STATUTORY INSTRUMENTS

2004 No. 1031

The Medicines for Human Use (Clinical Trials) Regulations 2004

PART 3

AUTHORISATION FOR CLINICAL TRIALS AND ETHICS COMMITTEE OPINION

Application for ethics committee opinion

14.—(1) An application for an ethics committee opinion in relation to a clinical trial shall be made by the chief investigator for that trial.

(2) A chief investigator for a trial shall make an application for an ethics committee opinion in relation to that trial to one ethics committee only, regardless of the number of trial sites at which the trial is to be conducted.

(3) Subject to paragraphs (4) and (5), the application for an ethics committee opinion in relation to a clinical trial shall be made to an ethics committee established or recognised—

(a) for—

(i) the entire United Kingdom, or

(ii) in relation to an area of the United Kingdom in which the chief investigator is professionally based; and

(b) in relation to a description or class of clinical trial into which the proposed trial falls.

(4) If a clinical trial—

(a) is conducted at one or more trial sites in Scotland;

(b) involves adults unable by virtue of physical or mental incapacity to give informed consent; and

(c) the chief investigator is professionally based at a hospital, health centre, surgery or other establishment or facility in Scotland,

the application for an ethics committee opinion in relation to that trial shall be made to the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000(**1**).

(5) An application for an ethics committee opinion in relation to a clinical trial involving medicinal products for gene therapy, other than a trial falling within paragraph (4), shall be made to the Gene Therapy Advisory Committee.

(6) An application shall be—

(a) in writing;

(b) signed by the chief investigator making the application; and

(**1**) 2000 asp. 4; *see*S.S.I. 2002/190.

(c) accompanied by the particulars and documents specified in Part 1 of Schedule 3.

(7) The application and any accompanying material shall be supplied in the English language.

(8) For the purposes of this regulation, a chief investigator is professionally based at the hospital, health centre, surgery or other establishment or facility at or from which he primarily conducts his professional practice.