Summary: Intervention & Options

Department /Agency:	Title:	
HFEA	**Impact Assessment of HFE (Procedure for Revocation, Variation and Refusal) Regulations 2009**	
Stage: FINAL	**Version:** FINAL	**Date:** April 2009
Related Publications: Consultation Report on Regulations to Implement the HFE Act 2008 – Part 3: The Human Fertilisation and Embryology (Procedure for Revocation, Variation and Refusal) Regulations		

Available to view or download at:

http://www.hfea.gov.uk

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What is the problem under consideration? Why is intervention necessary?

Section 19(6) of the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008) allows the Human Fertilisation and Embryology Authority ("the HFEA") to make regulations governing the procedure for revoking, varying or refusing a licence. The draft HFEA (Procedure for Revocation, Variation and Refusal) Regulations 2009 set out the procedure to be followed by the HFEA in this regard. The regulations are necessary to enable the HFEA to fulfil its duty as a public body under the Human Rights Act 1998, and to provide a fair and transparent process in cases where the revocation, variation, or refusal of a licence is a potential outcome.

What are the policy objectives and the intended effects?

The policy objectives are to establish a fair and transparent process by which the Authority is able to determine cases in which the revocation, variation or refusal of a licence is a potential outcome. The decisions in such cases will be made by a Licence Committee which will sit with a legal adviser and will be able to seek advice from clinical, specialist and scientific advisers as necessary. There will be clear procedural details on issues such as case management; representation and procedures at hearings; and the evidence that the Committee is able to consider before making its decision.

What policy options have been considered? Please justify any preferred option.

1. Decisions are currently already made by a Licence Committee acting in accordance with the HFEA (Licence Committee and Appeals) Regulations 1991. Those regulations do not contain much procedural detail. Option one would be to retain a minimalist approach to setting out process in the new regulations.

2. Option 2 would be to provider clearer procedural detail in new Regulations.

Option 2 is the preferred option, as aids the fairness and transparency of the decision making process and aids better decision making by the Committee.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The regulations were subject to a three month public consultation. The HFEA will monitor and review the ongoing effects of the regulations.

Chair's Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the Chair of the HFEA:



Professor Lisa Jardine CBE .....Date: **29 May 2009**

Summary: Analysis & Evidence

Policy Option: 2	Description: Option 2 Provide clearer procedural detail in new Regulations.

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	The average annual cost is based on an average of 3 revocation, variation or refusal hearings per year. The average cost of a Licence Committee meeting includes the cost of legal advice. NB: These are not additional costs but reflect the current system cost.
£ 0	
Average Annual Cost (excluding one-off)	
£ 10,400	**Total Cost** (PV) **£ 10,400**

Other **key non-monetised costs** by 'main affected groups' N/A

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups' N/A
One-off **Yrs**	
£ 0	
Average Annual Benefit (excluding one-off)	
£ 0	**Total Benefit** (PV) **£ 0**

Other **key non-monetised benefits** by 'main affected groups' N/A

Key Assumptions/Sensitivities/Risks The vulnerability of HFEA to legal challenge should be reduced by the establishment of clearer processes. The cost of legal challenge is hard to quantify but could be more than £100,000.

Price Base Year N/A	Time Period Years N/A	**Net Benefit Range** (NPV) **£ 0**	**NET BENEFIT** (NPV Best estimate) **£ 0**

What is the geographic coverage of the policy/option?			UK	
On what date will the policy be implemented?			October 2009	
Which organisation(s) will enforce the policy?			HFEA	
What is the total annual cost of enforcement for these organisations?			£ N/A	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			Yes	
What is the value of the proposed offsetting measure per year?			£ N/A	
What is the value of changes in greenhouse gas emissions?			£ N/A	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 0 Decrease of £ 0 **Net Impact** **£ 0**

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Introduction

1. The draft Human Fertilisation and Embryology (Procedure for Revocation, Variation and Refusal of Licences) Regulations 2009 will replace the Human Fertilisation and Embryology (Licence Committee and Appeals) Regulations 1991 (the "1991 Regulations").
2. The regulation making power is set out in new section 19(6) of the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008).
3. All decisions relating to the revocation, variation or refusal of a licence are currently made by a Licence Committee of the Authority acting in accordance with the 1991 Regulations.

Reason for intervention

4. The 1991 Regulations were made before the implementation of the Human Rights Act 1998. They do not provide much of the procedural detail that is now considered routine in the procedures of healthcare regulatory bodies.

Policy Objectives

5. The policy objectives for the regulations are to set out a fair and transparent process by which the Authority can determine cases in which revocation, variation or refusal of a licence is a potential outcome.
6. The decisions in question are currently made by the Authority's Licence Committee. Under the proposed framework, the Licence Committee will continue to make these decisions but will be assisted by having clear and transparent procedures which are set out in regulations which adopt the format used by other health care regulators. This will assist the HFEA to carry out its duty as a public body under the Human Rights Act 1998.

Consultation

7. The Department of Health undertook a widespread public consultation on the regulations over three months from January to March 2009. This consultation allowed different groups of people to respond to the proposed policy. A consultation report was published on the Department of Health Website on 6 May 2009.
8. The consultation asked for comments on the key policy proposals behind the draft regulations. There was broad support for the proposal that there should be a lay majority on the committee, which is in line with accepted best practice in the healthcare regulatory field. A strong theme emerging from the consultation response was the need to ensure transparency and accountability at all stages of the licensing process. There was little objection to the principle that the draft licensing regulations should set out the details of the procedure to be followed by the Licence Committee, or the details specified in the draft regulations. However, a broader concern was expressed about the definition of "routine" applications, and the process by which matters would be allocated to the executive Licence Panel or to the Licence Committee.
9. The HFEA welcomed the comments made in response to the consultation. The procedures relating to the executive Licence Panel will be set out in the HFEA's written protocols and standing orders to ensure transparency. The HFEA will publish criteria to be employed in allocating matters to the executive Licence Panel or to the Licence Committee.

Links to other policy areas and strategies/programmes of work

10. These regulations are linked to the regulations that set out the appeals process, ("The Human Fertilisation and Embryology (Appeals) Regulations") which were also part of the public consultation process.

Policy options

- Maintain a minimalist approach to setting out procedure of the Licence Committee in regulations
- Clarify procedural detail in the regulations, in order to improve fairness and transparency, and to aid improved decision making by the Licence Committee. – This is the preferred option.

Risks and benefits

Option 1 – maintain minimalist approach

11. The current regulations are extremely thin on procedural detail. Persons whose cases are considered by the Committee are unsure about what is expected of them, or the process to be followed. The lack of clarity also leaves the HFEA vulnerable to legal challenge.

Option 2 – clarify procedural detail – preferred option

12. Decisions to revoke or vary a licence effectively determine a person's civil rights and obligations and engage the requirements of article 6 of the European Convention on Human Rights. Persons whose cases are being considered by the Licence Committee will have a fairer opportunity to present their case if they are fully aware of the process to be followed by the Licence Committee; the rules of evidence that will be applied; and the standard of proof to be considered by the Committee. Setting out clear procedural rules improves both transparency of the process and aids improved decision making by the Committee.

Costs *for preferred option 2*

13. Decisions on whether to revoke, vary or refuse a licence will continue to be made by the Licence Committee.
14. The Regulations simply clarify the process to be followed by the Licence Committee when making its decision. The Authority currently considers very few cases in which revocation or variation of a licence (other than on the application of the centre) or refusal of the licence is a potential outcome. In 2008, the Authority had one such case.
15. The HFEA does not consider that the proposals will have a significant cost impact on the fertility sector.

Equality issues

16. The Equality Impact Assessment, Annex A, sets out in equality issues in further detail.
17. The HFEA believes that the proposals are unlikely to have any adverse impact on equality, including with regard to race, disability, age, gender, sexual orientation and human rights.
18. Updating these regulations will have a positive effect promoting equality of opportunity and eliminating unjustifiable discrimination in terms of age, gender and sexual orientation.

Enforcement, sanctions and monitoring

19. Appeal from decisions of the Licence Committee lie to an arms length Appeal Committee, and ultimately, to the Court of Appeal on a point of Law. Decisions of the Licence Committee are also subject to the High Court's judicial review jurisdiction. An annual report on the Licence Committee's activities will be presented to the HFEA.

Implementation and delivery plan

20. Regulations will be commenced 1 October 2009.

Post – implementation review

21. The HFEA has specific functions to monitor developments in their field of interest, including advising Ministers as required. The effectiveness of the HFEA will be monitored primarily through the usual procedures for oversight of arm's length bodies, including clearance and monitoring of business plans and annual accountability reviews.

Summary and conclusion

22. Option 2 will meet the Government's stated objectives to provide a legislative framework that is fit for purpose into the future.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	Yes
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	Yes
Race Equality	Yes	Yes
Disability Equality	Yes	Yes
Gender Equality	Yes	Yes
Human Rights	Yes	No
Rural Proofing	No	Yes

Annexe

Equality Impact assessment

Purpose and Effect

1. The Authority is an executive Non-Departmental Public Body sponsored by the Department of Health. The Authority was created by Section 5 of the ***Human Fertilisation and Embryology Act 1990*** ("the Act"), and began operating on 1st August 1991.

2. The general functions of the Authority are set out in Section 8 of the Act which provides: *"The Authority shall-*
   a) keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State if he asks it to do so, about those matters,
   b) publicise the services provided to the public by the Authority or provided in pursuance of licences,
   c) provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act, or may wish to do so, and
   d) perform such other functions as may be specified in regulations."

3. The Act, and the draft *Human Fertilisation and Embryology Authority (Procedure for Revocation, Variation and Refusal of Licences) Regulations 2009* set out procedures for the variation, suspension or revoking of licences; and for appeals against the determination of a Licence Committee.

4. The three equality strands where there are existing statutory duties on public bodies to have due regard to promoting equality and eliminating unlawful discrimination are race, disability and gender equality.

5. Outlined below are the main proposals that will be reflected in the new licensing regulations ("the regulations") and an assessment of their potential impact.

Initial scoping assessment and action plan for the HFE Bill Licensing Regulations

Summary of the purpose and aim of the regulations

6. Under the current regulatory framework, decisions about cases in which the revocation, variation or refusal of a licence is a potential outcome, are made by the HFEA's Licence Committee. The Act, and ***the Human Fertilisation and Embryology Authority (Licence Committees and Appeals) Regulations 1991***, (SI 1991/1889) set out procedures for the variation, suspension or revocation of licences; and for appeals against the determination of a Licence Committee.

7. Under the regulations, these decisions will continue to be made by a Licence Committee. However, the regulations contain more procedural detail than the 1991 regulations.

8. The aim of the regulations is to implement procedures which are compliant with Human Rights legislation and which ensure fairness and transparency in the licensing process. The regulations will facilitate improved decision making by the Licence Committee.

Assessment

Race

9. The regulations are unlikely to have any impact on people on grounds of their race because race is not a consideration that influences licensing decisions.

10. In addition, race is not a consideration for membership of the licence committee or panel. Membership of either determining body is open to employees of the Authority and members of the committee must be members of the Authority. The HFEA has a duty to meet race equality requirements with respect to its employees thereby ensuring equality of opportunity for membership of the committee or panel.

11. We have assessed that there are no specific opportunities to promote equality of opportunity through these regulations because race forms no part of the decision making process facilitated by these regulations. However, as stated above, the membership of the committee and panel shall be open to all employees and members of the Authority thereby facilitating equality of opportunity.

12. The aim of the proposed regulations is to implement procedures which are compliant with Human Rights legislation and ensure fairness and transparency in the licensing process which will indirectly aid in the elimination of unjustifiable discrimination on the basis of disability.

13. The proposed regulations do not deal with issues such as harassment and are therefore unlikely to have any direct impact on the elimination of harassment.

14. The regulations may indirectly promote good relations between people of different groups i.e. different applicants, because they promote uniform and consistent decision making by the panel.

Disability

15. We are unable to judge whether the proposed regulations will impact differently on people on grounds of disability although it is considered unlikely. The HFEA is committed to the elimination of unlawful discrimination on the basis of disability. These regulations aim to achieve fairness and transparency in the licensing process and do not treat applicants with disabilities any differently from other applicants. It is, however, accepted that the precise impact of these regulations on those with disabilities is not known.

16. We consulted on these regulations before implementation and engaged with appropriate stakeholder groups such as disability representatives from the British Medical Association. No information gathered through the consultation has prompted the HFEA to modify the regulations in light of how they would impact on people on grounds of disability. The HFEA will continue to monitor and review these regulations with respect to these different groups of people and will identify and address equality issues as necessary.

17. The proposed policy is thought not likely to help to eliminate unjustifiable discrimination. The reason is that issues of unjustifiable discrimination are not applicable.

18. The proposed policy is thought not likely to help to eliminate harassment. Harassment is not relevant to the proposed legislation.

19. The proposed policy is thought not likely to promote good relations between people of different groups. The reason is that this consideration is not applicable to this policy.

Gender or Transgender

20. The regulations are not likely to impact differently on people on grounds of their gender or transgender status. Gender and transgender issues are not a consideration relevant to licensing and have no impact on any licensing decisions made by the committee or panel.

21. The HFEA is committed to the elimination of unlawful and unfair gender discrimination both within the organisation and within the sector it regulates. Membership of the Licence Committee is not restricted by gender and the only limitation on membership is that members of the committee must be members of the Authority.

22. There are no specific opportunities to promote equality of opportunity through these regulations because gender forms no part of the decision making process facilitated by these regulations. However, as stated above, the membership of the committee and panel shall be open to all employees and members of the Authority regardless of gender or transgender status thereby facilitating equality of opportunity.

23. The aim of the proposed regulations is to implement procedures which are compliant with Human Rights legislation and which ensure fairness and transparency in the licensing process; an indirect consequence of these regulations therefore is the elimination of discrimination on the basis of gender.

24. The proposed regulations do not deal with issues such as harassment on the basis of gender or transgender status and are therefore unlikely to have any direct impact on the elimination thereof.

25. The regulations may indirectly promote good relations between people of different groups i.e. different applicants, because they promote uniform and consistent decision making by the committee and panel.

Age

26. These regulations are unlikely to impact differently on people on grounds of their age. Age is not a consideration when making licensing decisions.

27. Membership of the Licence Committee is not restricted by age. The only limitation on membership is that members of the committee must be members of the Authority.

28. These regulations do not give rise to any specific opportunities for the promotion of equality of opportunity across different age groups however, as stated above, the membership of the committee shall be open to all employees and members of the Authority regardless of age.

29. These regulations do not directly promote the elimination of unjustifiable discrimination on the basis of age, however the aim of the regulations is to implement procedures which are compliant with Human Rights legislation and which ensure fairness and transparency in the licensing process. An indirect consequence of these regulations therefore is the elimination of discrimination on the basis of gender.

30. The proposed regulations do not deal with issues such as harassment on the basis of age and are therefore unlikely to have any direct impact on the elimination thereof.

31. The regulations promote uniform and consistent decision making by the determining body ensuring that all persons whose applications are determined are treated equally. This may indirectly promote good relations between applicants.

Religion or Belief

32. The Human Fertilisation and Embryology Act 2008 ('the 2008 Act') allows for the licensing of certain research and treatment which, for some people, raises ethical and moral dilemmas. We consulted on these regulations before implementation and engaged with appropriate stakeholder groups. Responses covered a spectrum of religions and beliefs, with responses from different catholic groups, protestant groups and Islamic groups. Responses to the consultation confirmed that many issues of conscience were raised by these regulations, but it was difficult for many people to divorce their concerns about the regulations from unease about the wider issues of assisted fertility treatment, and embryology. This means that it was difficult for many individuals with different religion or belief to comment on the specific proposals behind the regulations, as they were against the principle of an Authority, and of fertility treatment in general.

33. While the regulations ensure a consistent and fair approach to decision making, it is not possible to establish how the decisions of the committee will impact on members of the wider public who hold certain religious or other beliefs. This however must be distinguished from how the regulations themselves will impact on this group of people. On balance the HFEA does not consider that the proposed regulations will impact differently on people on the grounds of their religion or belief.

34. The proposed policy is thought not likely to help to eliminate unjustifiable discrimination. The reason is that issues of unjustifiable discrimination are not applicable.

35. The proposed policy is thought not likely to help to eliminate harassment. Harassment is not relevant to the proposed legislation.

36. The proposed policy is thought not likely to promote good relations between people of different groups. The reason is that this consideration is not applicable to this policy.

Sexual Orientation

37. The proposed regulations are not likely to impact differently on people on grounds of their sexual orientation. Sexual orientation is not a factor in licensing decisions. Membership of the Committee is not restricted by sexual orientation. The only limitation on membership is that members of the committee must be members of the Authority.

38. The 2008 Act allows same-sex couples the same treatment as heterosexual couples. Based on small scale quantitative testing on the National Statistics Omnibus Survey, prevalence of the LGB population is estimated to be 2%. These findings are based on measuring the concept of sexual identity (rather than sexual behaviour or attraction), and are consistent with other surveys asking questions about sexual identity/orientation.

39. We have considered whether there are opportunities to promote equality of opportunity. We have concluded that the opportunities are not available.

40. The proposed regulations are likely to help to eliminate unjustifiable discrimination. The 2008 Act draws explicit attention towards equality of opportunity by allowing single

women and same-sex couples from receiving treatment by removing the consideration of the 'need for a father' before treatment. [1]

41. Following careful consideration, it is unlikely that people would be unjustifiably discriminated against on the basis of sexual orientation when either applying for a licence or as a member of a committee.

42. The proposed regulations are not likely to help to eliminate harassment because this is not relevant to the decision making process.

43. The proposed regulations are likely to promote good relations between people of different groups through uniform and consistent decision making by the determining body. This will ensure that all persons whose applications are determined are treated equally. This may indirectly promote good relations between applicants.

Action plan

44. In the light of the initial scoping assessment above, we identified the need to undertake a public consultation on these regulations. This consultation took place between January to March 2009 and allowed the full range of stakeholders with an interest to respond to the proposed policy. No information gathered through the consultation has prompted the HFEA to modify the equalities impact assessment.

45. The HFEA will monitor and review these regulations with respect to these different groups of people and will identify and address equality issues as necessary.

Competition assessment

46. The proposals retain the overall structure of regulation (that is, a statutory licensing authority and fee-paying licence holders) and many of its current aspects. Therefore no effect is envisaged on the 'market' structure or on the ability of suppliers to enter or exit the market or to compete.

Small Firms Impact Test

47. Most licensed clinics (which are predominantly private sector based) and research centres fall within the definition of small firm of having less that 50 staff and so can be considered to be small firms. All licensed clinics received a hard copy of the consultation document and were encouraged to respond to the consultation. The Department also met with the HFEA Licensed Centres Panel to discuss the impact of the regulations on clinics. The changes made in the Regulations should have a cost-neutral impact, whilst at the same time increased clarity in the law will also be of benefit in terms of investment decisions.

Legal Aid

48. The proposals will clarify the current law, bringing it up to date with current technology and attitudes. Setting out procedural details for the determination of licensing decisions in the regulations should reduce the potential of legal challenge.

[1] The Act removes reference to the clinic's need to consider 'the welfare of the child' including that child's 'need for a father before providing assisted fertility treatments. It was thought that this might be discriminatory to single or lesbian women. Therefore, the Act replaced the reference to 'need for a father' with 'need for supportive parenting' recognising the crucial role played by all parents. This statutory precedent means that it is unlikely that clinics would be able to refuse storage based on sexual orientation.

Health Impact Assessment

49. The proposals do not have a significant impact on human health, lifestyle or demand on NHS services, and therefore do not have any health impact relevant to this assessment.

Rural Proofing

50. The proposals do not have an impact upon rural communities, they will not impact upon the availability or cost of public and private services in rural areas, and there will be no impact upon rural business.