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)

1. Clinical trials shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with good clinical practice and the requirements of these Regulations.

2. Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated and continued only if the anticipated benefits justify the risks.

3. The rights, safety, and well-being of the trial subjects are the most important considerations and shall prevail over interests of science and society .

4. The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the clinical trial.

5. Clinical trials shall be scientifically sound, and described in a clear, detailed protocol.

6. A trial shall be conducted in compliance with the protocol that has a favourable opinion from an ethics committee.

7. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of an appropriately qualified doctor or, when appropriate, of a qualified dentist.

8. Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task(s).

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.

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

11. The confidentiality of records that could identify subjects shall be protected, respecting the privacy and confidentiality rules in accordance with the requirements of the Data Protection Act 1998 and the law relating to confidentiality.

12. Investigational medicinal products used in the trial shall be—

(a) manufactured or imported, and handled and stored, in accordance with the principles and guidelines of good manufacturing practice, and

(b) used in accordance with the approved protocol.

13. Systems with procedures that assure the quality of every aspect of the trial shall be implemented.

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(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.**

Conditions based on Article 3 of the Directive

14. A trial shall be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored.

15. The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with the Data Protection Act 1998 are safeguarded.

16. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial.