



British Fertility Society

response to the

Department of Health

Consultation on regulations to implement the Human
Fertilisation & Embryology Act 2008

March 2009

This document represents the British Fertility Society (BFS) response to the Department of Health “Consultation on regulations to implement the Human Fertilisation & Embryology Act 2008”.

The British Fertility Society is a multi-disciplinary organization representing professionals with an interest in reproductive medicine. The objectives of the society are:

- To promote high quality practice in the provision of fertility treatment.
- To provide a common forum for members of various disciplines having an interest in the science and treatment of infertility.
- To promote high quality scientific and clinical research in the causes and treatment of infertility.
- To provide professional leadership in the provision and regulation of infertility services.
- To promote the increase of NHS funding for and equity of access to fertility treatments.

Therefore the implementation of the Human Fertilisation and Embryology Act 2008 is an important issue for BFS members.

To respond to this consultation, BFS membership were circulated by email and asked to send in their replies to the BFS Secretary. This response represents the majority view of those who replied and was compiled by Dr. Allan Pacey and Mr Tony Rutherford on behalf of the Executive Committee.

It is submitted by the Honorary Secretary whose contact details are:

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The society **agrees** to the making its responses publicly available by the HFEA in accordance with the Cabinet Office Code of Practice on Written Consultation. In addition the society will be making this response available on its website (<http://www.fertility.org.uk>).

The consultation document sets out regulations in four areas as described below:

The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations.

The BFS is of the view that the current regulations for the Statutory Storage Period for gametes and embryos require urgent revision. Aspects of the current regulations are illogical and do not serve the best interests of patients or clinics. Therefore, the BFS is supportive of the need for revision but would like to make the following comments on the proposed regulations:

Regulations 3 & 5: The BFS agrees that the current statutory storage period for gametes and embryo should be changed to reflect equality for both sexes, but make biological sense. However, BFS members are concerned with the proposed change to a statutory storage period of 55 years. Our view is that a blanket time limit does not appear to be the best way forward. Experience from men who store sperm prior to cancer therapy indicates that only a relatively small proportion of this stored sperm is ever used in active treatment, estimated to be around 4 to 5%. Furthermore, some patients signing the current forms for gamete and embryo storage do not make a decision about use, but prefer to keep them until the end of the statutory storage period. Clinics find that patients frequently fail to inform of change of address or circumstances, which results in a significant administrative burden to keep track of those with gametes in store. There is a real threat that under the proposed legislation, that clinics may, by default, then find that they are liable to hold increasing amounts of stored material as time progresses.

We propose that the Department of Health consider introducing a system where consent is required to be given by all patients for extended storage after 10 years has elapsed. This can be renewed on a 10-year statutory rolling basis where there remains a sound biological indication. Each clinic storing gametes or embryos under this arrangement would enter a specific contract with the patient indicating clear responsibilities of both parties. For example, individual clinics may require more frequent review and only agree to shorter periods of storage. In this situation, the patient would be free to move their stored gametes to a second clinic prepared to store for longer, as long as this was within the defined statutory storage period. In this model, there is a clear distinction between the legal consent to storage for the statutory 10 years on a rolling basis (HFEA consent), and the contract between the individual and the clinic (clinic procedural consent). However, all patients would be obligated to have at least one consultation every 10 years to renew their consent. In situations where patients could not be traced (a common occurrence), and there has been a clear breach of the contract between the clinic and the patient, the clinic would be able to remove material from storage without fear of prosecution.

The BFS is of the view that the proposed wording “significantly and prematurely infertile”, which is to be used to control the gateway through which extended storage might be allowed, is flawed and is likely to be challenged, since current clinical tests of fertility in both men and women are imprecise. The BFS would far rather see a general

assessment of the individual's clinical need, supported by evidence from a registered medical practitioner being sufficient to allow a patient to keep their gametes or embryos in storage.

Regulations 6, 7, 8 and 9: The BFS agrees with the need for these transitional regulations, notwithstanding our view that revisions are required to the gateway that allows patients to keep their gametes and embryos in storage for an extended period.

The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal) Regulations.

The BFS welcomes the proposed improvements to the system of licensing clinics, and we have no specific comments on the regulations as outlined.

The Human Fertilisation and Embryology (Appeals) Regulations.

The BFS supports the need for a clear, robust and independent appeals process within the HFEA to enable licensing decisions to be reconsidered. However, the BFS would like to make the following comments:

Regulation 4: The BFS is concerned that a person cannot be appointed as a member of the Appeals Committee if 'they are a current or former member or employee of the Authority, have ever held an HFEA licence or been a Person Responsible'. The BFS considers that this could be too restrictive and may on occasions exclude individuals with key skills that would be valuable to the Appeals Committee. However, it is presumed that such individuals may take the role of advisors (Regulation 10) and therefore help the committee in this way.

Regulation 5: The BFS is concerned that the HFEA seems to be responsible for the appointment of members to its own Appeals Committee. In the interests of transparency, it would seem more appropriate that an independent body be responsible for these appointments.

Regulation 9: The BFS supports the need for the committee to report to the HFEA on an annual basis, but would support the notion that this report should also be submitted to a more independent body, again in the interests of transparency.

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

One of the key objectives of the BFS is "to promote high quality scientific and clinical research in the causes and treatment of infertility". As such, many BFS members have been frustrated that researchers have not been able to use data collected by the HFEA to answer important research questions. Therefore, the BFS is supportive of any mechanism by which such studies might now be made possible. However, the BFS would like to make the following comments:

Regulation 4: The structure of any application for access to protected information should be achieved in such a way to avoid the duplication of information required for other bodies involved in either obtaining funding for research projects (e.g. grant awarding bodies) or those involved in the regulatory aspects of undertaking research (e.g., the National Research Ethics Service or local Research Governance offices). The Department of Health and the HFEA should be mindful of the fact that the bureaucracy that is now required to undertake medical research in the UK is becoming overwhelming and to many BFS members is potentially inhibitory to undertaking research. Therefore the would urge that the application for protected information should not add to that burden and the BFS would suggest that serious thought is given to combining the applications process into the on-line Integrated Research Application System (IRAS).

Regulation 5: The setting of fees for processing applications and, where approved, collecting and issuing collected information, should be sufficiently transparent to allow researchers to build them into the cost of their grant applications.

Regulation 8: The BFS does not support the refusal of applications by the HFEA just because they do not have ethical approval. It would rather that outline approvals could be obtained pending full ethical approval being granted. Given the complexity of undertaking medical research (see Regulation 4) it may not be possible to obtain ethical approval until funding arrangements are in place and in turn grant awarding bodies may not release funding until it is clear that the work can take place and protected information be obtained. Therefore, to avoid such catch-22 situations, the HFEA should be willing to review outline applications, or more sensibly have approvals managed through the Integrated Research Application System of the National Research Ethics Service.

Regulation 11: The BFS does not support the three-year maximum period for a single authorisation of protected information being released before it is destroyed (see regulation 18). In the context of obtaining grant funding and undertaking a piece of research this will invariably lead to the approval running out before the research is completed and written up in a peer review publication. The experience of BFS members, a more sensible time-span would be to allow protected information to be released for up to a maximum of 10 years (depending on the project design).

Regulation 19: The BFS is supportive for the need for Annual Reports to be submitted to the HFEA in order to allow the monitoring of the use of protected information. However, since Annual Reports will also be required by the funder of any research as well as the LREC or MREC which gave ethical approval for the research to take place, the BFS would like to urge that duplication of Annual Reports is avoided as much as possible to reduce the burden on researchers (see comments on Regulation 4 above).

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Tony Rutherford (Chairman BFS)

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