
STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use
(Clinical Trials) Regulations 2004

PART 2

ETHICS COMMITTEES

United Kingdom Ethics Committees Authority

5.—(1) The body responsible for establishing, recognising and monitoring ethics committees in the United Kingdom in accordance with these Regulations is the United Kingdom Ethics Committees Authority, which is a body consisting of—

- (a) the Secretary of State for Health;
- (b) the National Assembly for Wales;
- (c) the Scottish Ministers; and
- (d) the Department for Health, Social Services and Public Safety for Northern Ireland.

(2) The functions of the Authority—

- (a) may, by agreement between them, be performed by any one of the Secretary of State for Health, the National Assembly for Wales, the Scottish Ministers and the Department for Health, Social Services and Public Safety for Northern Ireland acting alone, or any two or more of them acting jointly; and
- (b) may be performed by any one of the Secretary of State for Health, the National Assembly for Wales, the Scottish Ministers and the Department for Health, Social Services and Public Safety for Northern Ireland acting alone solely in relation to a part of the United Kingdom with respect to which the Secretary of State, the Assembly, the Ministers or the Department, as the case may be, have responsibilities.

(3) In accordance with the preceding provisions of this regulation, in these Regulations “the United Kingdom Ethics Committees Authority” (“the Authority”) means any one or more of the Secretary of State for Health, the National Assembly for Wales, the Scottish Ministers and the Department for Health, Social Services and Public Safety for Northern Ireland, and, in the case of anything falling to be done by the Authority, means any one or more of them acting as mentioned in paragraph (2).

(4) The Authority may appoint such persons as they think necessary for the proper discharge by them of their functions, and those persons shall be appointed on such terms and conditions (including conditions as to remuneration, benefits, allowances and reimbursement for expenses) as the Authority think fit.

(5) Arrangements may be made between the Authority and any relevant authority for—

- (a) any functions of the Authority to be exercised by, or by members of staff of, the relevant authority; or

(b) the provision of staff, premises or administrative services by the relevant authority to the Authority.

(6) Any arrangements under paragraph (5) for the exercise of any functions of the Authority shall not affect the responsibility of the Authority.

(7) In this regulation, “relevant authority” means any government department, local or public authority or holder of public office.

Establishment of ethics committees

6.—(1) The Authority may establish ethics committees to act—

- (a) for the entire United Kingdom or for such areas of the United Kingdom; and
- (b) in relation to such descriptions or classes of clinical trials,

as the Authority consider appropriate.

(2) The Authority may—

- (a) vary the area for which any committee they have established acts or, as the case may be, the descriptions or classes of clinical trials in relation to which such a committee acts; and
- (b) abolish any such committee.

Recognition of ethics committees

7.—(1) Subject to paragraph (3), the Authority may, by a notice in writing, recognise a committee as an ethics committee for the purposes of these Regulations if—

- (a) an application in relation to that committee has been made in accordance with paragraph (2); and
- (b) they are satisfied that the proposed arrangements for the membership and operation of that ethics committee would—
 - (i) enable that committee to perform the functions of an ethics committee adequately; and
 - (ii) comply with the provisions of Schedule 2.

(2) An application for recognition of an ethics committee shall be—

- (a) made in writing to the Authority; and
- (b) accompanied by such information, documents and particulars as are necessary to enable the Authority to determine the application.

(3) If any committee—

- (a) was established or recognised by—
 - (i) the Secretary of State,
 - (ii) the Scottish Ministers,
 - (iii) the National Assembly for Wales,
 - (iv) the Department of Health, Social Services and Public Safety, or
 - (v) a Strategic Health Authority, Health Board or Health and Social Services Board,for the purpose of advising on the ethics of research investigations on human beings, and
- (b) was in existence on 30th April 2004,

the Authority may recognise that committee in accordance with paragraph (1) without an application for recognition being submitted.

- (4) When recognising a committee the Authority shall specify—
 - (a) whether the committee may act for the entire United Kingdom or only for a particular area of the United Kingdom;
 - (b) the description or class of clinical trial in relation to which it may act as an ethics committee; and
 - (c) any other conditions or limitations that apply to that committee.
- (5) The Authority may—
 - (a) vary the area for which a committee recognised under this regulation acts,
 - (b) vary the description or class of clinical trial in relation to which it may act as an ethics committee, or
 - (c) vary or revoke any conditions or limitations imposed under paragraph (5),where it considers it necessary or appropriate to do so.

Revocation of recognition

- 8. The Authority may revoke a recognition of an ethics committee if they are satisfied that—
 - (a) the provisions of Schedule 2 are not complied with in relation to that committee;
 - (b) the committee is failing to perform its functions under these Regulations adequately or at all; or
 - (c) it is otherwise necessary or expedient to do so.

Constitution and operation of ethics committees

- 9. The provisions of Schedule 2 have effect in relation to ethics committees.

Other functions of the Authority

- 10.—(1) The Authority shall monitor the extent to which ethics committees adequately perform their functions under these Regulations.
- (2) The Authority may provide advice and assistance to ethics committees with respect to the performance of their functions.