
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

Good clinical practice and protection of clinical trial subjects

28.—(1) No person shall—

- (a) conduct a clinical trial; or
- (b) perform the functions of the sponsor of a clinical trial (whether that person is the sponsor or is acting under arrangements made with that sponsor),

otherwise than in accordance with the conditions and principles of good clinical practice.

(2) Subject to paragraph (5), the sponsor of a clinical trial shall put and keep in place arrangements for the purpose of ensuring that with regard to that trial the conditions and principles of good clinical practice are satisfied or adhered to.

(3) Subject to paragraphs (4) and (5), the sponsor of a clinical trial shall ensure that—

- (a) the investigational medicinal products used in the trial, and
- (b) any devices used for the administration of such products,

are made available to the subjects of the trial free of charge.

(4) The restriction in paragraph (3) shall not apply in relation to any charge payable by a subject under regulations made under—

- (a) the National Health Service Act 1977⁽¹⁾;
- (b) the National Health Service (Scotland) Act 1978⁽²⁾; or
- (c) the Health and Personal Social Services (Northern Ireland) Order 1972⁽³⁾,

in respect of any medicinal products or devices provided in pursuance of those Acts or that Order.

(5) If—

- (a) a clinical trial is conducted at more than one trial site; and
- (b) the request for authorisation to conduct that trial specifies that in relation to one or more trial sites the duties of the sponsor under paragraphs (2) and (3) are to be performed by a person other than the sponsor,

those duties shall, in relation to that site or those sites, be performed by the person so specified.

⁽¹⁾ 1977 c. 49.

⁽²⁾ 1978 c. 29.

⁽³⁾ S.I. 1972/1265 (N.I. 14).

Status: *This is the original version (as it was originally made).*
