
STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use
(Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS
AND ETHICS COMMITTEE OPINION

Interpretation of Part 3

11. In this Part—

“amendment to the clinical trial authorisation” means an amendment to—

- (a) the terms of the request for authorisation to conduct that trial or the application for an ethics committee opinion in relation to that trial,
- (b) the protocol for that trial, or
- (c) the other particulars or documents accompanying that request for authorisation or application for ethics committee approval;

“substantial amendment to the clinical trial authorisation” means an amendment to the clinical trial authorisation which is likely to affect to a significant degree—

- (a) the safety or physical or mental integrity of the subjects of the trial,
- (b) the scientific value of the trial,
- (c) the conduct or management of the trial, or
- (d) the quality or safety of any investigational medicinal product used in the trial;

“valid application” means an application for an ethics committee opinion which complies with the provisions of regulation 14; and

“valid request for authorisation” means a request to the licensing authority for authorisation to conduct a clinical trial which complies with the provisions of regulation 17, and “valid amended request” shall be construed accordingly.

Changes to legislation:

There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, Section 11.