Scottish Council on Human Bioethics

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Date: 8 December 2006 – Human Fertilisation and Embryology Authority

Consultation Paper on Donating Eggs for Research: Safeguarding Donors

Consultation response on behalf of the Scottish Council on Human Bioethics:

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan, non-religious registered Scottish charity comprising doctors, lawyers, psychologists, ethicists and other professionals from disciplines associated with medical ethics.

The SCHB subscribes to the principles set out in the ***United Nations Universal Declaration of Human Rights*** which was adopted and proclaimed by the UN General Assembly by resolution 217A (III) on 10 December 1948.

The SCHB is grateful to the HFEA for this opportunity to respond to the consultation entitled ***Donating Eggs for Research: Safeguarding Donors.*** It welcomes the HFEA's intent to promote public consultation, understanding and discussion on the matter.

In addressing the consultation, the SCHB has formulated the following responses:

Preliminary comments

1. Dissent about carrying out research on embryos per se.

The SCHB notes that UK legislation concerning embryo research is generally considerably more liberal than elsewhere in the world. Thus the Council is of the opinion that UK legislation should conform with relevant international declarations and conventions. In particular, we draw attention to the Council of Europe ***Convention on Human Rights and Biomedicine*** *(European Treaty Series - No. 164)* which has already been ratified by 20 European Countries, with another 14 signing their intent to ratify.
In this Convention*, Article 18 (2) (Research on embryos in vitro)* states that:

> "The creation of human embryos for research purposes is prohibited."

Consequently, the SCHB does not agree with the underlying premise of the current consultation. The Council moreover believes that the UK's reputation abroad would be severely undermined if it continues to refuse to ratify this Convention.

In addition, the SCHB does not agree that the proposed research is either 'necessary or desirable' and therefore may even contravene the ***Human Fertilisation and Embryology Act 1990.***

Moreover, the Council is concerned that the reasons given for justifying research (p. 5) include merely being 'desirable' 'to increase knowledge about the development of the embryo'. This could be used to justify practically anything, and falls a long way short of seeking remedies for serious diseases - which is the reason generally paraded as justifying research on embryos. The public are being encouraged to approve egg donation and research on embryos on the grounds that it will bring relief from serious disorders such as Alzheimer's and Parkinson's (p. 6); but if approval is gained, the guidelines could be used to allow (the donation of eggs for) research of the most trivial kind.

2. Anomalous distinction relating to donors of eggs for research that does or does not entail the creation of embryos.

The focus of the present consultation is the welfare of potential egg donors, not the ethical implications of the research itself. As the consultation document notes (footnote 1 on page 3), a licence is only required from the HFEA if the eggs are to be used to create embryos. Whilst we accept that, in the light of this, it is appropriate for the HFEA to limit this consultation to the use of eggs for creating embryos, we take this opportunity to highlight a serious failing in the law on this point.
Namely, it would appear that, provided the eggs are to be used for research that did not entail the creation of embryos, then potential donors would not have the protection of the guidelines and other regulations that are to be put in place as a result of this consultation. Clearly, since the women in question will be exposed to comparable risks, it makes no sense that they should not have comparable protection.
This inconsistency also exposes a potential loophole in the law whereby eggs ostensibly removed for non-embryo-forming research (and without taking appropriate steps to safeguard the women in question) could be clandestinely redirected to embryo research.
Consequently, the SCHB urges the HFEA to include this observation in its findings, and to recommend to the Government that this anomaly be rectified.

3. Egg sharing

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 (including eggs):

3.1. 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.

3.2. 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[1,2]

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.

3.3. 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)[3,4]

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

[1] 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.

[2] Comes into force on the 7th of April 2006.

[3] 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.

[4] 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

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[5] 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.

On 1 July 2003, Belgium began providing full reimbursement for six IVF cycles. In a recent article by Pennings and Devroey (2006) in Reproductive Biomedicine Online, the authors compared the numbers of egg sharers before and after this date. The main finding was a drop of approximately 70% which seems to confirm the fear that the majority of egg sharers donate to obtain a benefit in kind and because of restricted financial means.

Thus, the SCHB notes that, in the light and in the spirit of the legislation 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 or *"any other advantage whatsoever comparable to a financial gain such as benefits in kind or promotion for example"*. 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.
For the same reasons, any benefit in kind such as the reduction of fertility treatment costs encouraging the donation of eggs for research or the treatment of others would be completely unethical.
Thus, the SCHB is of the opinion that egg sharing does indeed amount to coercion, and that the alleged harm is likely or significant enough to amount to a sufficient and compelling reason to prohibit egg sharing.

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)."*[6]

[5] Explanatory Report[5] of the Additional Protocol on transplantation of organs and tissues of human origin: http://conventions.coe.int/Treaty/en/Reports/Html/186.htm

[6] The Regulation of Donor-Assisted Conception, HFEA, 2003, paragraph 8.

4. Destiny of embryos should gamete donors change their minds

The SCHB concurs that the HFEA should consider the destiny of embryos when gamete donors change their mind and no longer wish that their embryos (created using their gametes) be used for research.

Indeed, similar dilemmas have already occurred such as those faced by the two women Natallie 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[7].

5. Conflict of interest and egg sharing

The SCHB notes that there may be a conflict of interest in the procedure of obtaining consent for egg sharing and the use of eggs for research. This is because staff seeking consent from the patient may be working for a private fertility clinic for which the research results may be useful or important.

6. Giving Licences before consultations

The SCHB agrees that it was very inappropriate for the HFEA to announce that it had given a licence, in July 2006, to a Newcastle-based research team for women to give their eggs to research in exchange of treatment before a public consultation was undertaken.

The SCHB notes that the HFEA consultation indicated on page 4 that *"A licence Committee [of the HFEA] must consider applications when they are received and could not have delayed considering the application because a consultation on the same issue was being planned."*

The SCHB believes that this is an extremely concerning statement from the HFEA. Does this mean that it cannot refuse a licence because a consultation on a specific topic has not yet been undertaken?
The Council questions, therefore, this kind of irresponsible decision making process in which democratic and public consultation elements do not exist. In addition, the SCHB deplores such a practice which completely undermines public confidence in the consultations and work of the HFEA.

Answers to specific questions

SECTION A - Should egg donation for research be allowed?

1. Do you think that women should be able to donate their eggs to research,

a) as non-patient donors?

SCHB Response

No

Reasons:
In addition to the SCHB's fundamental disagreement to creating human embryos for research, the Council believes that it is irresponsible for women to be exposed to unnecessary risk in order to further this research. This is because:

(i) The potential value of research on embryos is over-stated. Although the reasons given to justify embryo research are usually that it will lead to cures of various serious disorders, any benefits are, at best, likely to be in the distant future and there are grave doubts that 'cures' will ever be realised using these techniques.

(ii) Conversely, the potential value of alternative research methods, such as using adult stem cells, is under-stated.

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[7] Women lose embryo battle - BBC - 1 October 2003, http://news.bbc.co.uk/1/hi/health/3151762.stm

(iii) The risks of egg removal procedures are under-stated. In up to 10% of IVF cycles, the extra hormones trigger ovarian hypertimulation syndrome (OHSS), in which fluid leaks from blood vessels, causing symptoms such as bloating and pain. Around 5% of cycles cause moderate or severe OHSS, with a risk of disabling strokes or even death. Indeed, for every 100,000 women undergoing IVF, about six will die[8]. To date (January 2006), only one death has been attributed to ovarian hyper-stimulation syndrome in the UK in approximately 500,000 stimulated cycles[9].

In this context we draw attention to the comment by Prof. Alison Murdoch of the Newcastle Fertility Centre in her written evidence to Parliament that "All women who successfully respond to superovulation will develop at least moderate OHSS"[10].

The SCHB notes that if such similar risks existed in the work-place of an employed person they would never be considered as acceptable.

Therefore, the Council believes that a woman should not be subjected to potentially life-threatening risks when it is of no benefit to her and of doubtful benefit to others. Indeed, it is hard to comprehend how the HFEA can be giving serious consideration to allowing women to be exposed to a potentially fatal procedure which has no potential health benefit to them.
Further, in the light of the deep misunderstanding about the potential values of embryo research and risks involved in egg donation, it casts doubts on whether the women in question are in a position to give properly informed consent.

b) through egg sharing arrangements?

SCHB Response

No

Reasons
It would appear that any 'egg-sharing' arrangement being considered is on the basis of the woman in question having an inducement such as reduced fees (or perhaps something more subtle such as a shorter waiting time) for her infertility treatment. This would clearly be tantamount to the commodification of human bodily parts by obtaining financial gain or comparable advantages.

Concerns related to the commodification of body parts are the coercion and exploitation of more vulnerable members of society.

2. Do you consider the medical risks of egg donation too great to allow non-patients to choose to donate eggs to research?

SCHB Response

Yes - for the reasons given in answer to Question 1(a).

3. Do you consider the ethical concerns so significant that people should not be able to choose to donate eggs for research?

a) for non-patient donors

SCHB Response

Yes - for the reasons given in answer to Question 1(a).

[8] Jo Whelan, Sex is for Fun, IVF is for Children, New Scientist, No. 2573, 21 October 2006, p. 43

[9] Making Babies: Reproductive Decisions and Genetic Technologies, Human Genetics Commission, January 2006, p.13.
[10] http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7we93.htm

b) for egg sharing donors

SCHB Response

Yes because there is an inducement - for the reasons given in answer to Question 1(b).

4. Do you consider egg donation for research to be significantly different to donation for treatment?

SCHB Response

The SCHB opposes both egg donation for research and treatment for the previously given reasons.

5. Do you consider the issues associated with non-patient donation for research to be different to those associated with egg-sharing for research?

SCHB Response

The SCHB opposes both non-patient donation for research and egg-sharing for research for the previously given reasons.