EXPLANATORY MEMORANDUM TO

THE HUMAN FERTILISATION AND EMBRYOLOGY (APPEALS) REGULATIONS 2009

2009 No.

1. This Explanatory Memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty. This Memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1. The Human Fertilisation and Embryology (Appeals) Regulations 2009 ("the Appeals Regulations") establish an appeals committee to hear appeals from licensing decisions made by the Human Fertilisation and Embryology Authority ("the HFEA"). The Appeals Regulations set out the constitution of the committee and make provision about advisers to the committee. The Appeals Regulations also establish the procedure for appealing against a licensing decision and the process for hearings by the appeals committee.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1. None

4. Legislative Context

4.1. The current system for appeals against licensing decisions by the HFEA is set out in the Human Fertilisation and Embryology Act 1990 ("the 1990 Act") and the Human Fertilisation and Embryology (Licence Committees and Appeals) Regulations 1991 ("the 1991 Regulations")[1]. These provide a framework structure for the constitution of the appeals committee and some detail on the process of appealing against licensing decisions.

4.2. The Human Fertilisation and Embryology Act 2008 ("the 2008 Act") replaces the relevant provisions of the 1990 Act relating to appeals and the Appeals Regulations will replace the 1991 Regulations.

4.3. The 2008 Act provides greater scope for the constitution of the appeals committee, including for the appointment of members that are not members of the HFEA.

4.4. The policy objectives of the Appeals Regulations are to set out a robust process for the committee hearing appeals and to ensure the appeals committee is sufficiently independent from the original decision of the HFEA. To achieve this, the Appeals Regulations set out, in detail, the procedure for appealing a decision and the process of an appeal hearing. The Appeals Regulations also set out the requirements of membership.

4.5. The Appeals Regulations are related to the Human Fertilisation and Embryology (Procedures for the Revocation, Variation or Refusal of a Licence) Regulations ("the HFEA Regulations"). The HFEA Regulations set out processes relating to the revocation, variation and refusal of a licence. The HFEA Regulations are not subject to Parliamentary processes and were made in May 2009.

4.6. Following debate at Public Bill Committee stage, the Appeals Regulations are subject to the affirmative procedure. The Appeals Regulations are made in exercise of powers conferred by section 20A(3), 20B(2) and 45(1),(3) and (3A) of the 1990 Act[2]. These powers (with the exception of section 45(1) which was already in force) were brought into force for the purpose of

[1] S.I 1991/1889

[2] Section 20A and 20B were inserted into the 1990 Act by section 21 of the 2008 Act. Section 45(3) was substituted by, and sub-section (3A) was inserted by, section 30 of the 2008 Act.

making the Appeals Regulations by The Human Fertilisation and Embryology Act 2008 (Commencement No.1 and Transitional Provisions) Order[3].

5. Territorial Extent and Application

5.1. These Regulations extend to the United Kingdom.

6. European Convention on Human Rights

6.1. The Minister of State for Public Health has made the following statement regarding Human Rights:

In my view the provisions of the Human Fertilisation and Embryology (Appeals) Regulations 2009 are compatible with the Convention rights.

7. Policy background

7.1. The 2008 Act provides for regulations to be made setting out the membership and procedures of a committee hearing appeals against licensing decisions made by the HFEA. Provision is also made for regulations to set out the procedure for reconsidering those decisions.

Membership and constitution of the Committee

7.2. Under the current system, the appeals committee must be formed from members of the HFEA. In practice, this will not be the members that sat on the committee which made the original decision that is being appealed. However, the policy intention behind the Appeals Regulations is to increase the independence of the appeals committee from the HFEA. The policy also takes into account requirements under common law and the European Convention on Human Rights for appeals procedures to be fair and impartial.

7.3. The 2008 Act provides that members of the appeals committee do not need to be members of the HFEA and the Appeals Regulations restrict committee membership to those who have not worked for or served on the HFEA, thereby increasing the independence of the committee

7.4. Under the current 1991 Regulations there is little detail provided regarding the constitution of the appeals committee and how it should operate. The policy is therefore that the Appeals Regulations should provide more detail relating to the constitution of the committee including terms of appointment and voting. By setting this out in regulations the committee processes will be more transparent.

7.5. The Appeals Regulations also enable the HFEA to appoint advisers to the appeals committee in certain circumstances, ensuring that the committee has access to any relevant expertise that is deemed necessary

Procedures on appeal

7.6. The current 1991 Regulations also set out very little detail on the procedure relating to appeals, One of the policy objectives for the Appeals Regulations was therefore that they should set out a detailed procedure for the appeals committee to following when considering an appeal. This ensures that the procedure is transparent for appellants and helps to increase the accountability of the committee.

7.7. The Appeals Regulations set out a robust appeals process, which is in line with modern regulatory practice. This includes provision for a system of notification and exchange of information between parties to the appeal, case management conferences and rules relating to evidence and representation at hearings. The Appeals Regulations require records to be kept of all decisions of the committee. Again these provisions help to safeguard the interests of those

[3] S.I. 2009/479

wishing to appeal and ensure that the committee operates under a clear and accountable procedure.

Consultation

7.8. The two principles of the regulations that were highlighted in the consultation were:

- HFEA members (current and previous) cannot sit on an Appeals Committee
- The Chair and Deputy Chair of an Appeals Committee are legally qualified.

8. Consultation outcome

The consultation process

8.1. The consultation took place over a twelve-week period between 5 January 2009 and 30 March 2009. The consultation set out two proposals for the regulations that respondents were asked to address. 35 responses were received specifically discussing the Appeals Regulations. The responses represented a diverse mix of stakeholders including the Human Fertilisation and Embryology Authority, clinical professionals, representatives of religious groups and professional bodies. Consultative meetings were also held with key stakeholder groups.

8.2. The two proposals consulted on are set out at paragraph 7.8. The majority of respondents were supportive of both proposals, recognising especially, the importance of a legally qualified Chair and Deputy Chair.

8.3. Concerns were raised by some respondents that the proposed Appeal Regulations prevented persons with relevant expertise from sitting on the committee. The Government recognises the importance of the appeals committee having access to expertise in such a complex and specialised field and to ensure this will be possible provision is made in the Appeals Regulations for the appointment of advisers.

8.4. As the majority of respondents were supportive of the draft Appeals Regulations and agreed with the proposals set out in the consultation, the Appeals Regulations have not been significantly amended from the draft version consulted on.

8.5. Further details of the responses to the consultation and the Governments response can be found on the Department of Health website.

9. Guidance

9.1. Guidance on the appeals process for appellants and for members of the appeals committee will be provided by the HFEA.

10. Impact

10.1. The impact on business, charities or voluntary bodies will be minimal as these regulations will only affect those centres appealing against a licence decision. Many licensed clinics and research centres fall within the definition of small firms (having fewer than 50 staff). All licensed clinics received a copy of the consultation document, and were consulted at a HFEA Licensed Centre Panel meeting. The changes made by 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.

10.2. The impact on the public sector is positive as the regulations are ensuring a more robust and independent appeals system, thus reducing the likelihood of challenge.

10.3. An Impact Assessment is attached to this Memorandum.

11. Regulating small business

11.1. The legislation applies to small businesses.

11.2. Many licensed clinics (which are predominantly private sector based) and research centres fall within the definition of small businesses (having less that 50 staff) and so can be considered to be small businesses. The regulations are likely to 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.

12. Monitoring & review

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

13. Contact

13.1. Stephanie Croker at the Department of Health Tel: 020 797 23054 or email: Stephanie.croker@dh.gsi.gov.uk can answer any queries regarding the instrument.

Summary: Intervention & Options		
Department /Agency: Department of Health	**Title:** Impact Assessment of HFE (Appeals) Regulations 2009	
Stage: FINAL	**Version:** FINAL	**Date:** May 2009
Related Publications: Consultation Report on Regulations to Implement the HFE Act 2008 – Part 3: The Human Fertilisation and Embryology (Appeals) Regulations		

Available to view or download at:

http://www.dh.gov.uk

Contact for enquiries: Stephanie Croker **Telephone:** 020 7973 3054

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

The Human Fertilisation and Embryology (HFE) Act 2008 ("2008 Act") requires regulations to be made to set out the process for appealing against decisions of the Human Fertilisation and Embryology Authority (HFEA) as well as to set up an Appeals Committee. Therefore, there is a legal requirement for these regulations to be made. The HFE (Appeals) Regulations 2009 replace the previous licensing and appeals regulations. The regulations set out the constitution and procedure of the Appeals Committee ("the Committee").

What are the policy objectives and the intended effects?

The policy objectives are to have a Committee that is independent from the HFEA to consider appeals made against licensing decisions.

The intended effect of this is to ensure the impartiality and autonomy of the Committee to reduce the likelihood of legal challenge. The regulations are also intended to set out a robust process of determination, leaving the Committee procedures less likely to be subject to legal challenge.

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

The policy options set out how the regulations provide for the set up the Committee. The options are: 1. The regulations provide for members of the Authority to sit on the Committee.

2. Members of the Authority are not permitted to sit on the Appeals Committee.

3. Members of the Authority are not permitted to sit on the Appeals Committee, and will be appointed by the Secretary of State.

Option 2 permits maximum independence from the HFEA whilst giving the HFEA the flexibility

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The HFEA will monitor and review the regulations.

Ministerial 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 responsible Minister:

Dawn Primarolo ..... Date: ***19th May 2009***

Summary: Analysis & Evidence	
Policy Option: 2	**Description: Members of the Authority are not permitted to sit on the Appeals Committee**

COSTS

ANNUAL COSTS	
One-off	**Yrs**
£ 23,000	1
Average Annual Cost (excluding one-off)	
£ 0	

Description and scale of **key monetised costs** by 'main affected groups' The one-off cost reflects the estimated costs of recruiting Committee members. The average annual cost will remain the same as the costs of running the Committee under the current system.

Total Cost (PV) **£ 23,000**

Other **key non-monetised costs** by 'main affected groups' The administration of the appointments process will fall to the HFEA.

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ 0	
Average Annual Benefit (excluding one-off)	
£ 1,100+	

Description and scale of **key monetised benefits** by 'main affected groups' It is difficult to estimate the financial benefits that will be achieved by having a fully independent Appeals Committee. There will be savings on legal advice, as the Chair of the Committee will be legally qualified. These and the reduced risk of legal challenge could eventually balance the one-off costs.

Total Benefit (PV) **£ 23,000**

Other **key non-monetised benefits** by 'main affected groups' The benefits of having a clear, robust appeals process will be significant to all potential appellants; it is also a requirement under common law and the European Convention on Human Rights for appeals procedures to be fair and impartial.

Key Assumptions/Sensitivities/Risks An independent Appeals Committee will reduce the risk of legal challenge to determinations and procedures of the Committee.

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

What is the geographic coverage of the policy/option?				UK	
On what date will the policy be implemented?				1 October 2009	
Which organisation(s) will enforce the policy?				HFEA	
What is the total annual cost of enforcement for these organisations?				£ 0	
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 - Increase of £ 0 Decrease £ 0 **Net Impact** **£** 0

Key:	**Annual costs and benefits:**	**(Net) Present**

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Introduction

1. Section 20 of the Human Fertilisation and Embryology Act 2008 (http://www.opsi.gov.uk/acts/acts2008/ukpga_20080022_en_1) ("2008 Act") provides that where the outcome of an application for a licence or an application for the revocation or variation of a licence is unsatisfactory, the applicant may appeal against that decision. This replaces the equivalent provision in the Human Fertilisation and Embryology Act 1990 (http://www.opsi.gov.uk/Acts/acts1990/Ukpga_19900037_en_1.htm) ("1990 Act").
2. Section 20A sets out a regulation-making power in relation to the membership of the Committee and section 20B sets out a regulation-making power in relation to the processes of the Committee.
3. The Human Fertilisation and Embryology (Appeals) Regulations 2009 (the "regulations") replace the Human Fertilisation and Embryology (Licence Committee and Appeals) Regulations 1991 ("1991 regulations").
4. The regulations set out the membership of an Appeals Committee and the processes for determining an appeal.
5. The regulations are subject to the affirmative procedure, and will be debated in Parliament.
6. The Impact Assessment for the Human Fertilisation and Embryology Bill can be found on the Department of Health's website - http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_080211

Background

7. There are requirements under the common law and the European Convention on Human Rights for appeals procedures to be fair and impartial. Concerns had been raised about the current appeal provisions in the 1990 Act, whereby an Appeals Committee must consist of members of the Human Fertilisation and Embryology Authority (HFEA). (http://www.hfea.gov.uk/)
8. The 2008 Act allows for the Authority to maintain one or more Appeals Committees and specifies that people who are not members of the Authority may sit on the Committee. The 2008 Act specifies that regulations shall make provisions about the membership and proceedings of appeals committees.
9. The regulations specify that an Appeals Committee should be made up of members who are not members of the Authority and this will increase the independence of the Committee from the Authority, thereby increasing the autonomy of the Committee.
10. The regulations add clarity to the procedural details of the appeals process. It will be for the HFEA to set up the Committee and produce further guidance as to how the Committee runs once the regulations come into force.

Position under the 1991 regulations

11. The licensing and appeals regulation-making power in the 1990 Act is set out at section 10. The 1991 regulations set out the composition of the Appeals Committee but include very little procedural detail. The membership of the Committee is not limited, however the quorum is 5 and at least two members of the Committee must not be authorised to carry out or participate in any activity under the authority of an HFEA licence.

12. Appeals hearings are rare, over the last four years there has only been three hearings.

Reason for intervention

13. It is a requirement under the 2008 Act for regulations to set out the membership and procedures of the Appeals Committee.

14. At present, the HFEA Appeals Committee consists of members of the Authority. In order to ensure maximum independence of the Appeals Committee the regulations state that the Committee must be constituted of members that are not members of the Authority.

15. The regulations set out a requirement for a lay Chair and Deputy Chair, who must also be legally qualified.

16. It is also the intention for the regulations to set out a robust procedure for the determination of an appeal; therefore the regulations clarify the procedural details for Committee processes.

Policy Objectives

17. The objective of these regulations is to have an appeals committee independent from the HFEA to consider appeals made against licensing decisions.

18. The regulations will set out the membership and procedural requirements for the Appeals Committee, to allow the Committee maximum independence from the HFEA.

Consultation

19. The regulations were subject to public consultation which ran from 5 January 2009 until 30 March 2009. Respondents to the consultation were supportive of the regulations. Following the consultation, it was necessary to make minor changes to the regulations and the majority of these were technical. The regulations were largely unchanged from the draft version, further information about the consultation and the consultation report can be found on the Department of Health website.

Links to other policy areas and strategies/programmes of work

20. These regulations are linked to the regulations being made by the HFEA that set out the process for the refusal, variation or revocation of a licence.

Policy Options

We considered three policy options:

- Option 1 – the current policy is retained, the regulations provide for the Committee to be members of the Authority.
- Option 2 – members of the Authority are not permitted to sit on the Appeals Committee. This is the preferred option.
- Option 3 – members of the Authority are not permitted to sit on the Appeals Committee, and will be appointed to the Committee by the Secretary of State.

Benefits and risks

21. As part of deciding which policy option to take forward the risks and benefits of each were evaluated.

Option 1 – maintain current policy, the regulations provide for the Committee to be members of the Authority.

22. One of the policy objectives of the regulations is to make the Committee as independent from the HFEA as possible. If, as is the current position, members of the Authority sit on the Committee the Committee would not be as independent from the Authority as is possible under the 2008 Act.

23. The 1991 regulations do not set out details of the process by which an Appeals Committee should determine an appeal, by re-making these regulations without adding further detail, the Committee may be left open to legal challenges on points of procedure.

24. Maintaining the current position, may risk legal challenge to the appeals process. It would be impossible to calculate the costs of a legal challenge; however, it could be in the region of £100,000. Even if this were only to happen every 5 years, the annual average cost could be £20,000.

25. The costs of recruiting members to an Appeals Committee will be saved, as Authority members are already in post, they will not be recruited specifically for the purpose of sitting on the Appeals Committee.

Option 2, the preferred option – Appeals Committee members must not be members of the Authority

26. It is of key importance that the Appeals Committee is independent from the Authority. Making provision in regulations that members of the Authority cannot sit on an Appeals Committee increases the independence and autonomy of the Committee.

27. The regulations set out the membership requirements for the Committee, however will allow the HFEA to set out procedural matters, for example the recruitment of members. Recruitment may then be contracted to an outside body under new sections 8B (agency arrangements) and 8C (contracting out) of the 2008 Act. This will also act to increase the independence of the Committee from the Authority.

28. There is, on average, less that one appeal hearing a year, therefore an Appeals Committee will need to be maintained even though they will not meet on a regular basis.

29. The costs of recruiting members will not be insignificant, roughly parallel to the costs of recruiting Authority members.

30. On balance, it is thought that the flexibility provided by this option, and the independence from the Authority is sufficient to the outweigh additional recruitment costs.

Option 3 – Appeals Committee members must not be members of the Authority and will be appointed by the Secretary of State

31. Option 3 will also increase the independence and autonomy of the Appeals Committee.

32. Provision is set out for appointment to the Authority by the Secretary of State, however this power does not extend to the appointment of members of a committee of the HFEA. The Appointments Commission can advise the HFEA on the recruitment of members of the Appeals Committee. The options under new sections 8B and 8C are still available to the Authority.

Costs

33. The costs of each policy option were also evaluated, the costings for policy option two are set out in the Summary and Analysis of Evidence. It is recognised that option 2 will result in increased costs for the HFEA due to the recruitment of Appeals Committee members. However it is likely that these costs will be recovered from the savings made by changes to the licensing system. The regulations that have been produced by the HFEA set out the process by which a licence is granted, revoked or suspended. Under the system set out by the regulations a Licence Panel made up of employees of the HFEA will be able to deal with applications and this will only be elevated to a Licence Committee hearing if the issue is in anyway contentious. By setting up the Licence Panel, the HFEA will save a considerable amount of money on maintaining and running multiple Licence Committees.

34. The annual one-off cost is for the initial recruitment of members. Each member can sit on the Committee for a maximum of two terms, each term being three years. This would mean that there may be further recruitment costs after three and then six years. The costs here reflect the initial recruitment costs to establish the Committee.

	Estimated cost (£)
Cost of Committee meeting (including attendance fees, expenses and catering) based on costs of Licence Committee meetings	2,000
Average number of Appeals Committee hearings over last 4 years	0.75
Average cost per year of Appeals Committee, including training for members	1,600
Average legal cost per Committee meeting	1,100
Cost of recruiting 7 Appeals Committee members (based on costs of recruiting members to the Authority	23,000

Summary of cost/benefit analysis for preferred option 2.

	Total benefit per annum	Total cost per annum
Members of the Authority are not permitted to sit on the Appeals Committee	The average costs of legal advice at the hearings is £1,100. This will be saved as the Chair and Deputy Chair will be legally qualified. The cost of a fully independent Appeals Committee is immeasurable. This will significantly reduce the possibility of legal challenge, which could be in the region of £100,000.	The cost of the initial recruitment of members of the Appeals Committee can be estimated as £23,000. The average annual cost of Appeals Committee hearings can be estimated as £1,600. The administration of the appeals process will fall to the HFEA.

Equality issues

35. The Government believes that the proposals for the appeals regulations are unlikely to have any adverse impact on equality, including with regard to race, disability, age, gender, sexual orientation and human rights.

36. Making these regulations will have a positive effect promoting equality of opportunity and eliminating unjustifiable discrimination in terms of age, gender and sexual orientation.

37. A full Equality Impact Assessment is at Annex A.

Enforcement, sanctions and monitoring

38. Existing law in this area is enforced through a range of sanctions including criminal penalties as well as measures attaching to the appeals process. The HFEA has inspection and monitoring functions. The Government proposes that a similar range of measures will continue, but this will be reviewed in light of the emerging issues following the Macrory review of penalties.

39. An annual report on the Appeals Committee's activities will be presented to the HFEA.

Implementation and delivery plan

40. The regulations will be debated in Parliament in summer 2009.

41. The regulations will be commenced on 1 October 2009.

Post – implementation review

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

Summary and conclusion

43. It is a requirement in the 2008 Act that regulations are made to set out the membership and procedures of an Appeals Committee. There are also legal requirements for appeals hearings to be fair and impartial. Option 2 gives the Appeals Committee maximum independence from the Authority.

44. Option 2 meets 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	Yes
Rural Proofing	No	Yes

Annexes

Equality Impact Assessment

Purpose and intended effect

1. The Department is replacing the current licensing and appeals regulations.[4] The new regulations will only cover appeals.
2. The regulations set out the process by which an appeal against a decision made by the Human Fertilisation and Embryology Authority (HFEA) can be made. The regulations also set out the membership of the Appeals Committee, the powers the Committee has and the process for an appeal.
3. The HFEA is a statutory licensing body whose remit involves licensing and inspection, producing codes of practice for licence holders, and providing advice to Ministers as required. The HFEA is also a "competent authority" responsible for overseeing the requirements of the European Union Tissue and Cells Directive[5] on setting standards of quality and safety for the storage of human tissues and cells, with regards to human gametes and embryos.
4. The three equality strands where there are existing statutory duties on public bodies to have due regard to promoting equality/eliminating unlawful discrimination are race, disability and gender equality. The Department of Health has opted in addition to have a policy of promoting equality/eliminating unjustified discrimination in relation to religion and belief, sexual orientation, and age.
5. Outlined below are the main proposals that will be reflected in the proposed regulations and an assessment of the impact.

Initial scoping assessment and action plan for the regulations

Summary of the purpose and aim of the proposed policy

6. Currently the Appeals Committee of the HFEA is made up of Authority members. The Human Fertilisation and Embryology Act 2008 ("2008 Act") allows for people who are not members of the Authority to sit on the Committee. The 2008 Act provides for regulations to govern the procedures of the Committee.
7. There are legal requirements under common law and the European Convention on Human Rights for an appeals procedure to be fair and impartial. This will also act to increase the robustness of decisions made by the Committee.
8. The 2008 Act amends the Human Fertilisation and Embryology Act 1990 ("1990 Act") to ensure that appeals made against decisions of the Authority are taken forward fairly and impartially.

Assessment

Race

9. The policy is not likely to have a negative impact on people on grounds of race. The reason for this is that race is not a consideration of membership of an Appeals Committee. The only limitations on membership are that the Chair and Deputy Chair must be legally qualified and members must be independent from the Authority. Additionally, race should not impact decisions made by the Appeals Committee.

[4] The Human Fertilisation and Embryology (Licence Committees and Appeals) Regulations 1991 (SI1991/1889)
[5] 2004/23/EC as implemented by The Human Fertilisation and Embryology (Quality and Safety) Regulations (SI 2007/1522) and The Human Tissue (Quality and Safety for Human Application) Regulations (SI 2007/1523)

10. We expect appointments to the Committee to be in accordance with the Code of Practice of the Commissioner for Public Appointments which specifically states that appointments should be based on merit and should deliver the principles of equal opportunities. Therefore, the policy should have a positive impact in terms of promoting equality of opportunity, eliminating unjustifiable discrimination, and promoting good relations between people of different groups.
11. The policy is not likely to help eliminate harassment because it is not relevant to issues of harassment.

Disability

12. The policy is not likely to have a negative impact on people on grounds of race. As stated above, the only limitations on membership are that the Chair and Deputy Chair must be legally qualified. Our intention is that appointments to the Committee will be in accordance with the Code of Practice on Public Appointments.

Gender or Transgender

13. The policy is not likely to impact differently on people on the grounds of their gender. Gender should not impact on any appeals decisions to be made by the Committee and membership of the Committee is not restricted by gender.
14. We expect appointments to the Committee to be in accordance with the Code of Practice of the Commissioner for Public Appointments which specifically states that appointments should be based on merit and should deliver the principles of equal opportunities. Therefore, the policy should have a positive impact in terms of promoting equality of opportunity, eliminating unjustifiable discrimination, and promoting good relations between people of different groups.
15. The policy is not likely to help eliminate harassment because it is not relevant to issues of harassment.

Age

16. The policy is not likely to impact differently on people on the grounds of their age. Age does not impact on any decisions to be made by the Committee and membership of the Committee is not restricted by age.
17. We expect appointments to the Committee to be in accordance with the Code of Practice of the Commissioner for Public Appointments which specifically states that appointments should be based on merit and should deliver the principles of equal opportunities. Therefore, the policy should have a positive impact in terms of promoting equality of opportunity, eliminating unjustifiable discrimination, and promoting good relations between people of different groups.
18. The policy is not likely to help eliminate harassment as it is not relevant to issues of harassment.

Religion or Belief

19. We do not expect the regulations to impact differently on people on the grounds of their religion or belief. Issues surrounding the impact of the regulations on people on the grounds of their religion or belief were not identified following engagement with the relevant stakeholders.
20. The policy itself is not intended to affect people with different religions or beliefs differently in terms of the provision of fertility treatment or embryo research (although religion or belief may influence people's decisions about whether they wish to access these services).

Sexual Orientation

21. The policy is not likely to impact differently on people on the grounds of their sexual orientation. Sexual orientation does not impact on any licensing decisions to be made by the Committee. Membership of the Committee is not be restricted by sexual orientation.

22. We expect appointments to the Committee to be in accordance with the Code of Practice of the Commissioner for Public Appointments which specifically states that appointments should be based on merit and should deliver the principles of equal opportunities. Therefore, the policy should have a positive impact in terms of promoting equality of opportunity, eliminating unjustifiable discrimination, and promoting good relations between people of different groups. The policy is likely to help eliminate unjustifiable discrimination.

23. The policy is not likely to help eliminate harassment as it is not relevant to the proposed legislation.

Action plan

24. The regulations were consulted on for three months from January to March 2009. A full range of stakeholders were consulted, further details of the respondents can be found in the report of the consultation on the Department of Health website.

25. The regulations will be debated in Parliament in summer 2009.

26. The HFEA will monitor and review the effect of these regulations and will identify and address any equality issues as part of this process.

Competition assessment

27. The regulations support 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

28. Many licensed clinics (which are predominantly private sector based) and research centres fall within the definition of small firm (having less that 50 staff) and so can be considered small firms.

29. Licensed centres were consulted directly, each centre received a copy of the consultation document and were consulted via a meeting with the HFEA Licensed Centre Panel, which made clear that the regulations will be likely to 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

30. The regulations do not introduce new criminal sanctions or criminal penalties, therefore there will not be potential impacts on the workload or courts or legal aid costs.

Health Impact Assessment

31. The regulations 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

32. The regulations 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.