINICAL TRIAL SUBJECTS

PART 2

CONDITIONS AND PRINCIPLES WHICH APPLY TO ALL CLINICAL TRIALS

Principles based on International Conference on Harmonisation GCP Guideline(1)

10. All clinical trial information shall be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

(1) See Section 2 of the Note for Guideline on Good Clinical Practice (CPMP/ICH/135/95) published by the European Agency for the Evaluation of Medicinal Products in July 2002.