Consultation response from the Academy of Medical Sciences (AMS), Medical Research Council (MRC) and the Wellcome Trust to Department of Health Consultation on regulations to implement Section 33D and Section 45 of the Human Fertilisation and Embryology Act 2008

This is a joint consultation response from the Academy of Medical Sciences (AMS), Medical Research Council (MRC) and the Wellcome Trust on the regulations pertaining to 'Disclosure of information for research purposes' made under sections 33D and 45 (1) to (4) of the Human Fertilisation and Embryology Act (1990) only.

Disclosure of information for research purposes:

Overview:

The Academy of Medical Sciences, Medical Research Council and Wellcome Trust welcome the draft Regulations supporting the provisions in the Human Fertilisation and Embryology Act 2008 which enable access to information held on the HFEA register for research purposes.

The HFEA's recent statement[1] (24 March 2009) concerns the risk of birth defects associated with assisted reproductive technology. The need for new guidance on the potential risks of fertility treatments, forty years after their introduction, highlights the paucity of comprehensive research in this area to date. High-quality follow-up research is mandatory in fulfilling obligations of clinical care to patients involved in fertility treatments and their progeny. Researchers require access to relevant data in order to meet this duty, and therefore these regulations must fully support such research.

We are concerned to ensure the regulations facilitate research by:

- Ensuring access to as much relevant HFEA data as possible;
- Minimising the bureaucracy around applications for access and use of HFEA data; and
- Ensuring the framework for accessing identifying patient data is transparent, user-friendly and consistent with processes to access other patient data through the National Information and Governance Board (NIGB).

Specific Comments on Regulations:

Regulation 2 (1): Remit

We are concerned that limiting the regulations to data collected between 1 August 1991 (when the HFEA register was established) and 1 October 2009 (when the regulations come into force), will leave useful information collected outside of this period inaccessible. Such long standing data, which may include data collected under the auspices of the Interim (Voluntary) Licensing Authority- prior to the establishment of the HFEA database, is invaluable in assessing the effects of fertility treatments.

We believe urgent consideration is required of consent provisions for research using data collected from children once they reach the age of consent. Consent

[1] http://www.hfea.gov.uk/en/1804.html

obtained from parents to access data relating to children born after fertility procedures will only be valid until those children reach competence. New consent would be needed for the data to remain available to researchers. This may be feasible if researchers are in continued contact with families but not for long term non-linked cohort studies.

It is essential that information from children born through fertility procedures is accessible to allow the potential long term health impacts of these methods to be comprehensively investigated. Compromising long-term follow up studies due to the need to seek new consent in the course of a study risks long term effects of fertility treatment on offspring going undetected. We are willing to assist in exploring appropriate consent mechanisms to ensure such research can be carried out.

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

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 genetic, environmental and lifestyle factors with health and disease outcomes.

Regulation 2(1)(f): Definition of 'research establishment'

The regulations define 'research establishment' to mean a university or other body or institution that carries out medical or other research within the United Kingdom. We would welcome clarification of any proposed release of HFEA register data to groups outside the UK.

Regulation 5: Fees

The regulations need to be clear and transparent regarding the various fee levels for applying and receiving data from the HFEA. High quality research should be encouraged, and any proposed fee structure should not curtail this. We believe the cost of an application should be kept low with the cost of provision of data being proportionate. Currently, the range of the potential cost for an application as noted under section D34 (£450- £2,500) is quite significant without clarifying whether this fee is for an application to access information only, or also for the provision of the information if the application is successful. We also suggest that the fee for an application to extend an approval should be nominal.

Regulation 6: Agency Arrangements and provisions of services

The delegated process for reviewing applications from researchers to access data from the HFEA register must be transparent, consistent with NIGB guidelines and not duplicative or overly bureaucratic.

If the process of reviewing approvals is delegated to a third party (for example the NIGB), then the HFEA should establish clear criteria against which decisions pertaining to access to HFEA data is made. These should be consistent with NIGB guidelines for access to other identifying patient data. Any approval panel/board should be fully informed and include the relevant expertise pertaining to the quality and nature of the research under consideration.

Further clarification is also required for the potential role of NIGB in reviewing applications, for Northern Ireland and Scotland. Where it is necessary, we suggest the process for obtaining parallel territorial consents should be as integrated as possible.

The process to be applied to reviewing applications for access to data, either by the HFEA or a third party should consider how it is dealt with by other data custodians. For example, the Research Capability Programme proposes that data be held in 'safe havens', with specific access only allowed once approval for research is given.

To reduce administrative burden and duplication, the HFEA may wish to consider how approvals for research are dealt with through systems such as the Integrated Research Application System (IRAS). This allows applications to several organisations for research approval (e.g. Administration of Radioactive Substances Advisory Committee (ARSAC), Gene Therapy Advisory Committee (GTAC), and Research Ethics Committees (RECs)) to be submitted through one single process. This mechanism may assist in streamlining applications for HFEA data, for example by dealing with the requirement for having REC approval prior to making an application for access to HFEA data (see Regulation 8).

In regard to the provision of services, we propose the federating of data in the HFEA register with other databanks such as cancer databases would be very useful for researchers and also reduce the process of multiple access applications.

Regulation 7: Approvals under section 251 of the NHS Act

We wish to ensure that this Regulation as currently drafted does not result in dual oversight by both the HFEA and the NIGB, whereby a decision of the NIGB under Section 251 of the NHS Act is reconsidered by the HFEA as per Regulation 7 (c). It should be clarified that such review should only be to identify any exceptional reasons why the NIGB approval could not be accepted. If such dual oversight is considered necessary, we propose that there should be a simple, streamlined application process in which researchers submit a single application to obtain the relevant approval.

Regulation 8: Grounds for refusal of grant

We would prefer that the regulations allowed a parallel application process so that applications can be lodged at the same time. This would also save time once REC approval is provided. It will be important to ensure the RECs are aware of Regulation 8(a) requiring research ethics approval to be granted before an application for access to HFEA data can be approved. Again, we wish to avoid a process in which researchers might need to iteratively seek consent from multiple sources.

Regulation 11: Duration of authorisation
We suggest the duration of authorisation be extended to five to eight years. Research studies concerning fertility outcomes may require long-term data surveillance spanning generations. The three year period set out in the current regulations is too short as many long term cohort and longitudinal studies span a significantly longer timeframe.

The application process for an extension of approval should also be simple and straightforward, and should not place a burden on researchers in terms of time or expense.

Regulation 12: Notice of Decision
We suggest this section sets out an upper time limit of 90 days between when a researcher submits an application for access and receives a decision from the HFEA, which should include time taken for additional information requests.

Regulation 18: Destruction of protected information
We recommend that this regulation be amended to ensure that the original data be kept in safe storage for at least a 10 year period, or preferably a 20 year period. Both the Trust and the MRC in their Good Research Guidelines recommend the storing of data used for research for up to twenty years.

We would welcome further consideration of a HFEA data haven to permit long-term retention of data for verification purposes, while enabling copies of identifiable data outside of the HFEA to be destroyed.

Regulation 19: Annual reports and provision of information
We suggest the annual reporting requirements of the HFEA (introduced in regulation 9(c)) should be consistent with those of other organisations. Research institutions are already under substantial pressure to provide various bodies with annual reports. The procedures involved, particularly in relation to the provision of background information and updates, should be simple and pro-forma based to reduce reporting burden on researchers.

Regulation 21: Oversight Committee
We recommend that if an Oversight Committee is to be instituted, that the Regulations set out the range and nature of expertise required on the Committee, to include: scientific, ethical and lay representation.