Draft Regulations laid before Parliament under section 45(4) of the Human Fertilisation and Embryology Act 1990, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2010 No. 000

HUMAN FERTILISATION AND EMBRYOLOGY

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

Made - - - -	*2010*
Coming into force - -	*6th April 2010*

These Regulations are made by the Secretary of State for Health in exercise of the powers conferred by sections 33D and 45(1) to (3A) of the Human Fertilisation and Embryology Act 1990(**1**).

In accordance with section 33D(8) of that Act the Secretary of State for Health has consulted such bodies appearing to the Secretary of State to represent the interests of those likely to be affected by the Regulations as the Secretary of State considers appropriate.

A draft of this instrument has been approved by a resolution of each House of Parliament pursuant to section 45(4) of that Act.

Citation and commencement

1. These Regulations may be cited as the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 and shall come into force on 6th April 2010.

Interpretation

2.—(1) In these Regulations—

"the Act" means the Human Fertilisation and Embryology Act 1990;

"additional conditions" mean conditions imposed under regulation 8(2);

"application" except in regulation 9, means an application made under regulation 4 and "applicant" shall be construed accordingly;

"authorisation" means authorisation by the Authority under regulation 3;

"the Authority" means the Human Fertilisation and Embryology Authority;

"the Data Protection Act" means the Data Protection Act 1998(**2**);

(**1**) c. 37. Section 33D was inserted by section 25 of the Human Fertilisation and Embryology Act 2008 (c. 22).
(**2**) c. 29.

"the NHS Act" means the National Health Service Act 2006(**3**);

"the NIGB" means the National Information Governance Board for Health and Social Care established by section 250A of the NHS Act(**4**);

"parental responsibility" has the same meaning as in section 33B(6) of the Act(**5**) (consent required to authorise certain disclosures);

"processing" except in regulation 14, means using the disclosable protected information authorised under regulation 3 and "process" and "processed" shall be construed accordingly;

"relevant individual" has the same meaning as in section 31(4) of the Act(**6**) (register of information);

"research establishment" means a university or other body or institution that carries out medical or other research within the United Kingdom;

"research ethics committee" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004(**7**); or

(b) any other committee established to advise on the ethics of research investigations in human beings and recognised for that purpose by or on behalf of the Secretary of State; and

"research project" has the meaning given in regulation 4(4)(c).

(2) In these Regulations, "disclosable protected information" means information falling within section 31(2) of the Act(**8**) (register of information) which—

(a) is entered by the Authority on its register during the period from 1st August 1991 to 30th September 2009 (both dates inclusive) but does not fall within an exclusion in paragraph (3) of this regulation; or

(b) is entered by the Authority on its register on or after 1st October 2009 and is about a relevant individual but does not fall within an exclusion in paragraph (4) of this regulation.

(3) For the purposes of paragraph (2)(a), information is excluded where it—

(a) identifies or relates to an individual who has donated gametes other than for research purposes only;

(b) identifies or relates to an individual (or a person treated with that individual) who has received treatment services with donated gametes;

(c) identifies or relates to an individual who has donated (whether alone or with another) an embryo other than for research purposes only;

(d) identifies or relates to an individual (or a person treated with that individual) who has received treatment services with a donated embryo;

(e) identifies or relates to an individual who was conceived as a result of assisted conception using donated gametes or a donated embryo; or

(f) is in respect of—

(i) an individual who has refused to give consent for disclosure for the purposes of research;

(**3**) c. 41.
(**4**) c. 41. Section 250A was inserted by section 157 of the Health and Social Care Act 2008 (c. 14).
(**5**) Section 33B of the Act was inserted by section 25 of the 2008 Act.
(**6**) c. 37. Section 31(4) of the Act was substituted by section 24 of the 2008 Act.
(**7**) S.I. 2004/1031; relevant amending instruments are S.I. 2006/1928 and 2008/941.
(**8**) c. 37. Section 31(2) was substituted by section 24 of the 2008 Act.

(ii) an individual who has not attained the age of 16 years, where the parents of, or other persons with parental responsibility for, that child indicated in writing that information relating to that child could not be disclosed for the purposes of research; or

(iii) an individual who has not attained the age of 16 years, where at the time that treatment services or non-medical fertility services were being provided to the persons who became the parents of that child, those persons indicated in writing that information relating to any child born as a result of those treatment services could not be disclosed for the purposes of research.

(4) For the purposes of paragraph(2)(b), information is excluded where it—

(a) is in respect of a relevant individual who has attained the age of 16 years unless the relevant individual has consented to the disclosure of the information by the Authority for research purposes in accordance with regulations made under section 33D of the Act (disclosure for the purposes of medical or other research);

(b) is in respect of a relevant individual who has given written notice to the Authority that they do not consent to the disclosure for research purposes by the Authority of information about them provided at the time of giving that notice the relevant individual was competent to give it;

(c) is in respect of a relevant individual where a person having parental responsibility for the relevant individual has given written notice to the Authority that they do not consent to the disclosure for research purposes by the Authority of information about the relevant individual;

(d) is in respect of a relevant individual where, at the time treatment services or non-medical fertility services were being provided to the persons who became the parents of the relevant individual, those persons indicated in writing that information relating to any child born as a result of those treatment services could not be disclosed by the Authority for research purposes in accordance with regulations made under section 33D of the Act (disclosure for the purposes of medical or other research);

(e) identifies or relates to an individual who has donated (whether alone or with an individual) an embryo other than for research purposes only; or

(f) identifies or relates to an individual who has donated gametes other than for research purposes only.

(5) Any notice given under these Regulations shall be—

(a) in writing; or

(b) transmitted by electronic means in a legible form which is capable of being used for subsequent reference.

Authorisation for disclosure of information

3. The Authority may grant an authorisation to a research establishment for the processing of disclosable protected information in accordance with these Regulations.

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,

(6) 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.

(7) 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.

(8) 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.

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

(10) 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.

Advice and assistance from NIGB

5. Where requested by the Authority, the NIGB may provide advice and assistance to the Authority in relation to the exercise by the Authority of its functions under these Regulations or such other matters as may arise in relation to the processing of information under these Regulations (as specified in the request).

Authorisation where approval has been given under section 251 of the NHS Act

6. Where—

(a) an approval has been given under regulations made under section 251 of the NHS Act (control of patient information) in respect of the research project included in the application;

(b) the research project is to take place in England or Wales; and

(c) the Authority, having considered the application, is of the opinion that that there are no exceptional reasons why the disclosable protected information should not be processed under these Regulations for the purpose of the research project,

(2) the Authority shall grant an authorisation.

Grounds for refusal of grant

7.—(1) Subject to paragraph (2), the Authority must not grant an authorisation where it is satisfied that—

(a) a research ethics committee has not given a favourable opinion in relation to the research project;

(b) the processing of the disclosable protected information is not necessary for the purposes of the research project;

(c) the security arrangements in place at the premises at which the disclosable protected information is to be processed are inadequate for the security of the disclosable protected information; or

(d) the information to which the application relates is information from which an individual may be identified and it would be reasonably practicable for the purposes of the research project to be achieved otherwise than pursuant to the grant of an authorisation, having regard to the cost of and technology available for achieving that purpose.

(2) Where regulation 4(4)(f)(ii) applies (outstanding request for an opinion of a research ethics committee in relation to the research project), the Authority shall not refuse an application until it has been notified by the applicant of the outcome of the application to the research ethics committee.

(3) In addition to the circumstances set out in regulation 4(9), the Authority may refuse to grant an authorisation where—

(a) it reasonably estimates that the fee payable under regulation 13 would, if calculated without regard to paragraph (4) of that regulation, be likely to be in excess of £5000; or

(b) it is satisfied that the disclosure or processing of the information for the purposes of the research project is not necessary or expedient in the public interest or in the interests of improving patient care.

Authorisation subject to conditions

8.—(1) Where the Authority grants an authorisation, it must impose the conditions that—