

SCHEDULE 1

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

PART 3

CONDITIONS WHICH APPLY IN RELATION TO AN ADULT ABLE TO CONSENT OR WHO HAS GIVEN CONSENT PRIOR TO THE ONSET OF INCAPACITY

1. The subject has had an interview with the investigator, or another member of the investigating team, in which he has been given the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.
2. The subject has been informed of his right to withdraw from the trial at any time.
3. The subject has given his informed consent to taking part in the trial.
4. The subject may, without being subject to any resulting detriment, withdraw from the clinical trial at any time by revoking his informed consent.
5. The subject has been provided with a contact point where he may obtain further information about the trial.