

Scottish Council on Human Bioethics

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Consultation response to the Human Fertilisation and Embryology Authority (HFEA)

The Regulation of Donor-Assisted Conception

The **Scottish Council on Human Bioethics** (SCHB) is very grateful to the **Human Fertilisation and Embryology Authority** (HFEA) for this opportunity to respond to this timely consultation on the regulation of donor-assisted conception. It welcomes the HFEA's intent to promote public understanding and discussion. In addition, the SCHB acknowledges the need for tighter restrictions on the regulation of donor-assisted conception because of the recognised democratic right for (1) an individual to know his or her genetic inheritance or precedence and (2) society to consider its informed consent to the procedures.

In addressing the consultation entitled 'The Regulation of Donor-Assisted Conception', the SCHB has formulated the following responses:

1. Concern about the scope of the consultation

1.1 The SCHB is concerned that the HFEA consultation does not sufficiently address all the important ethical issues relevant to donor-assisted conception as such but seems to restricts itself to examining the manner in which it is possible to obtain sufficient amounts of gametes and embryos for assisted conception in the UK.

1.2 In this respect, the SCHB is unclear whether the HFEA has become a sort of advocate of (1) infertile couples seeking donor insemination and (2) fertility clinics seeking business, while disregarding the views of the general public. Is this the role of a regulatory authority such as the HFEA?

Many members of the UK public seem to be very uncomfortable with the present donor insemination guidelines. This is reflected by their general unwillingness to become gamete donors and especially if they are to lose their anonymity. [1]

In this regard, the question whether enough gametes should be found at all at the expense of the views of the general population should be seriously considered. The great majority of the UK population may be 'voting with its feet' to a procedure with which it does not agree!

1.3 The SCHB thus believes that the consultation is too limited in scope to represent the broader views of society concerning donor-assisted conception and cannot be considered as balanced.

2. What does compensation for donation mean?

The SCHB notes that the following national and international legal instruments have addressed the topic of compensation in the context of the donation of human organs, tissue and cells:

2.1 United Kingdom - *Human Fertilisation and Embryology Act 1990*

Section 41, paragraph (8):

Where a person to whom a licence applies or the nominal licensee gives or receives any money or other benefit, not authorised by directions [from the HFEA], in respect of any supply of gametes or embryos, he is guilty of an offence.

2.2 European Union - Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. [2],[3]

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This Directive should not interfere with decisions made by Member States concerning the use or non-use of any specific type of human cells, including germ cells and embryonic stem cells. If, however, any particular use of such cells is authorised in a Member State, this Directive will require the application of all provisions necessary to protect public health, given the specific risks of these cells based on the scientific knowledge and their particular nature, and guarantee respect for fundamental rights. Moreover, this Directive should not interfere with provisions of Member States defining the legal term "person" or "individual".

Article 12 (Principles governing tissue and cell donation), paragraph 1:

Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells.

Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted.

2.3 Council of Europe - Additional Protocol to the European Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin (ETS No. 186) [4],[5]

Article 21 (Prohibition of financial gain), paragraph 1:

The human body and its parts shall not, as such, give rise to financial gain or comparable advantage.

The aforementioned provision shall not prevent payments which do not constitute a financial gain or a comparable advantage, in particular:

- compensation of living donors for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations;
- payment of a justifiable fee for legitimate medical or related technical services rendered in connection with transplantation;

In this respect the official Explanatory Report [6] of the **Additional Protocol on transplantation of organs and tissues of human origin** indicated that Article 21 should be interpreted in the following manner:

113. It states in particular that the human body and its parts must not, as such, give rise to financial gain or comparable advantage. Under this provision, organs and tissues should not be bought or sold or give rise to direct financial gain for the person from whom they have been removed for a third party. Nor should the person from whom they have been removed, or a third party, gain any other advantage whatsoever comparable to a financial gain such as benefits in kind or promotion for example. A third party involved in the transplant process such as a health professional or a tissue bank may not make a profit from organs or tissues or any products developed from them (but see paragraph 115 below).

114. However, Article 21 states that certain payments that a donor may receive are not to be treated as financial gain within the meaning of this article. Essentially, apart from the last indent, these provide examples of expenses that may be incurred during or as a result of donation or other parts of the transplant process. This paragraph does not make exceptions to the principle laid down but gives examples of compensation to avoid possible financial disadvantage which may otherwise occur. In the case of the donor it allows for compensation for loss of earnings and other justifiable expenses.

115. The second indent of the first paragraph refers to payment of a justifiable fee for medical or technical services performed as part of the transplant process. Such acts might include the cost of retrieval, transport, preparation, preservation and storage of organs or tissues, which may legitimately give rise to reasonable remuneration.

2.4 Thus, the SCHB notes that, in the light and in the spirit of what is mentioned above, there should never be any risk of a donation taking place (even once) as a result of compensation being considered by a person as a financial incentive. In other words, no compensation should ever be given to a donor if he or she can perceive this compensation as a financial incentive to donate.

Accordingly, the SCHB believes that in order to ensure that a compensation is never seen as an incentive to donate organs, tissue or cells, it is important to prohibit all payments other than the reimbursement of necessary and verifiable expenses and loss of earnings. In other words, no fixed sum should be considered. This means that, in a similar manner to the donation of blood in the UK, no compensation for inconvenience should be considered in the donation of human organs, tissue or cells.

The SCHB is therefore in agreement with the statement of the 1998 HFEA consultation on the **Implementation of Withdrawal of Payments to Donors** which indicated that *"In order to ensure beyond doubt that donors were not motivated by financial gain, it would be necessary to abolish all payments and benefits (other than necessary expenses)."* [7]

3. Embryo adoption

The donation of gametes and embryo adoption are two distinct issues

3.1 With regard to the adoption of human embryos, the SCHB is concerned that this topic was included into the HFEA consultation relating to gamete donation when even the consultation admitted that:

Embryo donation is significantly different from gamete donation in that the embryos will have already been created for the treatment of a specific woman or couple. In almost all cases, they will be embryos left over after successful IVF treatment, when those whose gametes were used have already completed their families. People born as a result of embryo donation, unlike those born from gamete donation, are likely to be the full genetic siblings of other existing people and the full genetic offspring of the parents of those people. [8]

3.2 Moreover, having obtained legal advice from the EU Commission, the SCHB notes that the EU Directive mentioned in paragraph 2.2. does not address the potential usage of human embryos (nor was it drafted for such a purpose) but only the quality and safety aspects of human cells in healthcare settings. It is therefore difficult to see how the HFEA can use such a text as a basis on which to construct any form of ethical guidance on the adoption of human embryos other than that which is related to safety and quality.

3.3 In addition, the SCHB notes that many of the questions such as those found in paragraphs 23-25, 36-45 and 49-59 in the HFEA consultation seem to only address gamete donation and not embryo adoption. Was this intentional?

In the following response, the SCHB will, therefore, address the adoption of human embryos and gamete donation separately.

Criteria for embryo adoption

3.4 Concerning the creation of human embryos in vitro, the SCHB notes that in countries such as Germany, Austria, Italy and Ireland it is considered unethical to create human embryos in vitro if they are not immediately implanted into the mother. This happens in order to avoid the difficult problem, which exists in the UK, of having an ever increasing stock of frozen, unwanted and supernumerary embryos generally destined for destruction.

3.5 The SCHB also notes that patients should be asked to think about what they want to do with their potential left-over embryos before they are created. This is in agreement with Dr Richard Kennedy, secretary of the British Fertility Society and consultant gynaecologist at the Centre for Reproductive Medicine in Coventry, who indicated that *"it would be helpful to raise the issue of 'what will you do with these embryos?' before they are created."* [9]

3.6 The SCHB believes that it would be preferable if parents were better counselled as to the implications of a donation. They may initially have been motivated by a very vague idea of doing some good with something that was left over, without any real cost to themselves.

3.7 The SCHB recognises that even though an unacceptable large number of stored embryos does unfortunately exist in the UK, it would be preferable for these embryos to be given for adoption instead of being destroyed. Though some of the problems relating to the important biological 'bonds' that should exist between parents and children (see paragraph 4) do not exist in this case, the adoption of embryos, in a similar way as the adoption of children, is a very positive solution to an already existing difficult situation. This is in contrast to *creating* difficulties in kinship identities and the related biological 'bonds' which is what is happening in donor insemination. The SCHB would thus like to encourage the adoption by infertile couples of supernumerary embryos. [10]

3.8 The SCHB agrees with paragraph 41 of the HFEA report that no payment for expenses or inconvenience, or any other benefits, should be provided to those who give up for adoption surplus embryos that were created in the course of their own treatment.

3.9 With respect to the supply of embryos by one licensed centre to another, the SCHB concurs that HFEA directions should permit payments in respect of embryos supplied by one licensed centre to another which should be limited to covering the supplying centre's costs and expenses.

3.10 With regard to obtaining embryos from abroad, the SCHB agrees that the HFEA should authorise each import of embryos, on a case-by-case basis, in order to monitor transactions and any potential developments such as the use of any new countries in the provision of embryos, the increasing numbers of imports or the possibility of receiving infected embryos.

3.11 The SCHB is of the view that embryo adoption should be considered in the same light as the adoption of children born after birth. In other words, children born through embryo adoption should have the same right to know their genetic parents as children adopted after birth.

3.12 The Council is of the opinion that, if a child has been brought up knowing the truth about his or her adopted origins, he or she may find it beneficial to be enlightened about the fact that he or she was rescued from the frozen state. As well as wanting to meet his or her true live siblings the person may also need to be counselled because of the effect of being a survivor compared to many of the other embryos who perished when defrosted.

4. Relationships between children resulting from donor gametes and their parents

4.1 In addressing the issues raised by the regulation of donor-assisted conception, the SCHB believes that it is very important to examine the deep bonds that exist between parents and their offspring. For example, many parents, as the responsible partners in the creation of life, know that in some way they belong to the child and the child in receiving life belongs to them i.e. there exists a sort of mutual belonging.

The deep sense of loss or incompleteness felt by parents, unable to be directly responsible for the creation of life in their child, is the essential reason for their interest in assisted reproduction as opposed to, for example, adoption. In other words, the costly and sensitive procedures considered by all families seeking artificial conception are a pointer to the importance they attach to the biology of creation. They apprehend the possibility of their own inability to feel a sense of belonging with the child and the difficulties the child itself may experience in feeling that it did not belong to them.

4.2 This apprehension is also reflected in published reports which suggest, for example, that when Assisted Insemination by Donor (AID) has been used, the commissioning (non-genetic) father is significantly more reticent than the commissioning (genetic) mother of informing the child of its biological origins. Moreover, it has been indicated that only 21% of AID parents, in the Netherlands, have decided to inform their child of the way in which they were conceived compared to 94% of parents who have not used AID. [11]

More recently, researchers found that in 46 families in England with a child up to age of 8 who had been conceived through sperm donation only 13% had already told their child and 26 % said they intended to. But 43 % had decided against it and 17 % were still unsure what they would do. [12],[13]

And an earlier European study of donor insemination families in the UK, Italy, the Netherlands and Spain found that only 12% of the mothers had planned to tell the child about his or her conception procedure, while 75% had decided not to do so. By the time the children reached 11-12 years old, only 8.6% of parents had told their children about their conception procedure. [14]

This is all the more worrying since 50% of donor insemination children suspect, when growing up, that their social father may not be their genetic one before being told. [15]

But why do so few parents inform their children of the manner in which they were conceived? An answer may be found if the deep and important bonds which exist between the parents and their child are considered.

Other examples of the importance of the biological parent-child bonds:

Other perspectives of the strength of the parent-child bond can be noted in the following examples:

4.3 The dilemma faced by the two women Natalie Evans and Lorraine Hadley who lost their High Court battle, in 2003, to use the frozen embryos created with the help of their former but now estranged partners against their will. [16] It was, indeed, very clear to all that one of the main reasons why both men had refused to give permission was that they felt that some kind of bond would exist between them and the child which they did not want.

4.4 The assumed strength of the biological parent-child bonds which is reflected in the fears that many gamete donors have concerning the lifting of anonymity. For example, 90 % of UK clinics are already reporting a shortage of donors, and fertility experts expect the situation to get worse in April 2005, when donors lose their right to anonymity. [17]

4.5 Recent research results which show that more than four out of five US children conceived using donor insemination with an identifiable sperm donor would be likely to ask the identity of their donor and try to contact him. This would happen either when that information was available to them at the age of 18 or sometime later in their lives. Many said that they would also like to contact any other children of the donor. [18] But why do they want this contact?

4.6 The fact that UK clinics are expected to strive, as far as possible, to match the ethnic background and physical characteristics of gamete donors to those of an infertile partner; thus, in a way, making sure that the possible child is seen (in a visual sense) to 'belong' to its parents. [19] In this regard, Olivia Montuschi from the Donor Conception Network, which represents families of children conceived after sperm or egg donations, insisted that it was vital for children to share physical characteristics with their parents. She also indicated that "*If a child is significantly different in any way, either in physical characteristics or intellectual attainment, then it can make it harder for them to feel part of that family.*" [20] But why is it so important that children feel part of the family? Does this not reflect a deep sense of bonding or communality which should exist between the biological parents and the child?

4.7 The extremes to which some persons, such as Mr. David Blunkett, will go in order to prove their paternity over a child. But what, exactly, do these people feel towards the child they claim is 'theirs' and why do they go to such lengths? Moreover, it is interesting to note that, in Mr. Blunkett's case, the judge indicated that it was in the child's best interests to have his parentage determined at the earliest opportunity by a court ordering scientific tests. [21]

4.8 The more than 116,000 frozen human embryos that are presently stored in UK clinics resulting from IVF. This has

arisen because parents may [22],[23]:

- (1) Want to implant these embryos at a later date into the biological mother.
- (2) Be unsure of the moral status of these human embryos and therefore not want to see them destroyed either outright or in research.
- (3) Not want to give these embryos up for adoption because of the 'bonds' that exists between them and the embryos. In the UK, despite the high number of left-over embryos, only around 190 embryos/year are donated to infertile couples who cannot create their own. [24]

In this respect, Professor Ian Craft, director of the London Fertility Centre, said: *"It surprises me that so few couples agree to donate spare embryos if you consider the desperation of infertile couples to have children."* Adding that *"there are very few babies to adopt and so I would have thought these couples, who have been through infertility treatment themselves and who have completed their families, would be more sympathetic to others."* He also indicated that society should be making people more aware of the benefits that these supernumerary embryos may represent to childless couples. [25]

5. Concerns of the SCHB relating to Donor-Assisted Conception

5.1 The SCHB notes that Donor-Assisted Conception is not risk free for the woman giving the eggs since many eggs must be retrieved from female patients and this is not without the risks of ovarian hyperstimulation syndrome following aggressive hormonal treatments. [26]

5.2 It remains the Council's concern that some media-highlighted cases of obvious gamete insemination and embryo implantation errors have taken place. This has arisen when obvious racial differences were noticed. It is not known how often other true mistakes have occurred when racial characteristics were not present.

5.3 The SCHB notes that parents who use donor insemination are often bringing a child into the world in order for him or her to relate to themselves while often ignoring the relationship the child may want to have with his or her genetic parents. Though the parents may concede to tell their child the truth when they are older, they would then have to understand that the child may wish to see and know his or her genetic parents and express a sort of a 'love' which he or she may already experience. The child may also experience difficulties towards his or her genetic or social parents with the possibility of feeling a sense of rejection.

5.4 The SCHB is, therefore, of the opinion that until the above questions are answered satisfactorily concerning:

- (1) the important bonds that exist between the biological parents and the child, and
- (2) the unease the general population has concerning donor insemination,

then the possibility of promoting donated gametes in order to address infertility should not be envisaged. Accordingly, the SCHB cannot reply to the other questions posed by the HFEA in its consultation entitled ***The Regulation of Donor-Assisted Conception*** without undermining its stance that such procedures should not proceed until further investigations are undertaken and the serious doubts concerning these procedures are addressed.

1. For example, 90 % of UK clinics are already reporting a shortage of donors, and fertility experts expect the situation to get worse in April 2005, when donors lose their right to anonymity. In A. Frean, Couples may get chance to design the 'ideal' IVF baby, TIMESONLINE, 12 November 2004: <http://www.timesonline.co.uk/article/0,,2-1355182,00.html>

2. This includes haematopoietic peripheral blood, umbilical-cord (blood) and bone-marrow stem cells, reproductive cells (eggs, sperm), foetal tissue and cells and adult and embryonic stem cells. The Directive does not include organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body. After receiving EU legal advice it is also thought to cover human embryos but only with respect to their quality and safety aspects.

3. Comes into force on the 7th of April 2006.

4. The provisions of this Protocol, applicable to tissues, also apply to cells, including haematopoietic stem cells. However, the Protocol does not apply (1) to reproductive organs and tissue (comprising ova, sperm and their precursors); (2) to embryonic or foetal organs and tissues including embryonic stem cells; (3) to blood and blood derivatives.

5. Additional Protocol to the European Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin (ETS No. 186): <http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=186&CM=8&DF=12/10/04&CL=ENG>

6. Explanatory Report6 of the Additional Protocol on transplantation of organs and tissues of human origin:

<http://conventions.coe.int/Treaty/en/Reports/Html/186.htm>

7. The Regulation of Donor-Assisted Conception, HFEA, 2003, paragraph 8.
 8. The Regulation of Donor-Assisted Conception, HFEA, 2003, paragraph 21.
 9. Sarah-Kate Templeton, Spare embryos 'should be donated to infertile couples', The Sunday Herald, 21 September 2003: <http://www.sundayherald.com/36912>
 10. This should take account of the risk of incest if many embryos are adopted in a common location.
 11. Brewaeyts, A., Golombok, S., Naaktgeboren, N., de Bruyn, J.K., Van Hall, E.V., Dutch parent's opinion about confidentiality and donor anonymity and the emotional adjustment of their children, Human Reproduction, Vol.12, No.7, (1997)
 12. Sperm donation — should you tell your child?, Reuters, <http://www.msnbc.msn.com/id/6866305/>
 13. Poor couples 'want IVF anonymity', BBC News, 26 January 2005, <http://news.bbc.co.uk/1/hi/health/4205661.stm>
 14. Golombok et al, The European Study of Assisted Reproduction Families: The transition to adolescence, Human Reproduction, Vol. 17(3): 840-40 (2002)
 15. Mary Braid, Your daddy was a donor, The Observer, 20 January 2002, <http://observer.guardian.co.uk/review/story/0%2C6903%2C636020%2C00.html>
 16. Women lose embryo battle - BBC - 1 October 2003, <http://news.bbc.co.uk/1/hi/health/3151762.stm>
 17. A. Frean, Couples may get chance to design the 'ideal' IVF baby, TIMESONLINE, 12 November 2004: <http://www.timesonline.co.uk/article/0,,2-1355182,00.html>
 18. Children Positive about Sperm donors, BioNews No. 284, 15 November 2004
 19. This is also reflected in paragraph 18 of the HFEA consultation which states that: Clinics usually offer recipients gametes or embryos from donors who are a close physical match to the people receiving treatment. This is thought to be in the interests of the family concerned so that donor-conceived members of that family do not 'stand out' and risk becoming socially stigmatised as a result. Additionally, some recipients want donors with a certain background for non-genetic reasons, for example because they want a donor who shares their religion.
 20. A. Frean, Couples may get chance to design the 'ideal' IVF baby, TIMESONLINE, 12 November 2004: <http://www.timesonline.co.uk/article/0,,2-1355182,00.html>
 21. Blunkett wins right to seek access, BBC NEWS, 3 December 2004: http://news.bbc.co.uk/1/hi/uk_politics/4065177.stm
 22. Sarah-Kate Templeton, Spare embryos 'should be donated to infertile couples', The Sunday Herald, 21 September 2003: <http://www.sundayherald.com/36912>
 23. Couples' feelings mixed about extra embryos, 14 October 2003 (Reuters Health): <http://www.stjudemedicalcenter.org/healthnews/reuters/20031014elin022.htm>
 24. G Fuscaldo, J Savulescu, Spare embryos: 3000 reasons to rethink the significance of genetic relatedness, Reproductive BioMedicine Online, Volume 10, No 2 February 2005, <http://www.rbmonline.com/4DCGI/Article/Detail?38%091%09=%201550%09>
- Studies reviewing the fate of surplus human embryos reveal that close to 90% of couples choose to discard their excess embryos and that hundreds of embryos are disposed of annually. It has been argued that human embryos are a valuable resource and that there is a need to consider educational programmes to encourage couples to donate spare embryos to other infertile couples, rather than discard them. Surveys show that one reason that so few embryos are donated is that couples attach great significance to genetic parenthood. Advances in reproductive technology may necessitate a review of biological definitions of family and the importance of genetic relatedness. It can be argued that it is unreasonable to conclude that genetic ties are so significant that embryos should be discarded rather than donated and raised by non-genetically related parents. It is suggested that education programmes should encourage reflection on people's beliefs about the importance of genetic relatedness with regard to what makes a family. Open embryo donation or directed embryo donation programmes might cause couples to change their minds, or alleviate their anxiety about donating embryos to others.
25. Sarah-Kate Templeton, Spare embryos 'should be donated to infertile couples', The Sunday Herald, 21 September 2003: <http://www.sundayherald.com/36912>

26. Delbaere, A., G. Smits, O. Olatunbosun, R. Pierson, G. Vassart, and S. Costagliola. 2004. New insights into the pathophysiology of ovarian hyperstimulation syndrome. What makes the difference between spontaneous and iatrogenic syndrome? *Human Reproduction* 19: 486-489.