CHRISTIAN CONCERN FOR OUR NATION/ CHRISTIAN LEGAL CENTRE RESPONSE TO THE DEPARTMENT OF HEALTH CONSULTATION ON REGULATIONS TO IMPLEMENT THE HUMAN FERTILISATION AND EMBRYOLOGY ACT 2008

MARCH 2009

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Instructions on How to Respond

"We would like to hear your views both on the draft regulations and on the key proposals set out in section 6. Please number your response according to the proposal that you are addressing. If you have any specific comments on the regulations themselves, or any other part of the consultation please also mark this on your response. If you are responding on behalf of an organisation, it would be useful if you could include some details of the organisation including the people that are represented.
Send your comments to hferegulations@dh.gsi.gov.uk by the 30th March 2009.

Please note that parts of your response may be published in a summary report of the consultation (names of individuals would not be included). If you would prefer your response not to be included in a report, please state this clearly.

We would prefer your comments to be sent electronically to the email address above. However, if you would prefer to respond in writing, please send your response to:

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Human Fertilisation and Embryology Act 2008 Regulations Consultation
Department of Health
609 Wellington House
133-155 Waterloo Road
London SE1 8UG"[1]

Response

About Us

Christian Concern for our Nation (CCFON) is a policy and legal resource centre that identifies changes in policy and law that may affect the Judeo-Christian heritage of this nation. The team of lawyers and advisers at CCFON conduct research into, and campaign on, legislation and policy changes that may affect Christian Freedoms or the moral values of the UK. CCFON serves a mailing list of 25,000 supporters. http://www.ccfon.org

CCFON is linked to a sister and separate organisation, the Christian Legal Centre, which takes up cases affecting Christian freedoms. http://www.christianlegalcentre.com.

Executive Summary

1. The Human Fertilisation and Embryology Authority ("HFEA") consultation allows responses to 4 sets of proposed regulations that are said to implement the Human Fertilisation and Embryology Act 2008.
2. In our opinion, the first set of regulations would be far better if they simply implemented the Act by updating the extended statutory storage limit for embryos from 5 to 10 years and repeal the 1996 regulations on embryos, to which the extension from 5 to 10 years has already been made in the 2008 Act. It appears to be contrary to Parliamentary intention in the 1990 Act to allow for such permissive extensions up to 55 years, by means of a negative procedure that will not be debated in Parliament. A negative resolution procedure[2] means that such instruments once laid in Parliament after 40 days, become law unless there is an objection from either House of Parliament.
3. The extension for the storage of gametes or embryos only requires one doctor to say that someone has or is likely to develop significant and premature infertility, be it the gamete provider, the embryo provider, the woman being treated, or simply a man or woman who has been allocated the gamete or embryo by the clinic.
4. This means that there is no longer a ban on surrogate mothers being treated with gametes or embryos with extended storage, nor is the storage limit anchored to a maximum age of 55, but rather 55 years applies across the board regardless of the age of the person or couple undergoing treatment. This may lead to older parents and to families containing Zimmer frames and prams at the same time. Theoretically, a 35 year-old could store embryos or gametes up to the age of 90. There are no rules preventing close relatives who would normally be forbidden to marry each other from donating gametes or embryos. This means that it would be possible for a (soon to be) infertile homosexual or heterosexual man of 35 to store his parent's embryo and years later, after they have died, to have a child without a partner by a surrogate mother. The number of years proposed would even allow a woman to give birth to her uncle or aunt from an embryo donated by her grandparents, as there are no age restrictions on storage. Relying on the clinics to argue the welfare of the resulting children and for age appropriate use of IVF, places an undue burden on the clinics, and history show that it is not a sufficient safeguard.
5. Little account is taken of the safety of freezing gametes or embryos for such a long period. In view of the recent concern that IVF babies may be 30 per cent[3] more likely to have defects, extending storage for an extraordinary length of time appears to be an unsound policy even on health grounds. Such proposed permissive regulations, which are being issued without Parliamentary debate, should not be allowed in a civilised society
6. The impetus for this change is a single case of Turner Syndrome ("TS") where a mother wanted longer storage for her eggs in order to be able to donate them to her daughter. No mention was made of the fact that the daughter could have IVF treatment using other donor eggs when she reached adulthood.
7. The first set of regulations would also allow extensions to the storage of embryos that have been tested up to a total of 55 years with no safeguards whatsoever, merely requiring the consent of the persons who supplied the gametes which

created the embryo in question. These embryos include those that have been tissue-typed to ascertain their suitability to become "saviour siblings". The potential for commercial exploitation of such rules, which are ethically and morally abhorrent, is enormous. These rules treat gametes and embryos like commercial commodities with a shelf-life of 55 years and allow for "spare part" embryos to be kept for older siblings' use for the same length of time.

8. The second and third sets of regulations set out the internal procedures for appeals against the refusal, revocation or variation of a licence application. It allows for 2 internal appeals in addition to an appeal to the High Court on a point of law. The procedures are very detailed considering that there are only about 3 hearings envisaged annually in the second set of regulations and about one a year in the third set of regulations. This demonstrates how the HFEA procedures favour those applying for a licence, but do not allow any internal appeal for those concerned about permissive HFEA decisions. Any public interest group seeking to protect the "special status " of the human embryo[4] and/or rights of parties affected by HFEA decisions will need to go to the expense of applying for Judicial Review and has no means of representation within the HFEA's appeal procedure if concerned about the granting of a licence. This shows a lack of fairness, transparency and accountability in the HFEA's licence decision-making procedures.
9. The fourth set of regulations allows for the provision of IVF and NHS non-IVF treatment data on IVF patients (and presumably on their offspring) to researchers without consent if the researcher pays a fee. Sensitive information that could identify donors of gametes and embryos and those conceived as a result, will not be provided without consent, but other information will be. The regulations even fail to ensure that an attempt is made to obtain consent. In our opinion such information could be provided on an anonymous basis. Whilst there is a reassurance given that individuals can refuse to consent to disclosure, where a clearly stated objection to disclosure is made, the regulations provide no information on how to do so and no draft forms that patients can fill in.
10. In summary, the preferred option is that the current regulations should be updated rather than the first set of regulations being passed. Even better, the 1996 regulations should be repealed. The second and third sets of regulations should allow for public interest party intervention and the regulations should state clearly that such committees are open to the public. The fourth set of regulations should comply with the principle that consent should be obtained for the use of IVF treatment data and non-IVF NHS data by researchers and all such information should be provided only on an anonymous basis from which it is impossible to identify patients or their children. Research can still be conducted with names and identifying information blanked out.

Consultation Response

The Department of Health consultation document[5] requests a response to the draft regulations and the key proposals set out in section 6.[6] The key proposals are under the headings of the 4 new proposed regulations. For the sake of convenience we shall refer to the proposed regulations as "R1" to "R4" in our response.

Response to the 10 Key Proposals in Section 6 on Page 23 of the Consultation

The Proposed Regulations: The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ("R1")

Response to Appendix A and to Proposals 1 to 3: General Response to R1

It is possible to store gametes (eggs or sperm) and embryos not used at the time of their creation so that they are frozen for future use. The 1990 Act sets out normal periods for storage of 10 years for gametes and 5 years for embryos.

The proposed regulations are intended to replace the 1991 and 1996 regulations. Please see the Appendix for a more detailed description of the 1991 and 1996 regulations and of the proposed regulations.

We believe in the special status of the embryo as a human being enjoying human rights. Only those embryos that are intended for birth and life should be created. In Christian terms, an embryo is the precious start of a life and a gift from God worthy of full respect. We do not believe that embryos should be destroyed, but that clinics should create no more embryos than are intended for implantation into the wombs of wives. For this reason, storage of gametes and embryos should only be temporary. The welfare of the child and his or her best interests, including his or her right to both a mother and a father, requires that treatment should be restricted to married couples who have made that life-long commitment to each other and are able to provide the long-term stability needed for the child's upbringing.

Our response is based on the principle that embryos that are not required for treatment as described above, should not be created in the first place. Therefore, to extend the period of storage of embryos that are not intended for implantation and should not have been created in the first place even further is unnecessary.

The proposed regulations are unnecessary. The storage time limits provided in the proposed regulations have already been extended from 5 to 10 years for embryos as a result of the 2008 Act and there is no logic behind extending it any further.

There is no merit in the reasons for the change. It is argued that the situations identified in Parliament such as the mother who donated gametes for her daughter who had Turner Syndrome "…fed in to the Government's decision to review the law in this area."[7] The consultation goes on to explain that in preferred option 2, the proposed changes would include "…the case raised in Parliament of the young girl with Turner's Syndrome, whose mother had wished to put her own eggs in storage for her daughter's use. The 1991 regulations would only have allowed the eggs to be stored for ten years, and not extended as they were not intended for use by the gamete provider. Option 2 would permit extended storage as they would be used by the daughter, who would meet the requirements of the proposed regulations."[8]

However, this issue was barely raised during the passage of the Human Fertilisation and Embryology Act ("HFE Act"). Andrew Stunell, Liberal Democrat MP, raised it as an issue by reference to a letter from a constituent and a response from the HFEA in similar terms to the above quotation during the Second Reading of the HFE Act in the House of Commons on 12th May. In this case the mother was nearly 36 and the statutory storage period would only have allowed storage up to the daughter's 18th birthday. There was no further debate on this point.[9]

In the Public Bill Committee on 5th June 2008, where only 13 MPs were present (excluding the Minister and the Chair), Mark Simmonds MP raised a probing amendment lowering the storage limit from 10 to 7 years for gametes and embryos under clause 15. The Minister of State, Dawn Primarolo, responded by stating that**:**

> *I recognise that limits on the storage of gametes and embryos can cause some concern. The length of storage needs to ensure fairness, while also* ***taking into account the safety of freezing.*** *I believe that the statutory 10-year period for gametes, with extended storage for medical reasons, remains appropriate. I also consider that the same limits should be applied to embryos. Therefore, the Bill brings storage limits into line with each other.* [10] (Our emphasis).

It is surprising in view of this comment only last summer expressing concerns on the safety of freezing, that an extremely long extension of the limit up to 55 years is being proposed for anyone who happens to be likely to develop significant and premature infertility, even if they are not the gamete provider for the embryo or gametes in question.

Evan Harris, the Liberal Democrat MP who tabled many permissive amendments during the passage of the HFE Act, tabled one in this area that was only debated within the Public Bill Committee on 5th June 2008.[11] The debate included comments on surrogacy.

It is highly surprising that the Government are proposing such sweeping and contentious changes in these regulations regarding a matter that was raised only by two or three MPs and when not even a single amendment on it was fully debated or voted on, on the floor of the House of Commons.

The Parliamentary references to the single Turner Syndrome case failed to mention that the daughter concerned could still receive IVF treatment using donor eggs from someone other than her mother and that the statutory storage limits would not have prevented her from having a child. The Turner Syndrome Support Society states that:

> *"Girls with TS may have only a few or several of the features associated with TS, but short stature and infertility are nearly always present. The possibility of growth hormone treatment for short stature and IVF for infertility are options now available to those with TS."*[12]

A Health Care Issue Paper for those with TS states that the "uterus or womb is quite able to hold a pregnancy however. In this situation 'egg donation' or 'ovum donation' is the answer."[13]

We strongly disagree with the donation of gametes from close blood relatives. In the Bible, in the book of Leviticus chapter 18, verse 6, God told Moses "No–one is to approach any close relative to have sexual relations. I am the Lord".

Incest is taboo partly for biological reasons, namely to prevent genes becoming defective because of sexual relations between blood relatives, and partly because of the special nature of filial and sibling relationships, which should not be confused by sexual issues. The Sexual Offences Act 2003 ("SOA 2003") created two new offences of familial sexual abuse and prohibited adult sexual relationships between relatives as a result of a White Paper on protecting the public.[14] The reason for the change was the need to protect children within the family. The offences of familial sexual abuse created by the SOA 2003 prohibit sexual activity in family relationships where one of them is the other's parent, grandparent, brother, sister, half-brother, half-sister, aunt or uncle, or has been the other's foster parent. Sexual activity with an adult relative is also prohibited. An adult relative is defined as a parent, grandparent, child, grandchild, brother, sister, half-brother, half-sister, uncle, aunt, nephew or niece. There are also prohibited degrees of relationship for marriage. What is forbidden and seen as a criminal offence in terms of sexual activity should also be prohibited in the context of artificial insemination and IVF.

The wording of the Sexual Offences Act 2003 is drafted widely enough that it may even be possible to consider the proposed use of a mother's eggs by a daughter with Turner Syndrome to be not only ethically and morally wrong, but a criminal offence. Despite the fact, a purposive interpretation of that law is likely, so such a donation would be unlikely to result in prosecution.[15]

In our opinion, for the protection of the welfare of the child and to prevent unnatural family relationships, the HFEA should issue guidance advising clinics against the use of donations for all IVF treatment and for the storage of gametes and embryos, from close relatives and those with familial relationships or who would otherwise be within the prohibited degrees of relationships for marriage.

Whilst it is understandable that a close relative such as a mother may wish to donate an egg, this is not an acceptable solution and disrupts normal familial relationships. In a Canadian Turner Syndrome case on mother-to-daughter donation, CORE commented:

> *Is it natural for a young woman to carry in pregnancy her own half sibling, as any such pregnancy would be? The egg donor might like to describe herself as the grandmother but the genetic reality is that she would always remain the biological mother of the offspring, and the conception would have been achieved using her son-in-law's sperm. I think it is understandable that we feel uncomfortable when we start to unravel this story, and we should be particularly concerned about the psychological welfare of any baby born as a result.*[16]

The case of a 72 year-old sperm donor being father to his own grandchild has been reported.[17] A spokeswoman for the HFEA, which regulates the fertility sector, is reported to have said that it did not need to approve the decision. Donations from family members—such as sisters giving each other their eggs—are allowed under the law, she said.[18] Any baby produced from the treatment would be the grandfather's genetic child and its father's half-brother. However, as a matter of public policy, this should be prohibited both for the known problems of interbreeding caused to the genetic pool and the potential of its detrimental impact on the family itself, such as strained and unnatural relations. For example, if the grandfather falls out with the family he would then be legally entitled to apply for both a residence and/or access order for the child as the child's biological father. As a grandparent he would normally need to have the leave of the court to apply for access. Whilst a child may wish to know his own biological origin, it may well be an unpleasant shock to find out that your grandfather is your real father and since you may only find out at 18, he may well be dead by then.

In the case of *B and L v United Kingdom* (Application No.36536/02) the European Court of Human Rights found that there had been a violation of article 12 of the Convention in that the prohibition on marriages between a person and the parent of their former spouse and between a person and the former spouse of their child could not be supported as rational and logical. This resulted in the change to the Marriage Act 1949.[19] This means that it is possible for a former daughter-in-law to marry the grandfather of the family, her former father-in-law, once she had divorced her husband. The husband would be out of the picture in that case and no longer part of the family unit. However, in the case of the 72 year-old sperm donor, the son would have to come to terms with his wife being artificially inseminated by his father.

Our general answer to the question on these proposed regulations is that we consider them to be morally and ethically abhorrent and that the implications of such permissive regulations have not been properly or fully considered by other experts such as biologists, psychologists, psychiatrists and sociologists.

<u>Proposal 1: "Have the same infertility criteria and overall time limit applying to extension for gametes as for embryos."</u>

As already stated, we strongly object to these proposed regulations and the overall time limit of 10 years is already sufficient. To have a straight time limit of up to 55 years without any anchoring to the age of the woman being treated (being a maximum of age 55) may lead to much older parents requesting IVF treatment, to the detriment of the welfare of the child. The regulations have great potential for commercial exploitation and accord no special status to the DNA of the gametes and embryos—they simply treat them like commodities to be used and abused at the whim of those who demand the right to give birth to children. Children can be ordered as if they were products. The only condition is that the prospective parent(s) is/are likely to develop significant and premature infertility, and a surrogate womb can be used to facilitate the arrival of the child. Even consumer durables normally only have a manufacture guarantee of 12 months, not the potential shelf-life of 55 years.

Under preferred option 2,[20] as an understatement of these proposed changes, the consultation states that the provisions would allow a 56 year-old man to be treated using his own stored gametes. The changes actually mean that if a 35 year-old man or woman was undergoing cancer treatment that was likely to make him or her significantly and prematurely infertile, then that person's gametes could be stored for 55 years until they were 90, using a surrogate mother should they choose to do so. They could also have a third party's gametes or embryos stored once allocated to them, for a similar period. The consultation weakly argues in point A.12 that age will still be relevant in some cases, as it will be hard to argue that someone in their 60's who wants to extend storage is prematurely infertile and that the requirement that clinics take account of the welfare of the child will help to prevent the treatment of older patients. On this argument, a man of 55 may still be able to argue for extended storage of his gametes to a ridiculous age of 110. Whilst section 13(5) of the 1990 Act makes the conditions for licences for treatment conditional upon taking account of the welfare of the child, this is not stated within the regulations, nor does it need to be stated in the written opinion of the doctor. There appear to be no graduated 5-year extensions with renewals considered. The whole extra period up to 55 years in total can be added in one extension. In the regulations, the donors themselves only have to consent to an excess of 10 years and there is no specification in the regulations for them to be required to know that this storage may even reach as far as 55 years into the future.

A distinction needs to be made between gametes, which are the building blocks of embryos and embryos, which are human beings at the start of life and have a special status. In our opinion, the exceptions should be as exceptional as they were in the 1991 regulations and should only relate to the extended storage of a person's own gametes for their own use as a result of their own infertility. Gametes should only be stored for extended periods on the written advice of 2 doctors that the patient has or are likely to become, prematurely and completely infertile. Extensions should not be allowed for the treatment of surrogate mothers. Extensions for storage should not apply to embryos beyond 10 years. Only sufficient embryos for contemporaneous treatment of married couples should be stored and the already increased period of 10 years should be sufficient to meet such needs. In general, we would be opposed to any extended

storage of embryos beyond 10 years, as treatment should be contemporaneous or within 10 years. The current criterion relating to infertility necessary for the storage of gametes in the 1991 regulations is that of "impaired fertility" and rightly has a lower threshold, because it relates to a person's own use of his or her own gametes.

IVF should be seen as a last resort and efforts should be made to assist married couples to conceive naturally. The criterion of significant and premature infertility is very weak. For example, a man of 35 could well have a low sperm count on one test and depending on how quickly and widely the interpretation of "significant and premature" infertility is applied, may well be classified as qualifying for this extended storage until he turns 90. Yet, the same 35 year-old man could return to normal sperm count levels as little as 6 months later, as a result of simple lifestyle changes, such as wearing boxer shorts or experiencing less stress. This illustrates how infertility criteria should be defined as "has or is likely to become prematurely and completely infertile" in both cases.

Proposal 2: "Allow extension where someone has or will become significantly and prematurely infertile including cases where the person to be treated is not the gamete provider. For example, in cases using donated gametes or embryos and/or surrogacy."

We strongly disagree with the idea of extensions applying to persons other than the gamete and embryo provider. Surrogacy is also a contentious issue and as in the 1996 regulations, should be banned. The extra time of up to 10 years for embryos is already provided within the changes made by the 2008 Act. The Surrogacy Arrangements Act 1985 is worded so as to avoid the commercialisation of surrogacy.[21] Section 59 of the HFE Act 2008 relaxed some of the prohibitions for non-profit making bodies to facilitate such arrangements. The commercial and controversial ethical nature of surrogacy means that it is vitally important that the ban in the 1996 regulations is maintained.

Proposal 3: "Remove the age limit for the storage of gametes and embryos and replace it with an overall time limit of 55 years, irrespective of the age of the person who put them in storage."

We strongly disagree with the storage of gametes and embryos not being tied to the potential parent's age and do not think in any event that there is any need to extend periods in this way. However, in the circumstances explained under proposal one, for gametes only (for your own use), it is sensible to limit it in relation to the age of the woman and to the limit of natural child-bearing age, as the woman still has to give birth. The age of 55 as a maximum age is also a sensible limit for a man. It is not in the best interests of the child to allow such long periods of storage as children should have parents who are alive for the duration of their upbringing.

The regulations as drafted would allow an embryo to be provided to a heterosexual or homosexual man who was significantly and prematurely infertile at age 35 (for example as a result of cancer treatment), and had no wife or partner, with the embryo being produced by using a sperm and an egg from his parents, and to have that child by a surrogate mother up to the age of 90. The child could be born long after its biological

parents had died and would be both brother and son, or sister and daughter to the man being treated. The implications of these permissive regulations have not been fully considered and the ease with which regulations can be drafted should not be exploited so as to allow this to happen. The argument that drafting permissive rules allows the avoidance of legal challenges is not worthy of rational consideration. This is because if you have such permissive rules, it makes it more difficult for the clinics and doctors to argue in favour of the welfare of the child for the older parent. This could lead to much older women having children if doctors do not raise objections on health grounds. "In 2006 Patricia Rashbrook, 62, a child psychiatrist from Lewes, East Sussex, gave birth after receiving fertility treatment in Moscow." The social harm that could result from such changes is illustrated by the idea that Zimmer frames could be mixed with prams.[22] The need to provide care for both the elderly mother and the young child at the same time is detrimental both to Society and the State. Many would also find it repugnant if a 62 year-old decided to offer herself as a surrogate mother. The distorted idea that such changes are to be supported on the basis of equality opportunities ignores the biological fact that a woman has to carry the child whatever the provisions in the law.

R1 allow an incredibly long, general storage period of up to 55 years for everyone and anyone who happens to have or is likely to develop "significant and premature infertility", be it the gamete provider, any person who provided the gametes that created the embryo(s), or anyone, man or woman, who happens to want treatment (even using a surrogate) and regardless of the current age of the person concerned, or of the woman to be treated. The 1991 regulations only allow for storage up to the age of 55 for a person's own gametes for their own use and as a result of their own infertility. This now means that gametes or embryos may be used after the donor's death. In view of sections 39 and 40 of the HFE Act 2008, which deal specifically with the use of sperm after the death of a husband. It is highly surprising that measures that could result in such use after the death of any donor are being brought in under a negative procedure according to which they will be passed after 40 days if there is no objection and under which they are not even to be debated.

We strongly object to embryo testing even being considered as a ground for extension and it should not be in the regulations. Embryo storage is already extended from 5 to 10 years and even though we object to embryo testing there is absolutely no reason why this cannot be undertaken as soon as the embryo is created. The embryos tested are those that are at particular risk of suffering from a genetic abnormality, or suffering from a serious genetic gender-related condition, illness or disability, or whose tissue may be suitable for transplanting into an older sibling who suffers from a serious medical condition.[23] We are not aware of any debate in Parliament that would warrant such a dramatic change as to allow for extended storage with absolutely no safeguards with the only proviso being that the gamete providers of the embryo in question have to consent. In fact, the debate in Parliament showed that "saviour siblings" were regarded as such a controversial issue that a free vote was given. The increased storage of umbilical cord blood will mean that there may well be no medical necessity for such a provision in view of the increase in the availability of tissue types and stem cells that can be used for treatment as a result. Saviour sibling children may soon become a thing of

the past. However, even if there were safeguards regarding extended storage for embryo testing, the practice should not be allowed in the first place. It is morally and ethically wrong to allow such storage for such a length of time and cannot be justified.

This cannot by any stretch of the imagination be what Parliament intended and our opinion is that to allow such broad, sweeping regulations appears to be an abuse of the HFEA's regulation-making power. Reading section 14 of the 1990 Act[24] from which this regulation making power derives makes it clear that such exceptions were intended to be exceptional to the normal statutory storage rules and not so broadly applicable.

In our opinion, the first set of regulations should not be passed and the current regulations should be updated to cover the extension to 10 years for embryos that is found in the 2008 Act. This is the preferred option. Even better would be to repeal the 1996 regulations, as the 2008 Act already allows for an extension in the storage of embryos from 5 to 10 years. Such permissive regulations, which can be passed without Parliamentary debate, should not be allowed in a civilised society.

The proposed regulations treat gametes and embryos as commercial consumer commodities to be used and abused by anyone who happens to have, or to be likely to develop significant and premature infertility.

The Second Set of Proposed Regulations: The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal) Regulations ("R2")

Response to Appendix B and to Proposals 4 to 5

Proposal 4: "There is a lay majority on the Licence Committee that makes decisions on refusal, revocation or variation."

The intention is to replace the Human Fertilisation and Embryology Authority (Licence Committees and Appeals) Regulations 1991[25] with R2, which deal with procedures for revocation, variation or refusal of licence applications and another set of regulations dealing with procedures for appeals.

The regulations set out the procedures to be followed by the licence committee of the Human Fertilisation and Embryology Authority, when considering representations under section 19(4) of the Act that oppose a proposal to revoke, vary or refuse a licence.[26]

It is agreed that a lay majority may be preferable; however regulation 3 could be more clearly and concretely drafted than persons who do not have "a professional interest". It is important that such people are independent of the HFEA and are not members, employees or former employees. To ensure fairness, it is more important that lay membership consists of a balance of those who are in favour and of those who oppose the activities permitted by licence under the Act. The committee needs to be chaired by someone broadly neutral on the issue who cannot vote. The proposed regulations

suggest that the quorum is either 3 or 5 members. The original regulations for license committees require a quorum of 3. A quorum of 5 would seem to be preferable in the proposed regulations rather than to allow the option of 3 or 5.

Proposal 5: "The procedure to be followed when the Authority is minded to revoke, vary or refuse a licence is set out in detail in the regulations."

The current regulations are not very detailed in relation to procedure. However, these regulations appear to go from one extreme of little detail to a very detailed procedure and seem to be beyond what is necessary in view of there being only an average of 3 revocation, variation or refusal hearings per year.[27] This mirrors a court-type procedure for what are effectively internal review procedures. Similar types of rules are proposed for evidence and it is questionable whether or not this is far too legalistic for such a procedure. Something in-between the two would seem preferable. For example, reference is made in regulation 4 to providing a "skeleton argument" instead of a "summary of the main points and arguments".

In terms of openness and transparency, it is unclear if it is intended for the hearings to be open to the public to attend or not. In terms of interpretation, regulation 2 provides a definition of "in private" and it is clear that case management meetings are to be held in private in regulation 7 and that there will be private deliberations in regulation 13 of the Committee after the person has made a closing statement. In our opinion, such hearings should be open to the public in the same way that a member of the public may sit at the back of a court. The regulations should clearly state that they are open to the public to attend.

The regulations, as they mirror court-type proceedings, should allow for interested third-party interventions, so that public interest groups can receive all information and become a party to the proceedings and be allowed to make representations. Even if they did not mirror such proceedings, in the interests of fairness and transparency such third party interventions should be allowed, regardless of how detailed the procedures themselves are.

The Third Set of Proposed Regulations: The Human Fertilisation and Embryology (Appeals) Regulations ("R3")

Response to Appendix C and to Proposals 6 to 7

Proposal 6: "HFEA members (current or previous) cannot sit on an Appeals Committee."

It is agreed that current or previous HFEA members cannot sit on an Appeals Committee. This should also apply to R2. It is disagreed that the quorum should be only 3. The current regulations refer to 5 as a quorum for appeals. In our opinion this should be 7. However, it would be preferable for the Committee to be appointed by the Secretary of State rather than the HFEA, to ensure independence and it should

consist of eleven members, with 7 members who sit at the meetings with the Secretary of State, ensuring a balance of those in favour of, and those opposed to activities permitted under licence. The Chair should be broadly neutral. The regulations themselves should ensure selection maintains independence. This proposal is similar to an idea within an amendment proposed by an MP (known as NC8) that attracted 16 signatories during the passage of the HFEA Bill.[28]

Proposal 7: "The Chair and Deputy Chair of an Appeals Committee are legally qualified."

It would seem helpful to have a legally-qualified Chair or Deputy Chair, but that person would need to be totally independent of the HFEA so that they did not even have the HFEA as a former or current client. In addition, it would be important to ensure that the Chair or Deputy Chair is broadly neutral. The regulations should ensure the independence of the legal firm being used and that there are a panel of firms from which a Chair or Deputy Chair are randomly selected with a different Chair or Deputy from a different legal firm every year and with a Chair or Deputy not serving for more than a total of 2 years in any 10-year period.

These Appeal Committee hearings, like R2, need to be open to the public to attend and this needs to be clear on the face of the regulations. Again, public interest groups should be allowed to be a party to the proceedings and to intervene.

It appears that the regulations have been written from a legalistic perspective by someone with knowledge of court procedures. The regulations repeat the detailed procedures already in R2. A more detailed procedure may be appropriate for an appeal, but it is rather elaborate considering that there are only expected to be, on average, less than one appeal hearing a year.[29] For example, the term "skeleton argument" is used in regulation 16 as opposed to terms such as "the grounds of appeal" in the current regulations.

There appear to be extraordinary measures taken to ensure fairness and transparency to those who apply for licences so that if a licence for a clinic or a research grant licence is refused, the person applying for the licence can have a hearing on its refusal, then can appeal and is then even allowed to appeal to the High Court on a point of law under section 21 of the 1990 Act. Yet a public interest group must immediately incur the expense of a judicial review claim if they wish to challenge a decision on the grant of licence. Decision-making by the HFEA should be subject to public accountability and transparency, not just accountable to licence applicants.

In our opinion, the legislation should be changed to make real use of such Appeals Committees so that public interest groups could have an internal way of reviewing the grant of licence decisions. Such regulations should be made user-friendly so that internal challenges do not entail legal expense and are simple enough to follow without the need for legal representation or costs. For example, in the Human Fertilisation and Embryology Bill a new clause amendment to allow for public interest groups to access

an internal appeals system (so that there would be greater fairness and transparency of HFEA decision-making on the granting of licences and more accountability) was tabled (please see link for details).[30]

The Fourth Set of Proposed Regulations: The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations[31] **("R4")**

Response to Appendix D and to Proposals 8 to 10

Proposal 8: "The HFEA is the responsible body for considering applications for information for researchers, drawing on the expertise and resources of the Patient Information Advisory Group (PIAG) which currently approves access to NHS patient data."

The HFEA keep a register that holds details of IVF 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.

The consultation document explains that:

> *For England and Wales, section 251 of the National Health Services Act 2006 (formerly section 60 of the Health and 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.*[32]

Section 251 (headed "Control of patient information") and section 252 (headed "Patient Information Advisory Group") of the NHS Act 2006[33] authorises the Secretary of State to allow for information to be processed in the interests of improving patient care, or in the public interest and allows consultation with the patient advisory group on the processing of patient information.

This means that R4 will also allow researchers access to a patient's non-IVF-related NHS records without their consent. This is presumably to allow researchers to look at data on offspring, but the consultation does not spell this out. The suggested safeguard in this case, is that the HFEA takes account of the views of the Patient Information Advisory Group. The regulations are unclear as to how this is intended to operate in practice. The explanatory notes to regulation 7 say it is where the "Authority is satisfied that there are no reasons why the information should not be used for the purpose of the research". However, no information is given on how the Authority will exercise that discretion. This needs to be made clearer and open to proper consultation in further codes of practice.

It is disagreed that the principle of doing research without consent in these regulations should be allowed. This concerns highly sensitive personal information on fertility treatment which many would regard as being the type of information that would require the highest level of protection and confidentiality. R4 even propose to extend this access to the use of information without consent for normal NHS records. Whilst the consultation maintains that a clearly-stated objection to disclosure could not be overridden,[34] the regulations should make it crystal clear that this refusal will also apply to information obtained under approvals in accordance with section 251 of the NHS Act 2006.

Proposal 9: "Donor information is excluded from the types of identifying information that can be released without consent."

The fourth set of regulations proposes to allow researchers to pay a fee to access this database to conduct research. This would allow disclosure, without consent, for records from 1st August 1991 to 30th September 2009. Whilst research into the effects of IVF on patients' health and offspring is useful, and the most sensitive data on the use of donor gametes would not be disclosed without consent, generally, there is not even any attempt to obtain consent as this is considered to be too costly an option.[35] In our opinion, in view of the sensitive nature of the data on the HFEA register that could be obtained under approvals under section 251 of the NHS Act 2006, the HFEA should ensure that it is only given to researchers without explicit consent where identifying information is completely removed from the data. If it is possible to do that for donor information, it should be possible to do that for all data. The HFEA will not release the identifying information of Peer reviewers used for reviewing the granting of specific research licences; this data on people's IVF treatment is far more sensitive.

In addition, the regulations should ensure that an effort is made to obtain the patient's consent to the research. It is surprising that the emphasis upon the need for consent in Schedule 3 of the Human Fertilisation and Embryology Act 2008 is being ignored, particularly in view of the conditions placed upon research for the use of human cells without consent for adults who lack capacity.

It is agreed that donor information should be excluded from the types of identifying information that can be released without consent, but this exclusion should extend to all information given to researchers that could be "identifying information". Research can still be conducted without knowing the identity of the person concerned.

Proposal 10: "Information is released subject to certain specific conditions being met."

The regulations do not provide sufficient safeguards in the conditions that would need to be met for the release of information. The only real safeguard appears to be Research Ethics Committee approval. Although the regulations are difficult to interpret, the security of data appears to relate to research premises only, as opposed to those for agency arrangements or contracting out. The loss of confidential information that

was stored on a memory stick on a train, by a third-party contractor when dealing with "administrative, professional or technical services"[36] under the regulations is a possibility, and this loophole may not have been closed by these regulations. The regulations should state clearly that only information that does not identify the patient will be provided to researchers. Whilst there is a reassurance given that individuals can refuse to consent to disclosure, by a clearly-stated objection, the regulations provide no information on how to do so, and no draft forms that patients can fill in.

There need to be full advertising campaigns to ensure that anyone who does not want their data disclosed to researchers can be allowed to make their refusal known. Clear, simple, short opt-out forms should be readily available at GP surgeries with leaflets printed nationwide. This should apply to the non-IVF, NHS data as well as the data that the HFEA holds. The forms to be completed by GPs and by patients to opt out of these regulations should be part of the regulations and should state clearly where this information can be sent. Forms should allow patients to opt out of research altogether. This is in addition to the need to include, as a requirement of the regulations, that efforts should be made to obtain each patient's consent. In all cases, "identifying" information should be removed before such information is given to researchers or others, and this should be stated clearly in the regulations themselves.

The conditions in the regulations provide few safeguards and this is the reason why the option of removing all identifying information is the best one. There are no conditions or criteria for the agencies or other bodies referred to in regulation 8, or any guidance or code of conduct or membership required by the HFEA in the regulations. In our opinion, such work should be kept in-house by the HFEA as an internal body in view of the sensitive nature of such data. The HFEA should not only be the body dealing with authorisation, but also with any "administrative, professional or technical services relating to those functions". External contractors should be very tightly regulated and they must guarantee the utmost integrity in dealing with this confidential, sensitive data. It may be that the intention is only to use professional services in relation to matters such as research authorisation considerations, but "administrative" and "technical" services suggests that data work will be included as well.

This also applies to the approval under section 251 of the NHS Act 2006 for non-IVF patient records and the criterion used by the Research Ethics Committee. The regulations do not give any criteria for refusal by the Research Ethics Committee; this needs to be tightened up, as do the criteria for NHS approval. Conditions should include the stipulation that research is not permitted where full consent can be obtained, but has not been, and that data for which consent has not been given should not contain identifying information. Research needs to prove that it is in the public interest to conduct such research. There should be tightly-drafted regulations on the qualifications and the references of all persons who seek to conduct such research, so as to ensure suitable qualifications and integrity. They should need to undergo a similar type of process as that for the grant of licences for embryo research to verify their suitability, qualifications, research, experience and references. There should be a

condition that the research is necessary and desirable and in the public interest. Such codes of conduct and conditions should be subject to further public consultation.

Whilst the HFEA are proposed as the authorising body for research project authorisations, the regulations appear to allow the Authority to contract out on agency arrangements under the regulations for "any administrative, professional or technical services relating to those functions". There do not appear to be any further conditions for the contracting out or agency arrangements.

The provisions for security could be strengthened in the regulations, because data is not just stored in premises and the use of such data and its storage by HFEA contractors for administrative, professional or technical services and by the researchers require stringent conditions. Regulation 8(c) and 18 are inadequate. The appropriate arrangements for the destruction of protected information are not sufficiently rigorous. The regulations should specify the shredding of all manual records with identifying information in addition to software security, so as to ensure the deletion of all computer or other records. These regulations should include security stipulations to ensure there are sufficient overall safeguards covering all data, so that there is no possibility of data stored on a memory stick being left on a train.

The regulations are far too researcher-friendly and even allow for reviews of refusals. Instead, there should be far more rights of refusal without review, where research is likely to infringe patient confidentiality and where research cannot easily be said to be in the public interest. In fact, the criteria for research being in the public interest are not even given in regulation 8 as a ground for refusal of a grant for the processing of this sensitive information.

Regarding fees, the consultation suggests that the fees are likely to be in the region of £450 to £2,500 per application with the cost being passed on to the researcher.[37] Regulation 5 states that the Authority may require an applicant to pay a fee in respect of administrative costs. It is important to make sure that the regulations indicate that the costs charged relate to the actual and reasonable costs of providing the information requested, and that the Authority does not make a profit. Otherwise, the Authority may be perceived to be selling sensitive personal data and that impression needs to be avoided where research is in the public interest.

Appendix

The Proposed Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations ("R1")

General Response to R1

It is possible to store gametes (eggs or sperm) and embryos that are not used at the time of their creation so that they are frozen for future use. The 1990 Act sets out normal periods for storage of 10 years for gametes and 5 years for embryos. The 2008 Act extends this to 10 years for embryos. The power to make these regulations comes from section 14(5) of the 1990 Act.[38] Section 14(5) of the 1990 Act allows for both a shorter period, or in circumstances specified in the regulations a longer period, for the storage of gametes or embryos. However section 14, which deals with conditions for storage licences, is drafted in such a way as to show that this regulation-making power is intended as an exception to the general rule.[39] The proposed regulations apply this exception to a much wider range of situations than the drafting of the 1990 Act would suggest is appropriate.

The Proposed Regulations

In order to understand the changes being proposed, it is helpful to describe the proposed regulations in addition to the 1991 and 1996 regulations that they will replace.

In R1, the "person to be treated" with the gametes or embryos and who may be allowed to extend their storage, means not only the woman who is to become pregnant, but also any man or woman to whom the embryo or gamete in question is allocated by the clinic. This will include persons who have not donated the gamete or embryo themselves, because it has simply been allocated to them. In order for R1 to apply to their gametes or embryos, the individuals who have supplied them need to consent in writing to their gametes or embryos (where they supplied the sperm or egg to create the embryo in question) being stored for more than 10 years for use in treatment services. "Treatment services" are services that have the purpose of assisting women to carry children. At any time within the initial 10-year normal statutory storage period for a gamete or an embryo, if a single doctor gives a written opinion that the person who provided the gamete (or who was one of the persons who contributed a sperm or an egg to the embryo in question) has or is likely to develop "significant and premature infertility", the storage period can be extended to 55 years. This means that an embryo or a gamete can be stored for a total of 55 years. It also means that if these individuals consent to the storage of their gametes or embryos for more than 10 years, they will find that the clinic will be allowed to store them for 55 years, which is significantly longer than 10 years.

Similarly, if the single doctor gives a written opinion that the "person to be treated" (which could mean a man or woman who has been allocated the sperm, egg or embryo by the clinic) has or is likely to develop "significant and premature infertility"; then again,

the storage period can be extended to 55 years. In other words, the person who has the "significant and premature infertility" can be independent of the people whose gametes created the embryos in question. No longer is the storage period for gametes and embryos connected with the societal and/or natural fertility span of the person for whom they are being stored (as was the case in the 1991 and 1996 regulations). Whereas the gametes or embryos would have been stored only until the woman being treated reached the age of 55 or a man's own stored gametes until aged 55; instead, an abstract period of 55 years' storage is substituted where the consent conditions are met. The divorce performed by the Department of Health is clear: no longer are gametes the cells of an individual that enable them to reproduce at a sensible age; instead, they are now a mere commodity that can be used by someone else to produce a baby on demand or left to children or grandchildren as an inheritance to aid their fertility.

In addition, the proposed regulations allow for the statutory storage period for embryos to be extended "…from 10 to 55 years if the people whose gametes were used to create the embryo consent to extended storage, and the embryo has been tested by a person licensed under the Act."[40] The embryos tested are those that are at particular risk of suffering from a genetic abnormality, or suffering from a serious genetic gender-related condition, illness or disability, or whose tissue may be suitable for transplanting into an older sibling who suffers from a serious medical condition.[41]

R1 also allow for the extended storage periods to apply to gametes or embryos that are already in storage. This means that the extension of the storage limit from 10 to 55 years applies to gametes, embryos and embryo testing by the clinic.

Replacement of 1991 Regulations Relating to the Storage of Gametes

R1 will replace the 1991 regulations[42] on extended storage for gametes and the 1996 regulations[43] on extended storage for embryos.

In the 1991 regulations, gametes are stored for use only by the gamete provider (or by the gamete provider and their partner) and based on their own impaired fertility. Additionally, the gametes must be provided when the provider is under 45 and can only be stored until the provider reaches the age of 55. This is so that the eggs or sperm of those with impaired fertility can be stored for their own use when they wish to complete their family.

Replacement of 1996 Regulations Relating to the Storage of Embryos

When these regulations were made, the normal storage period for embryos was five years, but this has been changed to ten years under the 2008 Act. The 1996 regulations[44] were made in order to extend the storage period for embryos beyond 5 years to cover two types of circumstances. In both cases, the "woman being treated" means the woman who it is intended should become pregnant at the date the embryo

was first placed into storage, whether or not she is one of the people who supplied the gametes that created the embryo.

In the first type of circumstance, both of the people who supplied the gametes used to create the embryo in question, have to consent in writing to extended storage and the "woman being treated" has to be under 50 when the embryo is first placed in storage, but the regulations only allow this storage to continue until she turns 55. In addition, the woman being treated may not be a surrogate mother. Two doctors are required to give a written opinion that one of the people who supplied the egg or sperm that created the embryo (or where the woman being treated is not one of those people, then the woman being treated), has or is likely to become "prematurely and completely infertile".

In the second type of circumstance, storage of an embryo may be extended if in the opinion of a single doctor, one of the people who supplied the egg or sperm that created the embryo (or where the woman being treated is not one of those people, then the woman being treated), has or is likely to develop significantly impaired infertility, or has a genetic defect such that her child may suffer from physical or mental abnormalities that would make him or her seriously disabled.

Having set the scene by describing the proposed regulations and the 1991 and 1996 regulations that it is proposed the new regulations will replace. The consultation asks for a response to the key proposals in section 6 on page 23. Please see the main body of the report for our response to the proposals.

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[1] See the consultation document at pages 23 and 27-28 on how to respond at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.

[2] See page 4 of the Factsheet on Statutory Instruments for the House of Commons at: http://www.parliament.uk/documents/upload/L07.pdf

[3] See: http://www.dailymail.co.uk/news/article-1163580/IVF-babies-health-alert-Test-tube-children-30-cent-likely-defects-warns-watchdog.html.

[4] See: paragraph 12 of a letter to Peers in connection with the Human Fertilisation and Embryology Bill which refers to the "special status of the human embryo at: http://www.parliament.uk/deposits/depositedpapers/2008/DEP2008-0287.pdf

[5] See the consultation document at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465. See especially page 23 where the key summary proposals state that if respondents wish to comment on any other part of the consultation document including the regulations themselves or the Partial Impact Assessments, they should indicate clearly to which part of the document their comments relate.

[6] See page 23: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.

[7] See page 41, point A.26: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.

[8] See page 42, point A.36: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.

[9] See from column 1145 of the debate on the Second Reading of the HFE Bill now the HFE Act 2008: http://www.publications.parliament.uk/pa/cm200708/cmhansrd/cm080512/debtext/80512-0017.htm#08051231000382.

[10] See column 138 under clause 15, amendment 5 and 34, and discussion with the Minister and Mark Simmonds MP at: http://www.publications.parliament.uk/pa/cm200708/cmpublic/human/080605/pm/80605s06.htm.

[11] See from column 138 to 141 regarding new clause 2:
http://www.publications.parliament.uk/pa/cm200708/cmpublic/human/080605/pm/80605s06.htm.
[12] See: http://www.tss.org.uk/what-is-ts.
[13] See: http://www.endocrineonline.org/pdf%20box/ts%20health.pdf.
[14] See: http://www.archive2.official-documents.co.uk/document/cm56/5668/5668.pdf.
[15] See the wording of the Sexual Offences Act 2003, sections 25 to 29 regarding victims under 16. Sections 64 and 65 concern sex with an adult relative.
Section 78 gives the meaning of "sexual" in the Sexual Offences Act 2003:

> *78 "Sexual"*
> *For the purposes of this Part (except section 71), penetration, touching or any other activity is sexual if a reasonable person would consider that—*
> *(a) whatever its circumstances or any person's purpose in relation to it, it is because of its nature sexual, or (b) because of its nature it may be sexual and because of its circumstances or the purpose of any person in relation to it (or both) it is sexual.*

See: http://www.opsi.gov.uk/acts/acts2003/ukpga_20030042_en_5#pt1-pb17-l1g64.
The explanatory notes for section 78 state:

> *Section 78: "Sexual"*
> *145. Section 78 defines "sexual" for the purposes of this Part. This definition is relevant to many of the offences under this Part. For example, section 2(1)(b) refers to penetration which is sexual and section 3(1)(b) refers to touching which is sexual.*
> *146. There are two alternative limbs to the definition of "sexual" in section 78. Paragraph (a) covers activity that the reasonable person would always consider to be sexual because of its nature, such as sexual intercourse. Paragraph (b) covers activity that the reasonable person would consider, because of its nature, may or may not be sexual depending on the circumstances or the intentions of the person carrying it out, or both: for example, digital penetration of the vagina may be sexual or may be carried out for a medical reason. Where the activity is, for example, oral sex, it seems likely that the reasonable person would only need to consider the nature of the activity to determine that it is sexual. But where it is digital penetration of the vagina, the reasonable person would need to consider the nature of the activity (it may or may not be sexual), the circumstances in which it is carried out (eg a doctor's surgery) and the purpose of any of the participants (if the doctor's purpose is medical, the activity will not be sexual; if the doctor's purpose is sexual, the activity also is likely to be sexual).*
> *147. If, from looking at the nature of the activity, it would not appear to the reasonable person that the activity might be sexual, the activity does not meet the test in either paragraph (a) or (b), even if a particular individual may obtain sexual gratification from carrying out the activity. The effect of this is that obscure fetishes do not fall within the definition of sexual activity.*

Digital penetration for medical reasons would not be seen as sexual. However, there is a potential argument on the literal, as opposed to the purposive wording of section 78, that a reasonable person might regard the nature of artificial insemination as "sexual" as it has the same result as sexual intercourse. See: http://www.opsi.gov.uk/ACTS/acts2003/en/03en42-b.htm.
See also the dictionary definitions of sexual:

> *Sexual*
> *adjective 1 relating to the instincts and activities connected with physical attraction or intimate physical contact between individuals. 2 relating to the sexes or to gender. 3 (of reproduction) involving the fusion of gametes. 4 Biology being of one sex or the other; capable of sexual reproduction.*

This can be found at the following link: http://www.askoxford.com/concise_oed/sexual?view=uk.

> *sexual*
> *adj.*
> *1. Of, relating to, involving, or characteristic of sex, sexuality, the sexes, or the sex organs and their functions.*
> *2. Implying or symbolizing erotic desires or activity.*
> *3. Relating to, produced by, or involving reproduction characterized by the union of male and female gametes*

This can be found at the following link: http://www.thefreedictionary.com/sexual.
[16] See: http://www.corethics.org/index2.php?d=news&sb=1&item=6.

[17] See: http://www.dailymail.co.uk/health/article-485798/Sperm-donor-72-father-grandchild.html.
[18] See: http://www.independent.co.uk/life-style/health-and-wellbeing/health-news/man-72-to-be-sperm-donor-for-son-and-daughterinlaw-396115.html.
[19] See: http://www.opsi.gov.uk/si/si2007/uksi_20070438_en_1 and http://www.legislation.gov.uk/RevisedStatutes/Acts/ukpga/1949/cukpga_19490076_en_11.
[20] See page 41, point A.24 at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.
[21] See: http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1985/cukpga_19850049_en_1.
[22] See: http://www.telegraph.co.uk/health/healthnews/4632597/Women-may-be-able-to-freeze-their-eggs-for-55-years-under-Government-plans.html.
[23] See regulation 4 on page 31 of the consultation, which refers to paragraph 1ZA(1)(b)(c) or (d), inserted by schedule 2 of the Act at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465 and http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080205.
[24] See: the whole of section 14 of the 1990 Acton page 23 in the illustrative text and section14(4) and (5) which allows regulation making powers for these regulations, at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080205
[25] See: http://www.opsi.gov.uk/si/si1991/Uksi_19911889_en_1.htm#end.
[26] See page 65 at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.
[27] See page 68 at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.
[28] See NC8 at: http://www.publications.parliament.uk/pa/cm200708/cmbills/120/amend/pbc1202210m.3266-3271.html.
[29] See page 102 point C25 at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.
[30] See Amendment NC25 at: http://www.publications.parliament.uk/pa/cm200708/cmbills/120/amend/pbc1202210m.3272-3278.html.
[31] See Appendix D for the regulations and the discussion of them at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.
[32] See page 128, point D.18 at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.
[33] See sections 251 and 252 at: http://www.opsi.gov.uk/acts/acts2006/ukpga_20060041_en_19#pt13-pb4-l1g251.
[34] See : D27 page 130 at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465
[35] See pages 123 to 125 on costs and points D.25 and D.31 on pages 129 and 130 at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.
[36] See regulation 6, 8 and 18 on pages 115 and 118 at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.
[37] See page 125 at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.
[38] See section 14 of the HFE Act 1990 and the following link, which illustrates how the HFE Act 2008 amends the 1990 Act, as the latter remains the main Act at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080205.
[39] See the general rules in sections 14(1) (c), (3) and (4) of the 1990 Act, to which these proposed regulations will create an exception at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080205.
[40] See page 33 of the explanatory note on regulation 4 at: http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465.
[41] See regulation 4 on page 31 of the consultation at: (http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_092465), which refers to paragraph 1ZA(1)(b)(c) and (d) of Schedule 2 of the Act at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080205.
[42] See the following link for the 1991 regulations on the storage of gametes: http://www.opsi.gov.uk/si/si1991/Uksi_19911540_en_1.htm.
[43] See the following link for the 1996 regulations on the storage of embryos: http://www.opsi.gov.uk/si/si1996/Uksi_19960375_en_1.htm.

[44] See the following link for the 1996 regulations on embryos: http://www.opsi.gov.uk/si/si1996/Uksi_19960375_en_1.htm.