STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 4

GOOD CLINICAL PRACTICE AND THE CONDUCT OF CLINICAL TRIALS

Conduct of trial in accordance with clinical trial authorisation etc.

29. Subject to regulation 30, no person shall conduct a clinical trial otherwise than in accordance with—

(a) the protocol relating to that trial, as may be amended from time to time in accordance with regulations 22 to 25;

(b) the terms of—

(i) the request for authorisation to conduct that trial,

(ii) the application for an ethics committee opinion in relation to that trial, and

(iii) any particulars or documents, other than the protocol, accompanying that request or that application,

as may be amended from time to time in accordance with regulations 22 to 25; and

(c) any conditions imposed by the licensing authority under regulation 18(2) or (6), 19(8), 20(5), **[**[F1]24(5)**]** or Schedule 5.

Textual Amendments

F1 Word in reg. 29(c) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **15**

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Section 29.