
STATUTORY INSTRUMENTS

2006 No. 1928

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006

Insertion of regulation 29A of the principal Regulations

16. After regulation 29 of the principal Regulations (conduct of trial in accordance with clinical trial authorisation etc.), insert the following regulation—

“Notification of serious breaches

29A.—(1) The sponsor of a clinical trial shall notify the licensing authority in writing of any serious breach of—

- (a) the conditions and principles of good clinical practice in connection with that trial; or
- (b) the protocol relating to that trial, as amended from time to time in accordance with regulations 22 to 25,

within 7 days of becoming aware of that breach.

(2) For the purposes of this regulation, a “serious breach” is a breach which is likely to effect to a significant degree—

- (a) the safety or physical or mental integrity of the subjects of the trial; or
- (b) the scientific value of the trial.”.