
STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use
(Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS
AND ETHICS COMMITTEE OPINION

Review and appeal relating to ethics committee opinion

16.—(1) This regulation applies where a chief investigator for a trial has been notified by the ethics committee to which he made an application in accordance with regulation 13 that the committee's opinion in relation to that trial is not favourable.

(2) This regulation does not apply in relation to an opinion given by—

- (a) the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000; or
- (b) an ethics committee pursuant to paragraph 2 of Schedule 4.

(3) Where the opinion was given by an ethics committee other than the Gene Therapy Advisory Committee, the chief investigator may within 90 days of being notified that the committee's opinion is not favourable, give a notice to the United Kingdom Ethics Committees Authority—

- (a) stating his wish to appeal against the opinion; and
- (b) setting out his representations with respect to that opinion.

(4) Where the opinion was given by the Gene Therapy Advisory Committee, the chief investigator may, within 14 days of being notified of that opinion—

- (a) give a notice in writing to the Committee requiring the Committee to review its opinion; or
- (b) give a notice in writing to the United Kingdom Ethics Committee Authority—
 - (i) stating his wish to appeal against the opinion; and
 - (ii) setting out his representations with respect to that opinion.

(5) Where the Gene Therapy Advisory Committee is required by a notice under paragraph (4) to review its opinion, it must do so within 60 days of receipt of the notice.

(6) On a review pursuant to paragraph (5), the Gene Therapy Advisory Committee may vary or confirm their opinion and shall give notice in writing to the chief investigator of the variation or confirmation.

(7) If the Gene Therapy Advisory Committee confirm their opinion pursuant to paragraph (6), a chief investigator may within the 14 days of being notified of the confirmation give notice in writing to the United Kingdom Ethics Committees Authority—

- (a) stating his wish to appeal against the Committee's opinion; and
- (b) setting out his representations with respect to that opinion

(8) Schedule 4 shall have effect to regulate the procedure where the Authority receives a notice in accordance with paragraph (3), (4) or (7).