



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

	Page
Key objectives.....	2
Introduction	2
Modernisation of research licensing process	3
Options for fee change	4
Options for changes to research licensing process	6
Summary	7
Response sheet	9
Annex: Partial Regulatory Impact Assessment (RIA)	12

CONSULTATION ON HUMAN EMBRYO RESEARCH LICENCE FEES AND PROPOSED CHANGES IN THE APPLICATION PROCESS

Key objectives:

1. The Human Fertilisation and Embryology Authority (HFEA) is seeking views on the following issues
 - The most appropriate and equitable level of fees to be levied on applications for human embryo research licences;
 - Proposed changes in the arrangements for peer review of research applications and inspection of laboratories

Introduction

2. The HFEA has statutory duties under the Human Fertilisation and Embryology Act 1990 and the Human Fertilisation and Embryology [Research Purposes] Regulations Act 2001 to regulate the creation, storage and use of human embryos for research purposes, and to issue licences for approved projects.
3. The HFEA has received over 150 applications for human embryo research licences since it was established in 1991. There are currently 30 licensed research projects in 23 centres, and the HFEA is processing about 12 research projects each year, including renewals. Research applications are increasingly complex; of the current licensed projects, eight relate to human embryonic stem cells and two involve parthenogenesis. These applications are far more demanding in terms of time and expertise.
4. There is also greater public and parliamentary interest in embryology research, particularly stem cell research. This makes it all the more important that the HFEA has in place robust licensing and monitoring systems, which give confidence that the statutory controls are being effectively implemented.

MODERNISATION OF RESEARCH LICENSING PROCESS

5. Historically, the regulation of human embryo research has not been developed as a dedicated function. Research projects have been handled alongside treatment and storage services, and there has not been a clear focus for the development of the work. With the increase in the number of applications and their greater complexity, this situation is no longer acceptable. Also it has led to some concerns that HFEA has not processed research applications quickly enough.
6. As part of the wider modernisation of the HFEA, we have established a more rigorous and transparent procedure for regulating research projects. These changes take account of the report of the Better Regulation Task Force (BRTF) on scientific research regulation.¹ This report recognised the need for regulation in this, sometimes controversial, area of science, and highlighted the importance of demonstrating that HFEA licence decisions are independent and evidence-based.
7. The new processes are aimed both to support the research community and ensure public confidence in the regulation of human embryo research. HFEA has set up a dedicated Research Licence Committee, and has recruited specialist research regulation staff, who have the appropriate level of experience and expertise. The new staff will be primarily dedicated to research regulation and will give this work priority at all times. As research applications do not come in a regular flow throughout the year, it is likely from time to time they will have the capacity to assist in other areas of HFEA work.
8. In addition to processing new applications the following functions are undertaken:
 - Providing advice to prospective researchers about how best to frame their proposal (this also helps reduce eventual processing time)
 - Inspecting research premises on application and annually (a requirement in the Act unless a Licence Committee decides otherwise)
 - Handling any adverse incidents
 - Following up progress reports and ensuring they are properly considered
 - Processing renewal application (with peer review)
 - Managing variations to the licence
 - Maintaining a database of records to answer questions from Department of Health (DH), MPs and members of the public
 - Liaison with DH, Medical Research Council (MRC) and other interested agencies

¹ Scientific Research: Innovation with Controls, Better Regulation Task Force, Cabinet Office Publications, January 2003

- Communicating appropriately with the public to encourage greater understanding of human embryo research and the HFEA's regulatory framework
9. There have already been significant improvements in the management of research licensing. Over the last year 90% of applications were approved within 16 weeks. It is proposed that this target is reduced to 90% within 12 weeks from April 2004.

OPTIONS FOR FEE CHANGE

10. Since the Authority was established in 1991, most of the costs of research regulation have been met from grant-in-aid from the DH, and from fee income from licensed treatment and storage centres. As a public body the HFEA is subject to Treasury rules, which do not allow for this kind of cross subsidy; the costs of research licensing should be met from licence fee income paid by those being regulated. The consultation in 2002 on HFEA licence fee structures concentrated on treatment and storage centres and did not cover research².
11. HFEA research licence fees are currently set at £200 — a sum which meets only a very small percentage of the actual costs of research licensing. Also not everyone pays the fee. Research licence fees are chargeable on new applications and on renewals, but not on variations to existing licences. Also, licensed treatment and storage centres are currently exempt from research licence fees, and fees paid by research-only centres cover all research applications made by the centre in that financial year. To remove cross-subsidies, these exemptions will need to be brought to an end. All research applications will need to attract the relevant fee, as will variations to a licence that are so significant as to constitute a new project.
12. Costs of research licensing include the Research Licence Committee, 50% of the cost of the Research Regulation staff and associated overheads of premises costs, IT and administrative support. This takes account of the intention, described in paragraph 7 above, that the staff will spend about 50% of their time on other regulatory work, and therefore half the cost will be met from other fee and DH grant-in-aid income. This will also give the necessary flexibility to take account of any future reduction in workload as a result of the streamlining of peer review proposed below. The Authority's assessment of the resources needed to fund the new systems, meet the performance targets, and address the concerns of the BRTF, is an annual income of £70,000, to be met from research licence fees.

² HFEA consultation on the modernisation of regulation and the new fee strategy, June 2002.

13. We have considered a wide range of options to deal with the cost of research regulation. The following four options have been considered but dismissed as impractical or not compliant with Treasury guidelines.

- **No change**
This is not seen as possible as the HFEA would continue to cross-subsidise the cost of research regulation mainly from fees for treatment and storage of gametes, in contravention of Treasury rules.
- **Cover the cost of research licensing costs from an increase in grant-in-aid**
Discussions with DH and Department of Trade & Industry (DTI) indicate that an increase in central funds is unlikely, particularly as this proposal would run counter to Government policy that the costs of regulation are met by those being regulated.
- **Reduce HFEA expenditure on research licensing**
This is not a viable option. It has been accepted that the effectiveness of the Authority's work on research regulation has been undermined by a lack of resources...
- **Differential fees, related to the ability to pay**
It is likely that the financial position of those applying for research licences will vary significantly. With the advent of stem cell research, with potential benefits far beyond embryology, intellectual property could be very valuable indeed. However, this proposal would not be in line with the principle that applicants' fees should meet the costs of their regulation.

14. The following three options present the most feasible solution to the funding issues, and meet the Treasury requirements; and it is these proposals on which we are inviting comments:

- **Option 1: Flat Rate Licence Fee**
A flat rate licence fee of £6,000 levied on all applications for new licences, would meet the costs of research regulation as set out above
- **Option 2: Differential Fee Related to Workload**
Not all research applications cost the same amount to process; a small scale project in embryo development from an established research centre could be processed relatively easily, compared with a large scale study of novel and controversial techniques from a new centre or multiple centres. The differential would need to be fairly broad to avoid any uncertainty for researchers as to costs. Possible differential fees would be £3,000 for small, straightforward projects and £9,000 for larger, more complex applications

- **Option 3: Spread the cost of licensing over the period of the licence**

Most of the costs incurred are in the initial application or re-application but there is an annual cost in terms of inspections, processing progress reports and occasionally investigating adverse incidents. However, it is felt that this option would increase the administrative burden, both for the applicant and for the HFEA.

OPTIONS FOR CHANGES TO THE RESEARCH LICENSING PROCESS

15. **Peer Review** A significant constraint on processing research licence applications quickly has been the time spent in undertaking peer review. There are two separate, if overlapping, issues on which peer review may be required: (1) the scientific basis of the research; and (2) whether the project fulfils the requirements of the 1990 Act. It is the statutory responsibility of the HFEA to assure itself on both these points before issuing a licence.

16. The requirements of the Act are to determine whether:

- the research meets the criteria of permissible research purposes defined in the Act
- whether the proposed use of embryos is necessary for the purposes of the research
- whether the proposed numbers of embryos to be used are appropriate

17. Many research proposals undergo peer review on the scientific basis of the research by funders, such as the MRC or by local ethics committees. It has been suggested that additional peer review by the HFEA on this issue is unnecessary, or could be restricted in scope. If HFEA is given, along with a licence application, a copy of any peer review already obtained, we could then either determine compliance with the Act internally or by a limited form of external review. This would be quicker than current processes.

18. If for any reason there has been no peer review, the applicant might obtain peer review themselves from a list of HFEA approved reviewers, to submit with the licence application.

19. **Deadline for responses from applicants** Another major bottleneck in the processing of licence applications is the failure of some applicants to respond to comments from the peer reviewers, and requests for further information from the licensing committee. A solution to this problem would be to set deadlines for the applicant to make their response. Failure to respond within, say 3 weeks, the deadline would

lead to the licensing process continuing without the applicants comments. This is standard practice with major funding agencies.

20. **Inspection of laboratories** Problems in arranging inspections can cause a further delay in the licensing process. A possible solution would be to ask the Centre, before submitting their application, to have already agreed with the HFEA a date for an inspection within the first 3 weeks of submission.

21. **Research Application Timetable** A standard procedure among research funders is for applications to be accepted at specified times of the year. This could be adopted for Research Licence Committees with their meeting dates available on the HFEA website.

SUMMARY

22. Views are sought on the proposals set out in this paper

Requirement to pay fees

- All research applications to attract a fee, including renewals

Fees

- **Option 1:** Flat Rate Licence Fee
- **Option 2:** Differential Fee related to Workload
- **Option 3:** Spread the cost of licensing over the period of the licence

Changes to licensing process

- Streamlining of peer review process
- Deadline for applicants to respond to comments on applications
- Early agreement on timing of inspections
- Standard Research Application Timetable

If you have any further suggestions for improving the regulatory process, we will be pleased to receive them.

23. The annex attached is a partial Regulatory Impact Assessment (RIA), drawn up by HFEA with respect to the options above. If you have any comments on the RIA, these would also be welcome.

24. The consultation period is 12 weeks and responses are requested by 30th June 2004. Please send the attached Response Sheet to:

**Trish Davies (Research Consultation)
Director of Regulation
HFEA
21 Bloomsbury Street
London
WC1B 3HF**



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

Response sheet

1. Do you agree that all research applications to attract a fee, including renewals?

YES / NO

Reasons

2. Which option offers the most appropriate licence fee necessary to support the HFEA research regulatory function?

Option 1: Flat Rate Licence Fee

YES / NO

Reasons:

Option 2: Differential Fee related to Workload

YES / NO

Reasons:

**Option 3: Spread the cost of licensing over
the period of the licence**

YES / NO

Reasons:

3. Do you agree with the following proposals to make the HFEA's regulation of human embryo research more effective?

Streamlining of peer review process

YES / NO

Reasons

**Deadline for applicants to respond to comments
on applications**

YES / NO

Reasons

Early agreement on timing of inspections

YES / NO

Reasons

Standard Research Application Timetable

YES / NO

Reasons

All responses will be placed in the public domain unless a request for confidentiality is requested (specifying the response for which confidentiality is requested, with reasons).

Copies of the responses (excluding contact details of the respondent) will be available for inspection by appointment with the HFEA. In line with Cabinet Office Guidance in the *Code of Practice on Written Consultation* a charge may apply to cover any costs incurred.

Please send replies by 30th June 2004 to:

**Trish Davies (Research Consultation)
Director of Regulation
HFEA
21 Bloomsbury Street
London
WC1B 3HF**



ANNEX

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

PARTIAL REGULATORY IMPACT ASSESSMENT

1. TITLE OF PROPOSAL

To introduce Realistic Licence Application Fees for Human Embryo Research

2. PURPOSE AND INTENDED EFFECT

(i) Objective

To cover the direct costs of research regulation from research licence fees

(ii) Background

The creation, storage and use of human embryos for research purposes is regulated by the Human Fertilisation and Embryology Act 1990 and the Human Fertilisation and Embryology [Research Purposes] Regulations Act 2001. The HFEA has statutory duties under the Act and regulations to issue licences for approved research projects. Historically human embryo research has been a small part of the work of the HFEA, and only a nominal licence fee has been levied.

The regulation of human embryo research by HFEA has not been developed as a dedicated function; research projects have been handled alongside treatment and storage services, and there has not been a clear focus for the development of expertise. This has led to some criticism of the effectiveness of regulation and concerns that HFEA has not processed research applications quickly enough. With the increase in the number and greater complexity of embryo research applications, this situation is no longer tenable. We now need to establish robust new processes that both support the research community and ensure public confidence in the regulation of embryo research. To do this we must also charge fees which reflect the real cost of regulation; the HFEA is required by DH to meet the costs of regulation from fees levied on licence holders.

(iii) Risk Assessment

Failure to fund effective regulation of embryo research risks undermining public confidence that such research is being carried out in accordance with

the law. Not increasing fees will continue cross-subsidy against Treasury guidance. The additional cost burden is borne partly by patients for fertility treatment in licensed clinics. Increasing fees too much could deter researchers in a Government priority area.

3. OPTIONS

The HFEA has considered the following seven options to address this issue.

Option One: No change. Research licence fees remain at £200. This would not cover staff costs directly attributable to research licensing.

Option Two: Cover the cost of research licensing costs from an increase in grant-in-aid. Discussions with government suggest this is not a viable option, and would be contrary to Treasury guidelines that the costs of regulation should be met by those being regulated.

Option Three: Reduce HFEA expenditure on research licensing. This is not a viable option. It has been accepted that the effectiveness of the Authority's work on research regulation has been undermined by a lack of resources.

Option Four: Differential fees, related to the ability to pay. It is likely that the financial position of those applying for research licences will vary significantly. With the advent of stem cell research, with potential benefits far beyond embryology, intellectual property could be very valuable. However, this option would not be in line with the principle that applicants' fees should meet the costs of their regulation.

Option Five: Spread the costs of licensing over the period of the licence. Most licence applications and re-applications result in three year licences. The licence fee is levied on a one off basis. Whilst most of the costs incurred are in the initial application or re-application, there is an annual cost in terms of inspections, processing progress reports and occasionally investigating adverse incidents. However, it is felt that this option would increase the administrative burden, both for the HFEA and the applicant.

Option Six: A flat rate fee levied on all applications. This would cover staff costs directly attributable to research licensing and associated overheads. At current costs this would be a fee of £6,000.

Option Seven: Introduce differential fees, related to workload. Not all research applications cost the same amount to process. For instance a small scale project from an established and compliant research centre in say embryo development could be processed relatively easily compared with a large scale study of novel and controversial techniques from a new centre or multiple centres. The differential would need to be fairly broad to avoid any uncertainty for researchers as to costs. Possible differential fees would be

£3,000 for small, straightforward projects and £9,000 for larger, more complex applications

It is felt that only **Options 5, 6 and 7** satisfy the objectives of meeting the costs of regulation, and these options are the subject of the Authority's consultation.

4. COSTS AND BENEFITS

The requirement for all research involving human embryos to be licensed by the HFEA has been in place since 1991. The need to comply with the 1990 HFE Act, and the related costs of compliance is well established. The only additional cost being considered is the cost of the new licence fee payable on application for a licence or a renewal of a licence.

Costs of processing research licence applications will be tightly controlled. They consist of the Research Licence Committee, 50% of the cost of Research Regulation Team and associated overheads of premises costs, IT and administrative support. This takes account of the intention that the Team will spend about 50% of their time on other work, and therefore half the cost will be met from other fee and DH grant-in-aid income. This gives a total annual cost of £70,000 to be met from research licence fees.

5. EQUITY AND FAIRNESS

The establishment of a realistic fee for research licence will ensure that holders of treatment and storage licences are not unfairly subsidising embryo research licences.

The organisations affected will be NHS, academic and private sector research centres carrying out embryo research. The financial support available to these organisations will vary significantly, and the Authority is concerned that the cost of regulation does not adversely affect the ability of researchers in smaller, less well-funded projects to undertake research in this area. Two of the three options allow for differential levels of fees.

6. SMALL FIRMS IMPACT TEST

Embryo research will take place in a range of institutions, including the NHS, academic and private sector. The decisions of commercial organisations involved in supporting major embryo research, such as stem cell projects, are unlikely to be affected by the licence fees being proposed by the HFEA. Other major research may be funded by agencies such as the Medical Research Council, whose grants would cover any licence and regulatory costs. We are concerned to ensure that small, possibly unfunded research projects in NHS or other academic institutions are not adversely affected. The proposals for differential fees are aimed at these groups.

7. COMPETITION ASSESSMENT

The main concern here is not about competition, but ensuring that small, less generously funded units do not find it prohibitive to apply for an embryo research licence.

8. ENFORCEMENT AND SANCTIONS

The HFEA is the regulatory body charged with ensuring compliance with the terms of the HFE Act, regulations and related guidelines; the sanctions for non-compliance are set out in the Act and are not affected by these proposals. The enforcement of research regulation will be carried out by Regulation Licence Committee, established under the terms of the 1990 Act.

9. CONSULTATION

The HFEA has discussed the matter with the relevant Government departments – DH and DTI. A 12 week Public Consultation is planned for early 2004 in line with Cabinet Office guidance.

10. MONITORING AND REVIEW

The impact of the fee increase will be monitored by the HFEA. Fees will be reviewed annually in the light of costs and numbers of applications received.

11. SUMMARY AND RECOMMENDATION

No change is not an option. Researchers must bear a more realistic licence fee to meet the costs of regulating human embryo research. To avoid deterring research the HFEA will endeavour to mitigate the impact of the fee increase by streamlining regulatory processes to reduce costs and, if agreed introducing differential fees.