

## Consultation on the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations

The consultation documents specifically asks for comments on particular proposals contained in the regulations. Please set these out in the format below.

If you have any more general comments about the proposals or about other aspects of the draft regulations, please set these out in the *further comments* section below.

### Comments on specific questions

<b>Question</b>	<b>Comments</b>
<p>What are your views on the proposed fee of £500 per day (£250 for a half day) up to a maximum payment of £5,000?</p>	<p>We suggest that the daily rate of £500 per day as contained in Regulation 13(3) for data processing is too high. We believe there could be savings for work with large datasets due to economies of scale, which are not reflected in the current cost structure, and suggest the HFEA review its costing set out on page 17 of the Impact Assessment.</p> <p>We welcome half day charging and agree a minimum fee of £250 per half day is appropriate and would recommend this be introduced as the lower limit of fee payable under regulation 13(3)(a).</p> <p>We are concerned that a request which may take longer than 10 days to process should not be refused on these grounds alone. (see ‘Grounds for Refusal of Grant’ under ‘Further Comments’).</p>

Do you agree that NIGB should be able to process applications on HFEA's behalf?	We agree that NIGB should be able to process applications on HFEA's behalf. We welcome the extension of NIGB's oversight function to include applications from across the UK.
Should the authorisation process, created by the regulations, continue to be used to allow applications for access to information collected from 1 <sup>st</sup> October 2009, where it relates to children born as a result of fertility treatment?	In order to maintain continuity, and avoid gaps in application of the regulations between October and April, we suggest the start date for the authorisation process be delayed until the implementation of these regulations, being 6 April 2010.
Is the age 18 cut-off point for access to information about children appropriate?	We suggest that the age of cut-off for access to information about children be reduced to 16 years to remain consistent with other legislation such as the Mental Capacity Act (2005) and Mental Health Act (1983) where a person of 16 years of age is presumed to have the capacity to provide consent.

### Further comments

Do you have any further comments you would like to make in relation to the draft regulations?

#### **Definition of 'protected information': Regulation 2 (1)**

As noted in our previous consultation response, we are concerned that data relating to donors and donor-conceived off-spring will not be made available for research. This will significantly reduce the data available for studies of both biomedical and sociological importance. In particular, research of clinical importance regarding the impacts of IVF treatment would be restricted, including: research into potential adverse health outcomes relating specifically to the use of donor gametes in fertility treatment, and assessment of physical and psychological outcomes for egg donors compared to women undergoing IVF treatment. We would welcome further discussion as to how adult donor information might be disclosed in a safe and confidential manner.

The overall size of the HFEA dataset is very important to biomedical research. Any reduction in the quality and range of the individual data in the dataset will reduce the power of large scale association studies using HFEA data. It is anticipated HFEA data will be used in studies seeking to correlate the links between IVF treatment with genetic, epigenetic, environmental and lifestyle factors and health and disease outcomes.

#### **Grounds for refusal of grant: Regulation 7**

**Regulation 7(1) (c):** We recommend the HFEA provide guidance on security arrangements, so that institutions which are processing protected or relevant individual information can ensure their arrangements are adequate.

**Regulation 7(3):** We do not believe regulation 7 (3) is a reasonable ground for refusing a

grant. Should an application be likely to be in excess of £5,000, or judged to take more than 10 days to process, a further process should be in place through which the application can be considered by the HFEA in discussion with the applicant. Consideration should be given to the importance of the research, and additional time negotiated to allow provision of the data.

**Authorisation subject to conditions: Regulation 8(2)**

We suggest that Section 8(2) of the Regulations include “and reasonable” after “appropriate” at the end of the sentence.

**Duration of authorisation: Regulation 10 (2) & (3)**

We welcome the extension of the period of authorisation to five years.

**Processing [of Information] by the research establishment: Regulation 15 (2)**

In regulation 15 (2), we recommend that the Department of Health should produce guidance to clarify for Institutions that they are able to process protected and individual information under the Data Protection Act (1998) without being in breach of the Act.

**Destruction of information: Regulation 18**

The regulations provide that protected or individual information be destroyed once the authorisation has been expired or has been revoked. This would usually mean the data will only be kept for five years from its date of production. This is inconsistent with research guidelines (for example the MRC Guidelines on Good Research Practice which recommends that data are retained for a minimum of 10 years). We recommend that the HFEA develops a database to keep the datasets it produces.

**Ethics committees:** We recommend that the regulations either allow other Ethics Committees to review applications or extend the remit of NHS Ethics Committees to non-NHS patients to enable review of applications for use of HFEA data, where not all patients in a dataset will be NHS patients.

**Time for processing applications for authorisation:** We support the proposed fee structure which requires fee payment only for the collation and provision of data, and not for the processing of the application to access data. As with other resources, we believe the regulations should include a timeframe within which the application will be processed from the date of submission of application, and would recommend 30 calendar days.

**Retention of data and publications**

We recommend that the HFEA also make publicly available the list of datasets being made available for research. This would enable researchers with similar requests for data to request access to existing data sets, avoiding duplication of effort.

We would recommend that researchers who use HFEA data be required to provide the HFEA with a copy of any publications based on HFEA data prior to publication for HFEA's information. It should be a condition of use of HFEA data, that the HFEA is acknowledged in the publication.