

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(a) and of all other powers enabling them in that behalf, hereby make the following 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 18 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 personal, or general, medical services under sections 17C or 19 of the National Health Service (Scotland) Act 1978(b);
 - (c) one registered nurse or registered midwife;
 - (d) one registered medical practitioner having experience in clinical pharmacology;
 - (e) one registered pharmaceutical chemist as defined by section 24(1) of the Pharmacy Act 1954(c) or a registered person as defined by Article 2(2) of the Pharmacy (Northern Ireland) Order 1976(d);
 - (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;

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

(b) 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).

(c) 1954 c.61.

(d) S.I. 1976/1213.

- (h) one member who is registered as a member of a profession to which the Professions Supplementary to Medicine Act 1960(a) 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 10 years.

(5) Where a person has been appointed as a member for a total of 10 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.

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 and a Vice-Chair of the Committee for such period or periods as the Scottish Ministers consider appropriate.

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 one half of its membership is present and those members include—

- (a) the Chair, or in the Chair's absence, the Vice-Chair;
- (b) two members from among those appointed under sub-paragraphs (a) to (h) of regulation 3(3) above; and
- (c) two members 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.

(a) 1960 c.66.

(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.

St Andrew's House,
Edinburgh
15th April 2002

HUGH HENRY
Authorised to sign by the Scottish Ministers

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations—

- (a) constitute the Ethics Committee (“the Committee”) referred to in section 51 of the Adults with Incapacity (Scotland) Act 2000 (“the Act”) (regulation 2);
- (b) make provision as to the membership, the qualifications of certain members and length of membership of the Committee (regulation 3);
- (c) make provision for the appointment of a Chair and Vice-Chair of the Committee (regulation 4);
- (d) make provision for payment by the Scottish Ministers of expenses of members of the Committee (regulation 5);
- (e) specify certain matters which the Committee must consider before approving research (regulation 6); and
- (f) makes certain procedural provision in relation to the conduct of the Committee in particular by—
 - (i) permitting the Committee to consider applications in such manner as it considers appropriate (regulation 7(1)),
 - (ii) providing for quorum arrangements (regulation 7(2)),
 - (iii) providing that a vacancy in membership will not invalidate its proceedings (regulation 7(3)),
 - (iv) permitting the Committee to determine the form of applications (regulation 7(4)),
 - (v) allowing the Committee to call for information from applicants and assistance from others (regulation 7(5)), and
 - (vi) permitting the Committee to remit matters to one or more members for report or recommendation (regulation 7(6)).

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