
STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use
(Clinical Trials) Regulations 2004

PART 2

ETHICS COMMITTEES

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.