

SCHEDULE 1

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

PART 5

CONDITIONS AND PRINCIPLES WHICH APPLY IN RELATION TO AN INCAPACITATED ADULT

14. The risk threshold and the degree of distress have to be specially defined and constantly monitored.

Changes to legislation:

There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Paragraph 14.