SCHEDULE 2

Regulations 7(1)(b), 8(a) and 9

ADDITIONAL PROVISIONS RELATING TO ETHICS COMMITTEES

1. In this Schedule—

"appointing authority" means—

(a) in relation to an ethics committee established under regulation 6, the Authority,

(b) in relation to an ethics committee recognised by the Authority after an application in accordance with regulation 7(1), the person who applied for recognition, [F1]...

(c) in relation to an ethics committee recognised without an application for recognition being submitted in accordance with regulation 7(3), **[**[F2]the Authority, or**]**

(d) **[**[F3]in relation to the Gene Therapy Advisory Committee, the Secretary of State;**]**

"expert member" means a member of an ethics committee who—

(a) is a health care professional,

(b) has professional qualifications or experience relating to the conduct of, or use of statistics in **[**[F4]clinical research**]**, unless those professional qualifications or experience relate only to the ethics of clinical research or medical treatment, or

(c) is not a health care professional, but has been a registered medical practitioner or a person registered in the dentists register under the Dentists Act 1984;

"financial year" means the twelve months ending with 31st March; and

"lay member" means a member of an ethics committee, other than an expert member.

Textual Amendments

F1 Word in Sch. 2 para. 1 omitted (29.8.2006) by virtue of The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **28(a)(i)**

F2 Words in Sch. 2 para. 1 substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **28(a)(ii)**

F3 Words in Sch. 2 para. 1 inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **28(a)(iii)**

F4 Words in Sch. 2 para. 1 substituted (1.5.2008) by The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941), regs. 1(1), **5(2)**

2.—(1) The provisions of this Schedule shall not apply in relation to the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000.

(2) The provisions of this Schedule, other than paragraph 13, shall not apply before 1st May 2005 in relation to an ethics committee established or recognised solely for the purpose of considering Phase I trials.

Membership

3.—(1) An ethics committee shall consist of—

(a) expert members; and

(b) lay members.

(2) An ethics committee shall have no more than 18 members.

(3) **[**[F5]The**]** members of an ethics committee shall be appointed by the appointing authority.

(4) A person shall not be eligible for appointment as a lay member of an ethics committee if, in the course of his employment or business, he—

(a) provides medical, dental or nursing care, or

(b) conducts clinical research.

(5) An appointing authority shall, in relation to an ethics committee, exercise their power under sub-paragraph (3) so as to ensure that—

(a) at least one third of the total membership shall be lay members; and

(b) at least half of the lay members must be persons who are not, or who never have been—

(i) health care professionals,

(ii) persons involved in the conduct of clinical research, other than as a subject of such research, or

(iii) a chairman, member or director of—

(aa) a health service body, or

(bb) a body, other than a health service body, which provides health care**[**F6; or

[F7(cc) an integrated care board.**]]**

[F8(6) References in sub-paragraph (5) to a health service body include—

(a) a Strategic Health Authority,

(b) a Primary Care Trust,

(c) the National Institute for Health and Care Excellence, F9...

(d) the Health and Social Care Information Centre.**]**

[F10(e) Health Education England, and

(f) the Health Research Authority.**]**

Textual Amendments

F5 Word in Sch. 2 para. 3(3) substituted (1.5.2008) by The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941), regs. 1(1), **5(3)**

F6 Sch. 2 para. 3(5)(b)(iii)(cc) and preceding word inserted (1.10.2012) by The NHS Commissioning Board Authority (Abolition and Transfer of Staff, Property and Liabilities) and the Health and Social Care Act 2012 (Consequential Amendments) Order 2012 (S.I. 2012/1641), art. 1(2)(b), **Sch. 3 para. 8(3)(a)**

F7 Sch. 2 para. 3(5)(b)(iii)(cc) substituted (1.7.2022) by The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), regs. 1(2), **19(2)(a)**

F8 Sch. 2 para. 3(6) inserted (1.4.2013) by The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013 (S.I. 2013/235), arts. 1(2), 11, **Sch. 2 para. 66(3)**

F9 Word in Sch. 2 para. 3(6)(c) omitted (1.4.2015) by virtue of The Care Act 2014 (Health Education England and the Health Research Authority) (Consequential Amendments and Revocations) Order 2015 (S.I. 2015/137), art. 1, **Sch. 2 para. 3(a)**

F10 Sch. 2 para. 3(6)(e)(f) added (1.4.2015) by The Care Act 2014 (Health Education England and the Health Research Authority) (Consequential Amendments and Revocations) Order 2015 (S.I. 2015/137), art. 1, **Sch. 2 para. 3(b)**

4. A member of an ethics committee shall hold and vacate office as a member in accordance with the terms of the instrument appointing him as a member.

5.—(1) The appointing authority shall appoint—

(a) one of the members of each ethics committee to be chairman of the committee;

(b) another member to be vice-chairman; and

(c) another member to be alternate vice-chairman.

(2) The members appointed as chairman, vice-chairman and alternate vice-chairman shall each be appointed for such period, not exceeding the remainder of his term as a member, as the appointing authority may specify on appointing him.

(3) Any member so appointed may at any time resign from the office of chairman, vice-chairman or alternate vice-chairman.

(4) Where the chairman has died or has ceased to hold office, or where he is unable to perform his duties as chairman owing to illness, absence or any other cause, references to the chairman in this Schedule shall, so long as there is no chairman available to perform his duties, be taken to include references to—

(a) the vice-chairman;

(b) if the vice-chairman is also is unable to perform his duties, the alternate vice-chairman; or

(c) if all three individuals are unavailable, a member appointed by the appointing authority for the purposes of acting as chairman until one of those individuals is available to perform his duties.

6.—(1) An ethics committee may—

(a) appoint sub-committees consisting of members of the committee; and

(b) make arrangements for the exercise, on behalf of the committee, of any of its functions by such a sub-committee,

in accordance with the standing orders and operating procedures adopted under sub-paragraph (3).

(2) Subject to **[**[F11]sub-paragraphs (4) and (4A)**]**, the meetings and proceedings of an ethics committee and its sub-committees shall be conducted in accordance with the standing orders made, and standing operating procedures adopted, under sub-paragraph (3).

(3) An ethics committee—

(a) shall, subject to approval by the Authority, make standing orders, and adopt standing operating procedures, for the regulation of its proceedings and business; and

(b) may, subject to approval by the Authority, vary or revoke such orders or procedures,

including provision for the suspension of the standing orders or operating procedures or any of them.

[[F12](4) All valid applications for an ethics committee opinion must be considered by a full meeting of an ethics committee.

(4A) Where a full meeting of an ethics committee has considered a valid application and reached a provisional opinion, it may delegate the final determination of its opinion in accordance with regulation 15 to the Chairman of the ethics committee or a sub-committee of specified members.**]**

[[F13](5) An ethics committee shall retain all the documents relating to a clinical trial on which it gives an opinion for—

(a) where the trial proceeds, at least three years from the conclusion of the trial; or

(b) where the trial does not proceed, at least three years from the date of the opinion.**]**

[[F14](6) For the purposes of this paragraph, a "full meeting of an ethics committee" is one at which at least seven members of the committee (including any members co-opted under paragraph 8) are present, including at least—

(a) one lay member who is not and never has been—

(i) a health care professional, or

(ii) a chairman, member, director, officer or employee of a health service body **[**F15or **[**F16an integrated care board**]]**; and

(b) one expert member.**]**

Textual Amendments

F11 Words in Sch. 2 para. 6(2) substituted (1.5.2008) by The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941), regs. 1(1), **5(4)(a)**

F12 Sch. 2 para. 6(4)(4A) substituted for Sch. 2 para. 6(4) (1.5.2008) by The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941), regs. 1(1), **5(4)(b)**

F13 Sch. 2 para. 6(5) inserted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **28(b)**

F14 Sch. 2 para. 6(6) inserted (1.5.2008) by The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941), regs. 1(1), **5(4)(c)**

F15 Words in Sch. 2 para. 6(6)(a)(ii) inserted (1.10.2012) by The NHS Commissioning Board Authority (Abolition and Transfer of Staff, Property and Liabilities) and the Health and Social Care Act 2012 (Consequential Amendments) Order 2012 (S.I. 2012/1641), art. 1(2)(b), **Sch. 3 para. 8(3)(b)**

F16 Words in Sch. 2 para. 6(6)(a)(ii) substituted (1.7.2022) by The Health and Care Act 2022 (Consequential and Related Amendments and Transitional Provisions) Regulations 2022 (S.I. 2022/634), regs. 1(2), **19(2)(b), Sch. para. 1(1)(3) (with Sch. para. 1(2)**

Deputies and co-opted members

7.—(1) **[**F17The appointing authority**]** may appoint a person to act as the deputy of an expert member or a lay member provided that the person would be eligible for appointment as an expert member or, as the case may be, a lay member.

(2) A deputy shall hold and vacate office as a deputy member in accordance with the terms of the instrument appointing him as a deputy.

(3) A deputy may vote as a member of the committee only if the member for which he acts as deputy is absent.

(4) A deputy member and the member for which he is deputy shall count as one member for the purposes of paragraphs 3(2) and (4) and 6(4).

Textual Amendments

F17 Words in Sch. 2 para. 7(1) substituted (1.5.2008) by The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941), regs. 1(1), **5(5)**

8.—(1) At any meeting of an ethics committee, the committee may co-opt up to 2 additional members for the purposes of that meeting.

(2) At any meeting of a sub-committee of an ethics committee, the sub-committee may co-opt an additional member for the purposes of that meeting.

(3) Subject to sub-paragraph (4), a person shall be eligible to be co-opted as a member only if he is or has been a member of **[**F18a committee that advises or has advised on the ethics of research involving human subjects**]**.

(4) **[**F19Sub-paragraph (3)**]** shall not apply in relation to the Gene Therapy Advisory Committee.

[[F20](5) A co-opted member shall hold and vacate office in accordance with the ethics committee's standing orders and operating procedures adopted under paragraph 6(3).**]**

(6) A member co-opted under this paragraph shall not count as a member for the purposes of paragraphs 3(2) and **[**[F21](5)**]**.

Textual Amendments

F18 Words in Sch. 2 para. 8(3) substituted (1.5.2008) by The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941), regs. 1(1), **5(6)(a)**

F19 Words in Sch. 2 para. 8(4) substituted (19.8.2010) by The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 (S.I. 2010/1882), regs. 1(1), **9(4)**

F20 Sch. 2 para. 8(5) substituted (1.5.2008) by The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941), regs. 1(1), **5(6)(b)**

F21 Word in Sch. 2 para. 8(6) substituted (29.8.2006) by The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (S.I. 2006/1928), regs. 1(1), **28(c)**

9.—(1) The appointing authority shall make arrangements for the appointment of such administrative and other staff for an ethics committee as they consider necessary to enable the committee to perform its functions.

(2) The appointing authority shall—

(a) secure the provision to an ethics committee of such accommodation and facilities as they consider necessary to enable the committee to perform its functions; and

(b) secure that arrangements are made for such administration, maintenance, cleaning and other services as may, in their opinion, be necessary for such accommodation and facilities.

(3) To enable an ethics committee to perform its functions, a health service body may make staff, premises and facilities available to an ethics committee under arrangements made with the appointing authority.

Expenses

10.—(1) The appointing authority shall, in respect of each financial year, pay to an ethics committee sums equal to the amount approved as the amounts of expenditure which they consider may be reasonably incurred by the committee in that year for the purpose of performing its functions.

(2) An ethics committee shall not incur expenses in excess of the amounts approved for that committee by the appointing authority under this paragraph.

11. The appointing authority may pay to members of ethics committees such travelling and other allowances as the authority may determine.

12.—(1) Within the period six months from the end of each financial year, every ethics committee shall prepare a report on the committee's activities during that year, which shall include a list of—

(a) the applications made to the committee in accordance with regulation 14; and

(b) the decisions made by the committee in relation to those applications.

(2) The ethics committee shall send a copy of the report to the Authority and, if the Authority is not the appointing authority for that committee, to its appointing authority.

13.—(1) This paragraph applies where—

(a) recognition of an ethics committee is revoked in accordance with regulation 8; or

(b) an ethics committee is abolished or ceases operation.

(2) If the person who was the appointing authority before revocation, abolition or the ceasing of operation of the committee ("the old committee") is the Authority, that person may nominate another ethics committee as responsible for the work of the committee.

(3) If the person referred to in sub-paragraph (2) was not the Authority, that person may only nominate an ethics committee with the approval of the Authority.

(4) If the person referred to in sub-paragraph (2) no longer exists or if that person fails to nominate another ethics committee, the Authority shall nominate such a committee.

(5) Where an ethics committee is nominated in accordance with the preceding sub-paragraphs—

(a) that committee shall consider any applications made to the old committee in accordance with regulation 14, if the old committee had not given an opinion before the date of revocation, abolition or ceasing of operation;

(b) that committee shall be the relevant ethics committee for any clinical trial in relation to which the old committee had given a favourable opinion in accordance with regulation 15.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, SCHEDULE 2.