
STATUTORY INSTRUMENTS

2010 No. 995

The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010

Applications

4.—(1) An application for authorisation must be made to the Authority.

(2) An application may be submitted by an appropriate person nominated by the research establishment.

(3) An application must—

- (a) be in writing; and
- (b) include the information referred to in paragraph (4).

(4) The information referred to in paragraph (3) is—

- (a) the name, qualifications, address, telephone number and email address of the applicant;
- (b) the name of the research establishment which is to carry out research processing the disclosable protected information;
- (c) a description of the medical or other research to be undertaken by the research establishment within the United Kingdom (“the research project”);
- (d) what disclosable protected information the applicant wants the Authority to disclose to the applicant for the purposes of the research project;
- (e) the address of the premises at which the research project is to be undertaken;
- (f) either—
 - (i) the favourable opinion of a research ethics committee for the research project; or
 - (ii) where at the time of the application, an application to a research ethics committee for the research project is outstanding, an undertaking to provide the Authority with information regarding the outcome of that application within the period of 14 days beginning with the date of notification by the committee;
- (g) the reasons why the processing of the disclosable protected information is necessary for the purposes of the research project;
- (h) a description of the security arrangements in place at the premises in respect of which the application is made relating to the processing of disclosable protected information; and
- (i) the reasons why the disclosable protected information cannot be obtained otherwise than pursuant to these Regulations.

(5) Where—

- (a) an authorisation has expired; and
- (b) a further application is submitted within the period of 90 days beginning with the date of expiry of the previous authorisation in relation to the same research project,

the application need not include any of the information mentioned in sub-paragraphs (b) to (h) of paragraph (4), if that information remains the same as that supplied in relation to the previous application.

(6) Where paragraph (5) applies, the applicant shall state what information has remained the same as that supplied by the applicant in relation to the previous application.

(7) The Authority may request further information, where—

- (a) the Authority is of the opinion that the information given by the applicant in accordance with paragraph (4) or (6) is incomplete in any material respect; or
- (b) the Authority considers that supplementary information is required in order for it to determine the application.

(8) The applicant shall provide the information requested within the period of 56 days beginning with the date of the request.

(9) The Authority need not further consider or determine the application until the applicant has provided it with such further information as requested by it under paragraph (7) and may at the end of the period specified in paragraph (8), refuse to grant the authorisation on the ground that the requested information has not been provided.