SCOTTISH STATUTORY INSTRUMENTS

2002 No. 190

ADULTS WITH INCAPACITY

The Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002

Made - - - -	*15th April 2002*
Laid before the Scottish Parliament - - - -	*17th April 2002*
Coming into force - -	*1st July 2002*

The Scottish Ministers, in exercise of the powers conferred by sections 51(6) and (7) and 86(2) of the Adults with Incapacity (Scotland) Act 2000[F1] and of all other powers enabling them in that behalf, hereby make the following Regulations:

F1 2000 asp 4. Section 87(1) contains a definition of "prescribed" relevant to the making of these Regulations.

Citation and commencement

1. These Regulations may be cited as the Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002 and come into force on 1st July 2002.

Ethics Committee

2. There is hereby constituted an Ethics Committee ("the Committee") for the purposes specified in section 51 of the Adults with Incapacity (Scotland) Act 2000.

Membership of the Committee

3.—(1) The members of the Committee may be appointed by the Scottish Ministers on such terms and conditions as the Scottish Ministers consider appropriate.

(2) No more than **[**[F2]30**]** members shall be appointed to the Committee at any time.

(3) The membership of the Committee shall, so far as practical, include at least–

(a) one person who has experience in relation to the treatment of adults who are incapable;

(b) one medical practitioner who provides **[**[F3]primary medical services pursuant to Part I**]** of the National Health Service (Scotland) Act 1978 [F4];

(c) one registered nurse or registered midwife;

(d) one registered medical practitioner having experience in clinical pharmacology;

(e) one **[**F5pharmacist registered in Part 1 of the register maintained under article 19 of the Pharmacy Order 2010**]** or a registered person as defined by Article 2(2) of the Pharmacy (Northern Ireland) Order 1976 F6;

(f) one registered medical practitioner who holds the position of hospital consultant;

(g) one registered medical practitioner having experience in the field of public health medicine;

(h) one member who is registered as a member of a profession to which the **[**F7Health Professions Order 2001 applies**]**; and

(i) three lay members.

(4) Each member may be appointed for a period not exceeding 5 years but no member may be appointed for consecutive periods exceeding **[**F812**]** years.

(5) Where a person has been appointed as a member for a total of **[**F912**]** years consecutively that person may only be appointed again as a member under paragraph (4) above after the expiration of a period of 2 years from the end of the person's previous membership.

F2 Word in reg. 3(2) substituted (20.2.2007) by The Adults with Incapacity (Ethics Committee) (Scotland) Amendment Regulations 2007 (S.S.I. 2007/22), regs. 1, **2(2)**

F3 Words in reg. 3(3)(b) substituted (31.5.2004) by virtue of The Primary Medical Services (Consequential and Ancillary Amendments) (Scotland) Order 2004 (S.S.I. 2004/212), art. 1, **sch. 1 para. 11**

F4 1978 c.29. Section 17C was inserted by section 21(2) of the National Health Service (Primary Care) Act 1997 (c.46) ("the 1997 Act"). Section 19 was amended by section 4 of and paragraph 29 of the Schedule to the Medical (Professional Performance) Act 1995 (c.51) and section 41(10) and (11) of and paragraph 39 of Schedule 2 to the 1997 Act (c.46).

F5 Words in reg. 3(3)(e) substituted (27.9.2010) by The Pharmacy Order 2010 (S.I. 2010/231), art. 1(5), **Sch. 4 para. 35** (with Sch. 5); S.I. 2010/1621, art. 2(1), Sch.

F6 S.I. 1976/1213.

F7 Words in reg. 3(3)(h) substituted (2.12.2019) by The Children and Social Work Act 2017 (Consequential Amendments) (Social Workers) Regulations 2019 (S.I. 2019/1094), reg. 1, **Sch. 3 para. 6**; S.I. 2019/1436, reg. 2(b)

F8 Word in reg. 3(4) substituted (21.5.2020) by The Adults with Incapacity (Ethics Committee) (Scotland) (Coronavirus) Amendment Regulations 2020 (S.S.I. 2020/151), regs. 1, **2(2)**

F9 Word in reg. 3(5) substituted (21.5.2020) by The Adults with Incapacity (Ethics Committee) (Scotland) (Coronavirus) Amendment Regulations 2020 (S.S.I. 2020/151), regs. 1, **2(2)**

Chair and Vice-Chair

4. Subject to regulation 3(4) and (5) above, the Scottish Ministers may appoint, from among the members of the Committee, a Chair**[**F10, **]** a Vice-Chair **[**F11and up to two Alternate Vice-Chairs**]** of the Committee for such period or periods as the Scottish Ministers consider appropriate.

F10 Comma in reg. 4 substituted for word (21.5.2020) by The Adults with Incapacity (Ethics Committee) (Scotland) (Coronavirus) Amendment Regulations 2020 (S.S.I. 2020/151), regs. 1, **2(3)(a)**

F11 Words in reg. 4 inserted (21.5.2020) by The Adults with Incapacity (Ethics Committee) (Scotland) (Coronavirus) Amendment Regulations 2020 (S.S.I. 2020/151), regs. 1, **2(3)(b)**

Remuneration

5. The Scottish Ministers may pay, to members of the Committee, such expenses related to their membership of the Committee as the Scottish Ministers consider appropriate.

Approval of Research

6. Before approving any research under section 51 of the Adults with Incapacity (Scotland) Act 2000 the Committee must take into account–

(a) the objectives, design, methodology, statistical considerations and organisation of the research;

(b) the relevance of the research and the study design;

(c) the justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and future participants;

(d) the suitability of the lead researcher;

(e) the adequacy of the written information to be given and the procedure for obtaining consent; and

(f) the arrangements for the recruitment of research participants.

Procedures

7.—(1) Subject to the provision of this regulation, the Committee shall consider applications in such manner as it considers appropriate in the circumstances.

(2) No approval of research shall be granted by the Committee unless at least **[**F12**[**F13**3]** members are present**]** and those members include–

(a) the Chair, or in the Chair's absence, the Vice-Chair **[**F14or an Alternate Vice-Chair**]**;

(b) **[**F15a member**]** from among those appointed under sub-paragraphs (a) to (h) of regulation 3(3) above; and

(c) **[**F16a member**]** from among those appointed under sub-paragraph (i) of regulation 3(3) above.

(3) The proceedings of the Committee shall not be invalidated by death or other vacancy in its membership.

(4) Application to the Committee for approval of research shall be in such form as the Committee may determine.

(5) The Committee may call for such information from an applicant as it may reasonably require in order to determine the application and may seek such assistance from other persons as it considers necessary for that determination.

(6) The Committee may refer to one or more of its members for report or recommendation on such matters as it considers appropriate in relation to its consideration of an application.

F12 Words in reg. 7(2) substituted (20.2.2007) by The Adults with Incapacity (Ethics Committee) (Scotland) Amendment Regulations 2007 (S.S.I. 2007/22), regs. 1, **2(3)**

F13 Word in reg. 7(2) substituted (21.5.2020) by The Adults with Incapacity (Ethics Committee) (Scotland) (Coronavirus) Amendment Regulations 2020 (S.S.I. 2020/151), regs. 1, **2(4)(a)**

F14 Words in reg. 7(2)(a) inserted (21.5.2020) by The Adults with Incapacity (Ethics Committee) (Scotland) (Coronavirus) Amendment Regulations 2020 (S.S.I. 2020/151), regs. 1, **2(4)(b)**

F15 Words in reg. 7(2)(b) substituted (21.5.2020) by The Adults with Incapacity (Ethics Committee) (Scotland) (Coronavirus) Amendment Regulations 2020 (S.S.I. 2020/151), regs. 1, **2(4)(c)**