

**HFEA consultation on human embryo research licence fees and proposed changes in the application process.**

**Response from the British Fertility Society  
June 2004**

The British Fertility Society has never before had to respond to a consultation over which there has been such universal incredulity at the proposals. It is seriously concerned at the lack of understanding displayed by the HFEA in all aspects of the research process and its place within clinical practice.

The BFS also expresses concern that this consultation document was circulated to PR of licensed IVF centres and not to those who are specifically involved in research including the PR for research licences. We challenge whether the circulation list has been wide enough to constitute an appropriate consultation?

BFS survey.

Given the specialist interest of this document, we have attempted to survey those involved in research in this field as well as members. Information on past and current research licence holders is not readily available. Nonetheless, we have contacted those responsible for 14 of the current licences and our responses are based on their views.

Our survey provided the following information.

1. Only 4 of the 14 projects are funded by Research Council money, 1 by the pharmaceutical industry. The remainder, where identified, are funded by small local sources e.g. local charities, University research funds, NHS Trusts.
2. Those who had funding from research councils and the commercial sector felt it likely that they would cover an increase in licence fees. The rest were quite sure that no specific funds would be found for an increased fee. In many cases the proposed fee would be up to 50% of the total funding allocated to the project.

To give insight into the views of members, specific individual comments from our survey are quoted below.

“must surely be a mistake?”

“will undoubtedly hinder research”

“The real loss would be good internally funded research, in which the NHS excels”

“the NHS should not be offering clinical services without an integrated programme of research and development. The eggs and embryos donated to research come from the very patient cycles from which HFEA funding is currently derived”

“A high fee will stop almost all ‘real’ research into human embryology. It’s totally unjustifiable”

“£6000 is outrageous!”

“If imposed there would need to be a 2-3 year notice of intent to allow for grant applications etc”

“The HFEA should be encouraging responsible research and therefore fees for research licenses should be nominal”

“What is the point of this - Peter to pay Paul. We would have to get the fee from research grants to pay another government quango. We are just wasting taxpayers money.”

“This is the worst news in this context that we could have”

“What the HFEA call research is often programme development but licensed under the dishonest title of research e.g. ICSI.”

“Drastic measures should be considered - such as withdrawing all help and support”

“Reviewers, myself included, do the reviewing free of charge, and would continue to do so, and the MRC and other bodies do not charge for a review process even when they are considering large sums of money.”

“It’s appalling!”

“Almost no grants are awarded without pilot data; do we have to pay £6000 to obtain the pilot data?”

Summary of the BFS response.

**The consultation document does not provide a case for raising additional income. On this basis, any request for an isolated increase in fees is most strongly rejected.**

An implicit intention of the HFE Act is to encourage and promote good research in this field. This was reinforced following the House of Lords Select Committee report in relation to therapeutic cloning and stem cells which resulted in the revision of the Act in 2003. The imposition of a licence fee of the scale proposed will effectively act against the intentions of Parliament. Research will be severely compromised.

The UK is acknowledged as a world leader in this field and the strong legal framework and associated regulation is widely admired. As researchers, we recognise the benefits this brings to us. Nonetheless the bureaucratic regulatory process has had a significant negative effect on the implementation of research and we welcome any internal improvements that the HFEA can make to facilitate the processing of applications.

In response to specific issues raised in the consultation, we make the following points.

1. Cross subsidy.

Research and development is an integral part of all clinical practice be it in the private or public sector. Whether the research is done in an NHS unit, a private unit or a non-clinical setting, outcomes will be published and available to benefit all. This is a core function in relation to Good Medical Practice.

Any arbitrary separation between treatment and R&D to meet Treasury rules is a dangerous precedent that must be resisted. Any fee to cover regulation of

licensed procedures and supporting funds from the DH should cover the integrated costs of treatment and R&D.

2. Current costs.

The consultation document explains the current procedures which are presumably all accounted for in the HFEA budget for this year. There is no case presented which justifies a need for additional expenditure. Indeed the proposals suggest that savings may be made. Who will benefit from the savings? Would the treatment fees be reduced accordingly for those units undertaking research?

3. Complexity of research

We challenge the premise that research is becoming more complex. As our understanding of embryology improves and the ethical attitudes of society to our work evolve, the limitations of the HFEAct are recognised. This is causing problems that we hope will be resolved with the current review of the Act. Researchers maybe more challenging to the HFEA but there is no evidence that this is more expensive.

4. Options for changes to the research licensing process

The suggestions for change are mostly internal procedural issues for the HFEA. They will have little impact on the cost of the process. It is difficult to understand why the HFEA has such difficulty with the peer review. Their remit as described in Section 16 is specific. Since the HFEA is only processing 12 applications (including renewals) per year, the administrative costs should be minimal. It is the reviewers who do the work and they are not paid.

The HFEA should be aware of the new COREC procedures with which all research must comply. These include evidence of scientific review, consent arrangements, site specific issues (staff and facilities) and are significantly more rigorous than previously applied. Duplication of regulation should be avoided.

5. Financial benefits of research IP.

It is totally inappropriate, and insulting to academic integrity, to try to justify a licence fee on the basis that there might at some stage in the future be financial benefits to the researcher of IP rights.