

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)

9. Subject to the other provisions of this Schedule relating to consent, freely given informed consent shall be obtained from every subject prior to clinical trial participation.

(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.