Summary: Intervention & Options

Department /Agency:	Title:	
Department of Health	Impact Assessment of the HFE (Disclosure of Information for Research Purposes) Regulations 2010	
Stage: Final	Version: 1.1	Date: 20 January 2010

Related Publications: Human Fertilisation & Embryology Act 1990 – disclosure of identifying information for research, report of second public consultation

Available to view or download at:

http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm

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

Since 1991, the Human Fertilisation and Embryology Authority (HFEA) has maintained an UK wide register of patients undergoing fertility treatments that involve the creation of embryos outside the body and/or the use of donated gametes (sperm and eggs) and embryos. The register is a valuable resource that could aid research into the long-term health implications of such treatments. Where consent cannot be obtained to the disclosure of identifying information, held on the register, for research purposes (excluding cases of refusal), an authorisation process is needed to determine if such disclosure would be justified.

What are the policy objectives and the intended effects?

Where it is not practicable to obtain consent to disclosure from the persons to whom the information relates, research bodies will be able to apply to receive identifying information, subject to strict controls, from an authorising body under the regulations, which will determine if the disclosure of such information is appropriate. This body is the HFEA, the national regulator and holder of the information, which will be able to seek advice from other expert bodies, such as the National Information Governance Board for Health and Social Care. The regulations allow a fee to be levied to cover the costs of collating and releasing information from the register, at £500 per day, with provision for a fee of £250 where only a half-day is needed.

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

1. Maintain current policy.

2. Limit disclosures solely to information where consent has been obtained from the person to whom the information relates.

3. Create an authorisation process to consider applications for access to identifying information where consent cannot be obtained.

The 3rd option has been adopted in the regulations because it allows for the best use of the data available. People will be able to withhold identifying information about themselves by notifying HFEA.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The effectiveness of HFEA's performance will be assessed through quarterly accountability reviews. Fees will be subject to regular review.

Ministerial Sign-off For Final Impact Assessment:

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:

..... Date: 19.1.10

Summary: Analysis & Evidence

Policy Option: 3	Description: Authorisation process for releasing information where consent cannot be obtained

COSTS

ANNUAL COSTS	
One-off (Transition) **Yrs**	Description and scale of **key monetised costs** by 'main affected groups' A fee to recover costs of collating and releasing information, up to a maximum payment of £5,000, will be charged where appropriate. Please see paragraph 54 of the evidence base. There will be no application fee. It is not possible to estimate the number of applications that will be made but the annual cost to HFEA should not exceed £25k
£ 0	
Average Annual Cost (excluding one-off)	**Total Cost** (PV) **£ 0.12m**
£ 25,000	

Other **key non-monetised costs** by 'main affected

BENEFITS

ANNUAL BENEFITS	
One-off **Yrs**	Description and scale of **key monetised benefits** by 'main affected groups'
£ 0	
Average Annual Benefit (excluding one-off)	**Total Benefit** (PV) **£ >0.12m**
£ >25,000	

Other **key non-monetised benefits** by 'main affected groups' The primary benefit of these regulations will be the ability to have evidence to establish or refute any causal link to development of a specific medical condition. We assume that the researchers who pay for the research data will value it at more than its cost.

Key Assumptions/Sensitivities/Risks Applicants will be self-selecting, applying for access to the data if they believe there are no other means of achieving the aims of their research project. Fees are prescribed in regulations, in the range of £250 to £5,000, for the collation and release of the data to successful applicants.

Price Base Year 2009	Time Period Years 20	**Net Benefit Range** (NPV) **£ Unknown**	**NET BENEFIT** (NPV Best estimate) **£ >0**

What is the geographic coverage of the policy/option?				UK
On what date will the policy be implemented?				6 April 2010
Which organisation(s) will enforce the policy?				HFEA
What is the total annual cost of enforcement for these organisations?				Nil
Does enforcement comply with Hampton principles?				Yes
Will implementation go beyond minimum EU requirements?				No
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 **0**	Small **0**	Medium **0**	Large **0**
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**

Evidence Base

Introduction

1. Section 31 of the Human Fertilisation & Embryology Act 1990 (1990 Act), as amended by section 24 of the Human Fertilisation & Embryology Act 2008 (2008 Act)[1], requires the national regulatory body, the Human Fertilisation & Embryology Authority (HFEA), to maintain a register of every fertility treatment cycle involving: (i) the creation of embryos outside the body, e.g. *in vitro* fertilisation (IVF) and/or (ii) the use in treatment of donated gametes (sperm and eggs) and embryos that have taken place in UK clinics, licensed by the HFEA, since August 1991.
2. The register also holds details of the patients, their partner if they had one, any offspring and all gamete and embryo donors. It represents one of, if not the most, comprehensive collections of data of this type in the world.
3. Section 25 of the 2008 Act amended the 1990 Act, inserting new section 33D. This section establishes a regulation-making power in relation to the disclosure of identifying information for research purposes in specific circumstances.
4. These regulations are subject to the affirmative procedure and, therefore, will be debated in Parliament.
5. The Impact Assessment for the Human Fertilisation and Embryology Bill, that later became the 2008 Act, can be found on the Department of Health's website - http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Regulatoryimpactassessment/DH_080209

Background

6. The register data has long been viewed as a valuable resource that might, if available to researchers, help to answer conclusively some of the questions about the long-term health and social implications of these fertility treatments. However, the sensitivity of these treatments has meant that identifying information has been subject to a higher level of protection than would normally be applied to health records. This extra level of protection has had the effect of significantly limiting the purposes for which such information could be disclosed.

Reasons for intervention

7. Prohibitions on disclosure contained in section 33 of the 1990 Act (a section repealed by the 2008 Act and replaced with new section 33A from 1st October 2009) were particularly strict with regard to the HFEA's register. Data from the register could not be disclosed to anyone, other than members and staff of the HFEA or persons to whom a HFEA licence applied, even with the consent of the person to whom that information related. At the outset of work on the 2008 Act, the Government made the commitment to consider how access to this data, for research purposes, might be improved.

[1] An illustrative text of the amended version of the 1990 Act can be found at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080205)

8. The exceptions to the prohibition on disclosure of identifying information were revised in new subsection 33A(2), supplemented by section 33B, as introduced by the 2008 Act. These include the introduction of an additional exception allowing disclosure of identifying information from the register with consent of the persons to whom the information relates, except where the information could make a link between a gamete or embryo donor and a person who was (or who may have been) born as a result of the use of that donation in treatment. Patients were already able to consent to disclosure of identifying information from local clinic records and this is an exception that is retained in subsection 33A(2).

9. However, the Government recognised that for some of the records, particularly the earliest records that are now 18 years old, it may no longer be practicable for research bodies to obtain the consent of the persons to whom the information relates.

10. To ensure that the greatest use can be made of the data for research purposes, while still protecting the confidence of the person(s) to whom the information relates, section 33D allows for the creation of an authorisation process to approve the disclosure of identifying information. Applicants will have to show that consent cannot practicably be obtained. If disclosure is approved, strict controls will be applied, regulating who can have access to the data and what use they are permitted to make of it.

11. This is the purpose of the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010. The authorisation process established by the regulations is intended to be a method of last resort, used only when all other avenues for obtaining the necessary information to carry out a research project have been exhausted. For this reason, these regulations cover data about patients and their partners collected from 1st August 1991 to 30th September 2009. Since 1st October 2009, when the amendments made to the 1990 Act by the 2008 Act came into force, patients have been able to indicate their willingness for identifying information about them to be used in research on a consent forms provided to them by their treating clinic along with the standard treatment consent forms. The only exception to the September 2009 cut-off date is identifying information about children born as a result of treatment. Applications can continue to be made for access to that data, collected on the register on and after 1st October 2009.

12. More information on the proposals for the authorisation process and how it is envisaged it will operate, can be found at Annex A.

Fee proposals

13. The regulations allow the HFEA to levy a fee for the provision of information from its register. The fee has been set to cover the cost of collating and releasing data and is prescribed in the regulations, see paragraph 54 of the evidence base.

Scrutiny of proposals

14. In 2004, the House of Commons Science and Technology Committee conducted an inquiry into human reproductive technologies and the law. In its March 2005 report[2] the Committee recommended that the data held on the HFEA's register should be applied as far as possible to research studies. Also in 2004, the Medical Research Council, in its report *Assisted Reproduction: A Safe Sound Future*, recommended that a monitoring framework for assisted reproduction technologies should be established, based on core data collected by the HFEA and linked to other health records and health outcome data.

[2] The report can be found at:
http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/cmsctech.htm

Both reports drew attention to the fact that the HFEA data was subject to stricter confidentiality requirements than other health information, taking the view that this adversely affected the conduct of research in this field.

15. These concerns and whether the higher level of confidentiality applicable to identifying information about these fertility treatments was still justified, were put out to public consultation in August 2005, as part of the wider consultation on the review of the 1990 Act. In December 2006 the Government published its proposals for the review. These included revising the confidentiality provisions in the Act so that data on assisted reproduction treatments would be more accessible for research purposes.

16. There was widespread support for the proposal, not just from professional bodies and research organisations but also from some patient groups and faith organisations. There was also a large body of support for removing the higher level of protection applied to these records, thereby placing them on an equal footing with other types of health information. Ultimately, the latter proposal was not developed because EU Directive 2004/23/EC, setting quality and safety standards for human tissue and cells intended for human application (which covers gametes and embryos), required a higher level of protection for health records, of the type already applied by section 33 (from 1st October 2009 section 33A) of the 1990 Act.

17. Prior to its passage through Parliament, the 2008 Act, then known as the Human Tissue and Embryos Bill, was subject to scrutiny by a Joint Committee of both Houses of Parliament. In its report of August 2007[3], the Joint Committee supported the proposals for an authorisation process, with the proviso that proportionate safeguards were introduced to protect patients' interests.

First public consultation on the regulations

18. While there had been considerable support for making access to identifying information more readily available for research purposes, the Government was conscious that the proposal to establish an authorisation process to allow disclosure without consent had not previously been put out to consultation. The draft regulations were issued for public consultation in January 2009[4].

19. 57 responses were received. A number of respondents were opposed to the principle of disclosure without the express consent of the persons to whom the information related. However, a number of key stakeholders, including patient organisations, accepted that disclosure for the purpose of research could be justified but that tight controls would need to be put in place to govern the handling and use of the information once released. No respondent disagreed with the application requirements contained in the draft regulations nor the proposed conditions that would be attached to any disclosure of identifying information.

HFEA as authorising body

20. Where views were expressed opposing the establishment of HFEA as the approving body, this was frequently a reflection of the general view that the regulations themselves were inappropriate.

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[3] The report can be found at: http://www.parliament.uk/parliamentary_committees/humantissue.cfm

[4] The consultation document can be found at: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_092465

Where comments were clear in their opposition to the HFEA, there was no consensus as to which organisation was more appropriate for this role, bearing in mind the limited national remits of bodes such as the National Information Governance Board for Health and Social Care (NIGB), covering England and Wales, and the Privacy Advisory Committee (PAC), covering Scotland, (*a Privacy Advisory Committee is also proposed for Northern Ireland*), who advise on the suitability of releasing other types of health information for research purposes where consent cannot be obtained, the PACs having a narrower advisory function than NIGB. The majority of respondents supported the proposal that the HFEA should take on this function, largely on the basis that this was the most practical option. There was, however, a strong body of support for NIGB having input in to the assessment of applications in view of its experience in this area. As a result, the ability of NIGB to advise and assist HFEA, if requested to do so, is more firmly established in the regulations.

Exclusion of donor information and information where there was a prior refusal

21. Views differed on the exclusion of donor related information, with research and professional bodies opposing the exclusion and patient and ethical bodies in support. The majority of respondents supported the proposal. There were no comments opposing the proposal that information about persons who have refused to give consent to disclosure should be withheld. In view of the comments, these two exclusions remain in the regulations.

22. Two further areas that attracted comment were the fees payable by research bodies and the ability of patients to give prospective consent to disclosure of identifying information about children that might be born as a result of their treatment.

Fees

23. Some of the respondents were of the view that the amount of any fee should be set out in the regulations. It had been the Government's intention that the HFEA itself should establish its fee proposals and consult on them before submitting them to HM Treasury and the Department of Health for approval. However, following further advice, the regulations now prescribe the fee for collating and releasing information to successful applicants. The fee will be £500 per day, with provision for a payment of £250 where only half a day's work is needed, up to a maximum payment of £5,000.

Unborn and yet to be conceived children

24. While patients can agree to the disclosure of identifying information held on the HFEA's register about children born as a result of their fertility treatment, respondents pointed out that there was no provision in the 1990 Act, as amended, to enable patients to agree to the disclosure of identifying information about any child that might be born as a result of their treatment. Although success rates are improving year on year, the live birth rate per treatment cycle started, even for the most optimal patient, is less than 33%. Concern was expressed that a valuable opportunity to study the health implications for offspring could be lost if their parents could not agree to disclosure at the start of their treatment (when they would complete consent forms for disclosure of their own information, if minded to do so), especially as it was proposed that the authorisation process should not be used for data collected about offspring after 30th September 2009.

25. The Government appreciated that asking treatment clinics, who are no longer involved in a patient's care once they become pregnant, to try and ascertain the wishes of parents once a child has been born could place a significant administrative burden on those clinics. Equally, new parents may not welcome being contacted to consider giving consent to the disclosure of information about a new born child at what is a busy and often stressful time when they have more pressing concerns. For these reasons, the regulations permit applications for access to identifying data collected on the register on and after 1st October 2009, where it concerns information about children born as a result of treatment.

26. The same application requirements will apply, as will the standard conditions attached to the disclosure of any information. Again, applicants will be required to demonstrate that it is not practicable to obtain consent to the disclosure of identifying information from the child's parent or guardian.

27. Use of the authorisation process also allows the aims of the project to be examined and, particularly, the claim that the research can only be carried out with identifying information about such children to be properly tested.

Other comments

28. Comment were also received proposing that:

    - The requirement for research ethics committee (REC) approval should be amended to allow applications to be made to the HFEA in parallel with the application to the REC but that no identifying information should be released until REC approval had been obtained.
    - Where contact with data subjects was proposed, the initial contact must be made by an individual, such as a GP, or organisation, such as the fertility clinic, known to that person, unless there are exceptional reasons to justify initial contact being made directly by the research body.

29. These suggestion have been accepted and incorporated into the regulations.

30. The report of the first consultation exercise and the Government's response was published in May 2009[5].

Second public consultation on the regulations

31. In view of the significance of the changes made, it was decided that the amended draft regulations should be published for a second round of public consultation.

32. Stakeholders and the general public were asked for their views on four question related to the key amendments:

    - would a fee of £500 per day (£250 for a half-day), levied by the HFEA up to a maximum payment of £5,000 (the equivalent of 10 working days) be appropriate? If not, what would be an appropriate fee for this activity?
    - Should the regulations contain an additional provision allowing NIGB to take on functions under these regulations, on behalf of the HFEA, if asked to do so by the Authority?
    - Should the authorisation process set out in the regulations continue to be available to research bodies who wish to seek access to identifying information, collected on and after 1st October 2009, about children born as a result of treatment, where it is not practicable to obtain consent to the disclosure from their parent or guardian?
    - Is the proposed age cut-off point of 18 years (the point at which a child is considered to have attained competency by reason of age) appropriate? If not, what age is more suitable?

33. The draft regulation were published for the second round of public consultation on 8th October 2009 . The consultation period closed on 2nd December 2009[6]. Details of the consultation was circulated to the same list of stakeholders. All those who responded to the first consultation were asked for their views on the amendments.

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[5] The report can be found at: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_098882

[6] The consultation document can be found at: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_106503

34. 20 responses were received from a range of stakeholders and members of the public.

Fees

35. A mixture of comments were received on the proposed fee. While some respondents thought the figure high, others thought it reasonable. There was no prevailing view for or against the proposal. What was clear from the responses was that, at this time, there is insufficient information available to judge whether the figure is an appropriate amount. No respondent was able to suggest an alternative amount nor recommend a fee regime whose principles this scheme should follow.

36. The original proposal of £500 per day (£250 per half day) is retained in the regulations but the fee will be kept under review.

The role of NIGB

37. As in the first consultation exercise, there was strong support for the involvement of NIGB in the authorisation process. For this reason, the regulations retain the provisions consulted upon in relation to the ability of NIGB to undertake functions under the regulations if asked to do so by the HFEA.

Continued use of authorisation process for identifying data about children

38. The majority of respondents supported the extended use of the authorisation process, where the identifying data requested related to children, or expressed no view on the proposal.

39. Where concern was expressed about the extended use of the scheme, it was generally a reflection of a wider concern about the principle of identifying information being disclosed without consent. Some respondents were also of the view that the impracticability of obtaining consent should not be interpreted too widely.

Cut of age for "child" data

40. Overwhelmingly, the respondents considered the cut-off point should be when the child reaches the age of 16 not age 18 as in the draft regulations. Most responses recommended this change to ensure the regulations mirrored the age limit in the Mental Capacity Act 2005, the Adults with Incapacity (Scotland) Act 2000 and guidance to General Practitioners.

41. The Government, mindful of the consistent views on this point, has amended the regulations to reflect an age 16 cut-off point.

42. The report of the second consultation and the Government's response was published on 11th January 2010[7].

Links to other policy areas and strategies/programmes of work

43. The concept of an authorisation process to approve disclosure of identifying information from health records for research purposes, where consent to the disclosure cannot be obtained, is not new or unique to these regulations.

44. For England and Wales, section 251 of the National Health Services Act 2006 (formerly section 60 of the Health & Social Care Act 2001) established a similar authorisation process, with the Patient Information Advisory Group (PIAG) created to provide advice to the Secretary of State for Health on the suitability of approving the disclosure of identifying information from health records where consent to disclosure could not be obtained. In January 2009 this function transferred to NIGB.

[7] The report can be found at: http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm

45. In Scotland, an advisory body has a similar function and a comparable advisory body is proposed for Northern Ireland. The rationale for why the regulations creat a new authorisation process is set out in paragraphs 4-6 of Annex A.

46. The research sector will be the principal user of the process created by the regulations, although use will be by self-selection. It is impossible, at this time, to estimate the number of applications that might be made annually or the nature of the research projects for which information might be sought. Other groups affected will be patients, their partners and offspring, unless treatment involved the use of donated gametes or embryos. However, people with information on the HFEA's register will have the right to withhold the identifying elements from disclosure by notifying the HFEA of their wishes.

Policy Options

47. Following analysis of the views of stakeholders, provided during the planning stages for the 2008 Act, three options were identified.

    - Option 1 – maintain current policy
    - Option 2 – disclose data only with the consent of the person(s) to whom the information relates
    - Option 3 – where consent cannot practicably be obtained, establish a process to authorise disclosure for research purposes.

48. The options were discussed in detail in the impact assessment published for the first consultation exercise in January 2009[8] and in the impact assessment published for the second consultation exercise in October 2009[9].

49. Following analysis of the responses to both consultation exercises, Option 3 has been adopted in the regulations.

Benefits and risks

50. The preferred option allows the optimum use of the HFEA data collection, with the caveat that a stated objection to disclosure could not be overridden. The most sensitive data, involving the donation and subsequent use in treatment of gametes and embryos are excluded from disclosure under this process.

51. The first option was discounted because it would have severely limited the benefit that could be derived from the existing data collection as the status quo would be maintained. The second option was also discounted, even though there was strong support in the first public consultation responses for disclosure only with the consent of the persons to whom it related. This option would have stood the best chance of being effective if a publicity campaign was conducted to encourage people with personal information on the HFEA register to inform the Authority if they were willing to allow identifying information to be released for research purposes. This could reasonably have been expected to deliver some increase in the range of data that could have been disclosed for research with consent, however, this would have come at a significant cost. There was also no way to guarantee that such a campaign would generate a sufficient level of response needed to enable the data sets issued from the register to be statistically meaningful. It was possible that the end result would provide little improvement on Option 1.

52. It was recognised that many people would have objection to information being disclosed by these means. For this reason, HFEA and patient groups will be asked to ensure that information on the regulations made to adopt this option is circulated to stakeholders, with

[8] http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_092465
[9] http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_106503

the assurance that patients can register their objection to disclosure with HFEA and this will be respected. People will not be asked to explain or to justify their wish to withhold identifying information. To coincide with the implementation of the regulations, if approved by Parliament, the Government will also consider how best to raise public awareness of the regulations to ensure that members of the public who may have personal information on the HFEA's register but no longer have any links with the fertility sector, are made aware of the regulations, their effect and their right to withhold identifying information about themselves (and their children where they are not old enough to be competent to give consent) from disclosure.

53. The Government believes the chosen option provides maximum benefit, allowing the most comprehensive possible data set to be disclosed, where appropriate to do so. It also enhances the active and ongoing use that is made of the historic data on the HFEA register.

Costs

54. Costs of collating and releasing information from the register are to be recovered from a fee payable by the applicant. The fee is prescribed in the regulations.

55. The fee is based on a daily rate of £500, with a half-day charged at £250, up to a maximum payable fee of £5,000 (giving a potential cost range of £250-£5,000). It is not an administrative burden, as such, because it covers costs of the HFEA and it is a self-selecting cost, therefore, researchers will choose to pay it in order to receive information should they decide there is no other means of obtaining the information needed to conduct their research. The HFEA's estimate of the potential costs of preparing and releasing data to researchers for a moderately sized data set, that would take 2.5 days to extract from the register, is set out at Annex B. There is no application fee.

56. The costs of considering an application will be met from the HFEA's existing resources. It is not possible to estimate the number of applications likely to be received each year but the cost of processing applications is not expected to exceed £25,000 per year.

Summary of cost/benefit analysis for preferred option

Option	Total benefit per annum	Total cost per annum
Authorisation process	This cannot be assessed at this time. However, it is assumed that the researchers who pay for the research data value it at more than the fee, hence the benefit will exceed the cost.	Cost of processing applications will be dependent on the number submitted. The outside estimate is 50 per year although it is expected to be far lower. Costs for collating and issuing data are estimated to be in the range of £250-5,000 per application. It is estimated that the annual cost to the HFEA would not exceed £25,000. Over 5 years (with discounting at the rate set by HM Treasury) the present value (PV) of this sum comes to £0.12m.

Equality issues

57. The Government believes that the regulations do not have any adverse impact on equality in regard to ethnicity, disability, gender or human rights.

58. The first consultation did reveal a concern about the principle of disclosure without consent but this was not limited to any particular community or faith groups. The regulations contain a prohibition that data will not be disclosed where it is known that the person to whom it relates is unwilling for this to take place. Provision will be made by the HFEA for people to register their refusal. Any refusal for the release of identifying information for research purposes will be treated as absolute and will be fully respected.

59. A full Equality Impact Assessment is at Annex C.

Enforcement, sanctions and monitoring

60. The regulations contain a requirement for an annual report to be submitted to the HFEA by the research body to whom identifying information has been disclosed to allow the use of the data to be monitored. This is a common requirement to enable regulatory and funding bodies to monitor the progress of research. The NIGB also has this as a standard requirement to enable it to monitor the processing of identifying information disclosed from other types of health record, where consent cannot be obtained.

61. Authorisation to process identifying information will be for a period of 5 years, renewable on application to the HFEA. This 5 year break point will allow the assertion that fully identifiable information continues to be needed to achieve the aims of the project to be examined by the HFEA.

62. The regulations also give HFEA the power to investigate any potential misuse of the data, allowing for the suspension of the authorisation to process identifying data while investigations are taking place and the withdrawal of the authorisation where misuse is proven.

Implementation and delivery plan

63. A wide ranging public consultation on the regulations took place from January to March 2009. A second consultation on the amendments made to the draft regulations, particularly in respect of the fee payable by applicants to receive information, took place from October to December 2009.

64. The regulations are to be debated in Parliament in February/March 2010.

65. The regulations will come into force, if approved by Parliament, on 6th April 2010.

Post implementation review

66. The effectiveness of the HFEA's procedures for assessing applications for identifying information and the disclosure of such data will be monitored through the usual procedures for oversight of arms length bodies, including quarterly accountability review meetings.

67. As the use that will be made of the authorisation process cannot be determined at this time, this will be kept under constant review, via the accountability review meetings, once the regulations come into force. This review will also include the suitability of the fee regime set out in the regulations. The Government believes this will allow the early identification of any aspect of the regulations that is not operating as effectively as intended, so if amendments are needed the regulations can be remade.

Summary and conclusions

68. The Government believes that it is vital that full use is made of the data held by the HFEA to assess if there are any adverse health or social implications of fertility treatments regulated by the 1990 Act. It believes that the option of establishing an authorisation process best fulfils this objective, while building in important safeguards for patients, their partners and offspring.

69. Regulations have been drafted to implement the chosen option and establish a process to consider disclosure of identifying information without consent, for research purposes only, where applicants are able to meet the requirements set out in the regulations. The disclosure of identifying information will be subject to strict conditions on its handling and use.

Specific Impact Tests: Checklist

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	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

Annexes

ANNEX A

AUTHORISATION PROCESS TO CONSIDER APPLICATIONS FOR ACCESS TO IDENTIFYING INFORMATION WHERE CONSENT CANNOT BE OBTAINED

Records of treatment and information held on the HFEA register

1. Section 31 of the Human Fertilisation & Embryology Act 1990 (1990 Act), as amended by section 24 of the Human Fertilisation & Embryology Act 2008 (2008 Act), determines the information that must be provided to the Human Fertilisation and Embryology Authority (HFEA) register by licensed treatment clinics. Drawn from the local clinic health record, which remains the primary record of the patient's treatment, the clinic must inform the HFEA of:

- the provision of every treatment cycle involving the creation of embryos outside the body, such as in *in vitro* fertilisation (IVF), or the use of donated gametes (sperm and eggs) or embryos. The notification requirement also includes details of the woman's partner where a couple are being treated together;
- the outcome of the treatment cycle, where this can be determined, including any live birth;
- details of all gamete and embryos donors.

2. Submission of such information is mandatory for all treatments and donations that have taken place in the United Kingdom since the HFEA came into operation on 1st August 1991. The data collection is now substantial. For example, between 1991 and 2006 there were 353,170 cycles of IVF treatment carried out involving the use of freshly created embryos. Up to the end of 2005, these cycles had resulted in 41,093 singleton births, 13,529 twin births and 1,086 triplet or higher order births, with a total of 71,417 babies being born[10].

3. The wealth of data available and assistance it might give to research into the long-term health and social implications of such treatments are the reasons why the Government has proposed the establishment of a process to authorise the disclosure of identifying information where it is no longer practicable to obtain the consent of the persons to whom the information relates.

Proposals for authorising body

4. The public consultation on the proposals for the 2008 Act indicated widespread support for opening up the HFEA register data for research purposes. The primary policy concern subsequently became how this aim could be best achieved. Consultations with a limited number of key stakeholders revealed no enthusiasm for the creation of a new authorising body, as allowed for in subsection 33D(2)(d) of the 1990 Act, as introduced by the 2008 Act, leaving two options:

- the bodies that already carry out this function in respect of all other types of health information:

[10] A Long Term Analysis of the HFEA Register Data (1991-2006), HFEA 18 June 2008.

- the National Information Governance Board for Health & Social Care (NIGB), which took on the functions of the Patient Information Advisory Committee (PIAG) in January 2009, (statutory body);
- the Privacy Advisory Committee (PAC) for Scotland, with a similar body proposed for Northern Ireland (both advisory bodies);

- the HFEA.

5. The HFEA was found to be the preferred option but there was a strong recommendation that it work closely with other expert bodies, particularly the NIGB.

6. Based on this advice, the regulations make the HFEA the authorising body, for three principle reasons:

   - HFEA is the holder of the register and the national regulatory body for fertility clinics that maintain the local records;
   - its expertise in this field renders it best placed to judge the merits of a research application, taking advice, where appropriate, from other expert bodies, such as NIGB that has expertise in assessing applications for access to identifying health information where consent cannot be obtained;
   - the NIGB and the two PACs have limited remits so might not be able to lawfully adjudicate on research projects that have a social welfare focus. In addition, the HFEA as the data controller, would have the final decision on whether or not to disclose the information, even if approval to the disclosure was recommended by NIGB or one of the PACs.

How the authorisation process is expected to operate

7. It is proposed that the HFEA will determine its own procedures for processing applications for access to identifying information. This will include:

   - the format of the application itself and the evidence that must accompany it (with the exception of the mandatory elements set out in the regulations, as described below);
   - internal procedures for assessing the merits of the applications, including seeking expert advice from other bodies;
   - the process for making the final decision on the application;
   - the process for considering any appeal against a refusal to disclose information.

8. In accordance with subsection 33D(5) of the 1990 Act and other healthcare applications of this type handled by NIGB and the PACs, the supporting information will need to provide evidence as to why identifying information is needed to achieve the aims of the project, why the aims cannot be achieved by other means (such as anonymised information or partial information for which consent can be obtained) and why it is not practicable to obtain consent of the persons for whom information being sought relates. Even if this can be demonstrated, disclosure is automatically prohibited in two circumstances:

- where it is known that the person to whom the information relates has stated that he/she is unwilling for identifying information to be disclosed to researchers (this includes refusal to the disclosure of identifying information about a non-competent child by a parent or guardian);
- where disclosure would identify gamete or embryo donors, patients treated with donated gametes or embryos, their partners and donor conceived offspring.

9. Some additional elements of the supporting evidence are:
   - the research project for which identifying information is sought satisfies the principles in subsection 33D(1) of the 1990 Act;
   - that disclosure of identifying information is necessary or expedient for research that is in the public interest or in the interests of improving patient care;
   - the project has received the approval of the Research Ethics Committee or that such approval is being actively sought;
   - full details of the security arrangements for protecting information.

10. The regulations also give HFEA the power to require any additional information it considers necessary to process an application. The HFEA will provide detailed guidance for bodies wishing to make such an application together with information on the approval process for the general public.

Involvement of other expert bodies

11. Under sections 8B and 8C of the of the 1990 Act, as inserted by the 2008 Act, HFEA has the power to enter into an agency arrangement or contract with another body for that body to discharge the Authority's statutory functions on its behalf. As indicated above, it will be for the HFEA, in negotiation with appropriate bodies, such as NIGB, to determine what use is made of these arrangements. The ability of NIGB to discharge functions, on behalf of the HFEA, if asked to do so by the Authority, is restated in the regulations. If asked to take on functions under the regulations by the HFEA, NIGB will acquire the power to consider application from across the United Kingdom but only in relation to information covered by the regulations. Although NIGB will acquire UK wide powers, for this purpose, it will consult the Privacy Advisory Committees in Scotland and Northern Ireland where it would be appropriate to do so.

Conditions of disclosure

12. The regulations apply the following standard conditions to any disclosure of identifying information approved through this process:

- that the person to whom the information relates (or where it relates to a non-competent child, their parent or guardian) has not refused to give consent after having been approached for permission to use identifying information about them in the research project.

  This also extends to cases where consent given is later withdrawn or where an individual makes it known to the research team that they are not willing for their personal information to be used in a particular element of the research project;

- in accordance with subsection 33D(2) of the 1990 Act, in addition to the requirement that the Data Protection Act 1998 and common law cannot be breached (subsection 33D(6) of the 1990 Act), the uses that can be made of the information will be limited to the purposes set out in the application (any additional use will require a further application to the HFEA);

- identifying information cannot be disclosed to any third party, unless that party is covered by the authorisation (should the research organisation wish to provide identifying information to a third party not named in the original application, a new application will need to be made to HFEA);

- that while fully identifiable information can be retained throughout the period of authorisation, if needed, the identifying element must be minimised as early as it is reasonably practicable to do so.

13. The regulations also contain a power for HFEA to apply additional conditions to the disclosure as it sees fit. Again, the HFEA will issue guidance on the appropriate handling and use of this information.

ANNEX B

FEE PROPOSALS

Introduction

1. As stated in Annex A, the HFEA register holds a substantial number of individual records relating to treatment cycles carried out in the United Kingdom since 1991, the patients undergoing treatment, their partners, resulting offspring and gamete/embryos donors. Depending on the size of the data set requested, the work undertaken by the HFEA to extract and validate the data could be considerable.
2. Data will need to be examined to ensure that no identifying donor information, including information about patients treated with donated gametes or embryos and donor-conceived offspring, that would identify them as such, is released as part of the data set. Accuracy of data sets will need to be verified before release to researchers.

Fee proposal

3. Regulation 13 specifies a fee of £500 per day up to a maximum payable fee of £5,000 – the equivalent of a full 10 days work by the HFEA. Provision is also made for a half day fee of £250, where a full day is not required, to ensure researchers only pay for the actual time taken by the HFEA to process and release data to the research teams. This gives a potential fee range of £250 to £5,000.

Key costs

4. To provide an illustration of how the daily rate of £500 has been calculated, the table below gives costs for a data set that would take approximately 2.5 days to extract from the register:

Activity	Breakdown(1)	Total cost
Information analyst to extract data from register and analyse	2.5 days(2) at £30.07 per hour	£563.81
IT and information senior management review of the data	4 hours at £65.14 per hour	£260.56
Other senior management review	3 hours at £66.66 per hour	£199.98
Finance support – administration	1 hour at £20.04 per hour	£20.04
Finance support – oversight from Head of Finance	1 hour at £50.11 per hour	£50.11
Total cost (based on processing taking 2.5 days)		£1094.50
Day rate		£437.80
Overhead costs @ 15%(3)		£503.47

Notes
(1) All staff hourly rates include ongoing costs of 25%, covering National Insurance and pensions contributions.
(2) One day is 7.5 hours.
(3) Includes non-personnel, office management costs e.g. rent, energy costs.

Source: Human Fertilisation & Embryology Authority

Applications likely to exceed upper cost limit

5. There may be requests for data sets that are particularly substantial or complex, that would require considerably longer than 10 days work to prepare and make the data available to researchers[11]. The HFEA will have the option of deciding whether or not to release the data. This will follow consideration of whether such an extensive data set in necessary to achieve the aim of the research project
6. Research teams who wish to have an estimate of cost to the HFEA of preparing and making a data set available, before confirming their wish to proceed, can obtain this from the HFEA.

Evaluation of fee post implementation

7. At this time, it is not possible to estimate the use that will be made of the authorisation process created by the regulations.
8. It is unclear how many applications might be made each year - 50 is the outside estimate, although the actual number is likely to be far smaller. It is also not possible to estimate the nature or complexity of the data sets that will be requested. Where larger data sets are requested, applicants will be required to demonstrate that the information sought is genuinely needed to achieve the aims of the project. They will need to show that the project cannot be completed with a smaller data set or with a partial data collection where consent to disclosure can be obtained.
9. The proposed fee is based on an estimate of the potential work needed by the HFEA to extract the data from the register, the verification of the data and its preparation for release to researchers, taking account of the categories of staff that will undertake this work to ensure an accurate data set is made available to successful applicants.
10. As there are a number of uncertainties at this time about the use of the authorisation process, its effectiveness will be monitored from the point of implementation: it is proposed this will be 6th April 2010. The effectiveness of the fee regime will be a key element of the review. The fee is intended to recover the cost to the HFEA of collating and releasing data. The effectiveness of the authorisation process and the fee will be discussed with the HFEA on a quarterly basis. This will enable the Government to determine the effectiveness of the proposed fee in meeting the cost recovery objective and allow early consideration of amendments should it become clear that a different regime better meets this aim.

Changes to fee regime

11. Where any amendment needs to be made to the fee regime, for whatever reason, new regulations will need to be made.
12. These will be subject to public consultation and then to debate and approval by both Houses of Parliament before implementation.

[11] Regulation 14(1) gives the HFEA 90 days, from the date payment is received, to make data available to the applicant.

ANNEX C

EQUALITY IMPACT ASSESSMENT

Purpose and intended effect

1. The Department of Health has made regulations under section 33D of the Human Fertilisation & Embryology Act 1990 (the 1990 Act), as amended by the Human Fertilisation & Embryology Act 2008 (the 2008 Act), that will allow disclosure of identifying information held on the Human Fertilisation & Embryology Authority (HFEA) register of fertility treatments, for medical or other research purposes, where consent to disclosure cannot be obtained from the person(s) to whom the information relates (or where a non-competent child, their parent or guardian).
2. The HFEA is a statutory licensing body whose remit involves licensing and inspection, producing a code 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 European Union Directive 2004/23/EC that sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells for human application, as they apply to human gametes (sperm and eggs) and embryos.
3. The HFEA is also required by section 31 of the 1990 Act, to maintain a register of every fertility treatment cycle involving (i) the creation of embryos outside the body, e.g. *in vitro* fertilisation (IVF) and/or (ii) the use in treatment of donated gametes and embryos that have taken place in UK clinics, licensed by the HFEA, since 1st August 1991, the date of the HFEA's inception. The register also holds details of the patients, their partners, any offspring and all gamete and embryo donors. It represents one of, if not the most, comprehensive collections of data of this type in the world.
4. The register data has long been viewed as a valuable resource that might, if available to researchers, help to answer conclusively some of the questions about the long-term health and social implications of these fertility treatments. However, the sensitivity of these treatments meant that identifying information was subject to a higher level of protection than would normally be applied to health records. This extra level of protection has had the effect of significantly limiting the purposes for which such information could be disclosed. Data from the register could not be disclosed to anyone, other than members and staff of the HFEA or persons to whom a HFEA licence applied, even with the consent of the person to whom that information related. At the outset of work on the 2008 Act, the Government made a commitment to consider how access to this data, for research purposes, might be improved to allow the data to be used to its fullest extent to assist research into the long-term health and social implications of assisted reproduction treatments.
5. The regulations give HFEA a new function in respect of the consideration of applications for and, where appropriate, the disclosure of identifying information for research purposes.

Summary of purpose of the regulations

6. The preferred position is that information will be disclosed with the consent of the persons to whom it relates and for data added to the HFEA's register from 1st October 2009 this will be the sole basis on which such information may be disclosed (except where the data is about children born as a result of fertility treatments under the age of 16, which is discussed in paragraphs 24-27 of the impact assessment). However, for the 18 years of data collected on the register up to that time, it may no longer be practicable to obtain such consent. The regulations establish a process where access to identifying information may be sought where it can be shown that it is not practicable to obtain consent and that the research project is judged to meet the basic requirement that its aims are in the public interest or in the interest of improving patient care. This process cannot be used to eliminate administrative burdens on research bodies and, where all practical avenues to obtain consent have not been explored, it is envisaged that access to identifying information will not be granted.
7. The effect of these regulations is to create a process that mirrors the one established by section 251 of the National Health Services Act 2006 (formerly section 60 of the Health & Social Care Act 2001) in which the Patient Information Advisory Group (PIAG) gave advice to the Secretary of State for Health on the suitability approving disclosure of identifying information from health records where consent to disclosure cannot be obtained. On the 1st January 2009 this function came within the remit of the National Information Governance Board for Health and Social Care (NIGB).
8. A separate authorisation process is needed because there is an additional level of protection applicable to records of IVF and donor gamete/embryo treatment. In addition, the existing bodies that already carry out this function, NIGB for England and Wales, the Patient Advisory Committee in Scotland and the Patient Advisory Committee proposed for Northern Ireland have limited national remits, related to certain areas of healthcare, so may not be able to advise on disclosure for research projects that have a social welfare focus.
9. More information on the proposed authorisation process, including the categories of data excluded from disclosure under the regulations, the information that will need to be supplied by applicants and the conditions upon which any authorisation will be granted can be found at Annex A to the Impact Assessment.

Assessment

10. 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 ethnicity, disability and gender equality. In addition, the Department of Health has opted to have a policy of promoting equality and eliminating unjustified discrimination in relation to religion and belief, sexual orientation and age.

11. The Government first consulted on the policy of opening the register to permit greater use by researchers in January 2009. The consultation document was circulated widely, including to community, faith and special interest groups. There was some concern about the proposal to allow disclosure without consent but this was not limited to any particular community, faith or special interest group. There was significant support for the principle that if disclosure was to take place, it must be strictly controlled. A second consultation exercise took place in October 2009, which sought comments on the amendments made to the draft regulations as a result of responses to the first consultation.

12. The effect of the regulations will be publicised so that any person who has personal data held on the HFEA's register will have the opportunity to make it known to the HFEA that he or she does not wish to have the identifying information disclosed (the parent or guardian of a non-competed child can similarly register their refusal for information about that child to be disclosed). Whatever that reason, people will not be asked to explain or to justify their wish to withhold their consent. Their refusal will be treated as absolute.

Ethnicity

13. The regulations are not thought likely to impact differently on people on the grounds of ethnicity. The reason for this is that ethnicity is not a factor in the provision of data to the HFEA's register, as this must be provided for all patients intending to undergo IVF or treatment with donor gametes or embryos.

14. The regulations have a positive impact, helping those with a clinical need. Some inheritable genetic conditions are known to be more prevalent in or limited to particular ethnic minority communities. Although many HFEA records do not record the ethnicity of a patient, partner or offspring, research linking specialist health registers to the HFEA data may be able to clarify if the provision of treatments, such as IVF, to an affected child's mother was significant in the occurrence of the condition.

15. The principles of the regulations may be considered differently by people on the grounds of ethic origins and the customs of their community but this is different from considering how they will impact upon them. For that reason, the regulations are not likely to impact differently on people on the grounds of their ethnic origin. The responses to the first public consultation did not reveal any concerns that might indicate that this is not the case.

16. We have considered whether there were opportunities to promote equality of opportunity that could be taken if the regulations had been adjusted. Equality of opportunity is available to all but there are not specific opportunities to promote equality of opportunity in the regulations.

17. The regulations are thought likely to help to eliminate unjustifiable discrimination. The reason for this is that the regulations cannot be used as a basis upon which to discriminate on the grounds of ethnicity.

18. The regulations are not likely to help to eliminate harassment. The reason for this is that the regulations are not relevant to issues of harassment.

19. The regulations are likely to promote good relations between people of different groups. The reason for this is that all people will be treated equally.

Disability

20. The regulations are not likely to impact differently on people on the grounds of disability. The reason for this is that disability is not a factor in the provision of data to the HFEA's register and the register does not record if a patient or their partner was disabled or not disabled. Disability occurring in offspring has also not been routinely collected and, generally, data of this kind, where it exists, is restricted to the occurrence of congenital abnormalities.

21. The regulations have a positive impact helping those with a clinical need. Some inheritable genetic conditions present as a physical or developmental disability in the sufferer. One of the likely areas for research, for which information may be sought, is a link between treatments such as IVF and, particularly, a variation of IVF known as Intra Cytoplasmic Sperm Injection (ICSI), and the incidence of certain disabling conditions.

Gender or Transgender

22. The regulations do impact differently on people on the grounds of their gender and this is difficult to avoid. The reason for this that between 1991 and 2010 it is the case that only a person with the physical gender of a woman and, therefore, able to conceive, carry and give birth to a child, has been able to undergo the fertility treatments regulated by the HFEA. Consequently, only women are shown on the register as patients for the purposes of the regulations. Where applicable, details of a male partner is recorded (see below at *Sexual Orientation* for status of female partners). Gamete donors and offspring are not treated differently on ground of gender but, where donor conception is involved, disclosure of such data is excluded by the regulations.

23. We have considered whether there were opportunities to promote equality of opportunity that could be taken if the regulations had been adjusted. The answer is no because the treatment is determined entirely by biological gender.

24. The regulations are thought unlikely to help to eliminate unjustifiable discrimination. The reasons for this is as above, namely gender is a factor in the treatment of individuals and how their personal information is recorded on the HFEA register.

25. The regulations are not likely to help to eliminate harassment. The reason for this is that the regulations are not relevant to issues of harassment.

26. The regulations are likely to promote good relations between people of different groups. The reason for this is that while information about the female patient and her partner is recorded on the HFEA register on the basis that the woman has undergone treatment services, the protection of personal information and the assessment of disclosure will be applied equally.

Age

27. The regulations are not likely to impact differently on people on the grounds of age. The reason for this is that age is not a factor in the provision of data to the HFEA's register as this information must be provided for all patients intending to undergo IVF or treatment with donor gametes.

28. The regulations are thought likely to help to eliminate unjustifiable discrimination. The reason for this is as above, namely that age is not a factor in the treatment of individuals.

29. The regulations are unlikely to help to eliminate harassment. The reason for this is that the regulations are not relevant to issues of harassment.

30. The regulations are likely to promote good relations between people of different groups. The reason for this is that all people will be treated equally.

Religion or Belief

31. The regulations are thought unlikely to impact differently on people on grounds of religion or belief. The HFEA register does not record this information. It was recognised that the regulations would raise issues of conscience. On these issues, religion or belief may play an influential role. Therefore, although everybody, regardless of religion or belief, would be treated equally under the regulations, a person's religion or belief may have conflicted with the proposed policy. The principles of the regulations may be viewed differently by people on the grounds of their religion or belief but this is different from considering how they will impact upon them. For that reason, the regulations are not likely to impact differently on people on the grounds of their religion or belief. The responses to the first public consultation did not reveal any concerns that might indicate that this is not the case.

Sexual Orientation

32. The regulations are thought unlikely to impact differently on people on grounds of sexual orientation. The HFEA register does not record this information. The new parenthood provisions in the 2008 Act, allowing same sex couples to be recognised as the legal parents of a child, will only affect data collected from 6th April to 30th September 2009. From 6th April 2009 the register will record the same sex partner of a woman being treated, who will be recognised as the resulting offspring's second parent. However, it is expected that because donor sperm will have been used in the couple's treatment, such records will be prohibited from disclosure.

33. We have considered whether there were opportunities to promote equality of opportunity that could be taken if the regulations had been adjusted. We concluded that the answer was no. From 6th April 2009 the partners of women undergoing treatment will be treated equally, irrespective of their gender.

34. The regulations are thought likely to help to eliminate unjustifiable discrimination. The reasons for this is that the regulations cannot be used as a basis upon which to discriminate on the grounds of sexual orientation.

35. The regulations are not likely to help to eliminate harassment. The reason for this is that the regulations are not relevant to issues of harassment.

36. The regulations are likely to promote good relations between people of different groups. The reason for this is that all people will be treated equally.

Action plan

37. 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. The authorisation process will be discussed with the HFEA on a quarterly basis to determine it effectiveness.

Competition assessment

38. The HFEA register is a national data collection required by statute. The regulations will primarily apply to data already held on the register. The regulations have no effect on the market structure and there is no scope for new suppliers to enter the market to compete.

Small firms impact test

39. It is possible that some of the research bodies seeking information from the HFEA register could be classified as small businesses. However, it will be for the research bodies themselves to determine if they wish to seek data by this method, so participation will be by self-selection, with no obligation to apply to access data by this route.

Legal aid

40. The proposal satisfies a request from stakeholders across the fertility and research sectors to have access to the data from the HFEA register. No data will be released without consent or the agreement of the HFEA as the authorising body. It is judged that there are no legal aid issues arising from these regulations.

Health impact assessment

41. While the proposals themselves do not have significant impact on human health, lifestyle or demand for NHS services, the release of data could have a significant impact on resolving, definitively, the question of whether there are any adverse health implications from such treatments. As this would be the purpose of the research, it cannot be estimated at this time.

Rural proofing

42. The proposals do not have an impact upon rural communities. They will not impact upon the availability or cost of public or private services in rural areas and there will be no impact upon rural businesses.