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 [F1];

(b) the National Health Service (Scotland) Act 1978 [F2]; or

(c) the Health and Personal Social Services (Northern Ireland) Order 1972 [F3],

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.

Textual Amendments

F1 1977 c. 49.

F2 1978 c. 29.

F3 S.I. 1972/1265 (N.I. 14).

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), **[**F4 24(5)**]** or Schedule 5.

Textual Amendments

F4 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**

[F5 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.**]**

Textual Amendments

F5 Reg. 29A inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **16**

Urgent safety measures

30.—(1) The sponsor and investigator may take appropriate urgent safety measures in order to protect the subjects of a clinical trial against any immediate hazard to their health or safety.

[F6(2) If measures are taken pursuant to paragraph (1), the sponsor shall—

(a) where paragraph (3) applies, as soon as possible; and

(b) in any other case, immediately, and in any event no later than 3 days from the date the measures are taken,

give written notice to the licensing authority and the relevant ethics committee of the measures taken and the circumstances giving rise to those measures.

(3) This paragraph applies for any period during which a disease—

(a) is pandemic; and

(b) is a serious risk to human health or potentially a serious risk to human health.**]**

Textual Amendments

F6 Reg. 30(2)(3) substituted for reg. 30(2) (8.5.2009) by The Medicines for Human Use (Miscellaneous Amendments) Regulations 2009 (S.I. 2009/1164), regs. 1, **3**

Suspension or termination of clinical trial

31.—(1) If, in relation to a clinical trial—

(a) the licensing authority have objective grounds for considering that—

(i) any condition, restriction or limitation which applies to the conduct of the trial and is set out in the request for authorisation or the particulars or documents accompanying that request, or

(ii) any condition imposed by the licensing authority under regulation 18(2) or (6), 19(8), 20(5), **[**F7 24(5)**]** or Schedule 5,

is no longer satisfied (either generally or at a particular trial site); or

(b) the licensing authority have information raising doubts about the safety or scientific validity of the trial, or the conduct of the trial at a particular trial site,

the licensing authority may, by a notice served in accordance with paragraph (2), require that the trial, or the conduct of the trial at a particular trial site, be suspended or terminated.

(2) A notice in accordance with paragraph (1) shall be served—

(a) in a case where the suspension or termination applies to the trial generally, on—

(i) the sponsor, or

(ii) the investigator at each trial site;

(b) in a case where the suspension or termination applies to the conduct of a trial at a particular trial site, on—

(i) the sponsor, or

(ii) the investigator at that trial site.

(3) The notice shall specify—

(a) whether the notice applies to the trial generally or to one or more of the trial sites;

(b) whether the notice requires suspension or termination of the trial;

(c) if the notice requires suspension of the trial—

(i) whether the suspension applies until further notice from the licensing authority or for such period as may be specified in the notice, and

(ii) any conditions which are to be satisfied before the trial or, as the case may be, the conduct of the trial at a particular site, may be recommenced; and

(d) whether suspension or termination is to take effect immediately on receipt of the notice or on such date as may be specified in the notice.

(4) If the licensing authority issues a notice under paragraph (1), they shall forthwith inform—

(a) where the notice has not been served on the sponsor, the sponsor;

F8(b) . . . . . .

(c) the relevant ethics committee;

F9(d) . . . . . .

F10(e) . . . . . .

(5) Subject to paragraph (6), at least one week before issuing a notice under paragraph (1) the licensing authority shall, by a notice in writing to the sponsor or the investigator—

(a) inform him that the authority is minded to issue a notice suspending or terminating the trial, or the conduct of a trial at a particular site, and of the reasons why they are so minded; and

(b) advise him that they may, within one week of the date of the notice, furnish the authority with written representations as to whether the trial, or the conduct of the trial at a particular site, should be so suspended or terminated.

(6) Paragraph (5) shall not apply where it appears to the licensing authority that there is an imminent risk to the health or safety of any of the subjects of the clinical trial.

(7) A person on whom a notice has been served in accordance with paragraphs (1) and (2) may, within 28 days, or such extended period as the licensing authority may in any particular case allow, of the notice being given, give notice of his wish to make written or oral representations to the appropriate committeeF11....

(8) Schedule 5 shall have effect to regulate the procedure for reference to the appropriate committee F12... following receipt of a notice in accordance with paragraph (7).

(9) Where the notice of suspension or termination is referred to an appropriate committee F13...it shall remain in force unless revoked in accordance with Schedule 5.

Textual Amendments

F7 Word in reg. 31(1)(a)(ii) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **17**

F8 Reg. 31(4)(b) omitted (31.12.2020) by virtue of The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **12**; 2020 c. 1, Sch. 5 para. 1(1)

F9 Reg. 31(4)(d) omitted (31.12.2020) by virtue of The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **12**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Reg. 31(4)(e) omitted (31.12.2020) by virtue of The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **12**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in reg. 31(7) omitted (30.10.2005) by virtue of The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 4(2)**

F12 Words in reg. 31(8) omitted (30.10.2005) by virtue of The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 4(3)**

F13 Words in reg. 31(9) omitted (30.10.2005) by virtue of The Medicines (Advisory Bodies) (No. 2) Regulations 2005 (S.I. 2005/2754), reg. 1(2)(b), **Sch. 3 para. 4(4)**

[F14Trial master file and archiving

31A.—(1) The sponsor shall keep a trial master file for a clinical trial.

(2) The sponsor shall ensure that the trial master file is readily available at all reasonable times for inspection by the licensing authority or any person appointed by the sponsor to audit the arrangements for the trial.

(3) The master file shall at all times contain the essential documents relating to that clinical trial.

(4) The essential documents relating to a clinical trial are those which—

(a) enable both the conduct of the clinical trial and the quality of the data produced to be evaluated; and

(b) show whether the trial is, or has been, conducted in accordance with the **[**F15relevant**]** requirements of **[**F16these Regulations**]**.

(5) The essential documents shall contain information specific to each phase of the trial.

(6) The sponsor shall ensure that any alteration to a document contained, or which has been contained, in the trial master file shall be traceable.

(7) The sponsor and the chief investigator shall ensure that the documents contained, or which have been contained, in the trial master file are retained for at least 5 years after the conclusion of the trial and that during that period are—

(a) readily available to the licensing authority on request; and

(b) complete and legible.

(8) The sponsor and chief investigator shall ensure that the medical files of trial subjects are retained for at least 5 years after the conclusion of the trial.

(9) The sponsor shall appoint named individuals within his organisation to be responsible for archiving the documents which are, or have been, contained in the trial master file and, subject to paragraph (2), access to those documents shall be restricted to those appointed individuals.

(10) If there is transfer of ownership of data or documents connected with the clinical trial—

(a) the sponsor shall record the transfer; and

(b) the new owner shall be responsible for data retention and archiving in accordance with paragraphs (2), (7) and (8).

(11) For the purposes of this regulation, an individual is an individual within the sponsor's organisation where—

(a) he is employed or engaged by the sponsor;

(b) he is acting under arrangements made with the sponsor for the purposes of managing or conducting the clinical trial;

(c) where the sponsor is an individual, he is the sponsor; or

(d) where the sponsor is a body of persons, he is—

(i) a member of the body, or

(ii) employed or engaged by such a member.**]**

Textual Amendments

F14 Reg. 31A inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **18**

F15 Word in reg. 31A(4)(b) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **13(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in reg. 31A(4)(b) substituted (31.12.2020) by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744), regs. 1, **13(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, PART 4.