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STATUTORY INSTRUMENTS

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**2010 No. 995**

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

**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.