



British Fertility Society

response to the

Human Fertilisation and Embryology Authority

public consultation on

Donating eggs for research: safeguarding donors

December 2006

This document represents the British Fertility Society (BFS) response to the Human Fertilisation and Embryology Authority Public Consultation “Donating Eggs for Research: safeguarding donors”.

The British Fertility Society is a multi-disciplinary organization representing professionals with an interest in reproductive medicine. The objectives of the society are:

- To promote high quality practice in the provision of fertility treatment.
- To provide a common forum for members of various disciplines having an interest in the science and treatment of infertility.
- To promote high quality scientific and clinical research in the causes and treatment of infertility.
- To provide professional leadership in the provision and regulation of infertility services.
- To promote the increase of NHS funding for and equity of access to fertility treatments.

Therefore the use of human eggs in research studies is an important issue for BFS members.

To respond to this consultation, BFS membership were circulated by email and asked to send in their replies using the standard proforma. This response represents the majority view of those who replied and was compiled by Daniel Brison on behalf of the Executive Committee.

It is submitted by the Honorary Secretary whose contact details are:

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The society **agrees** to the making its responses publicly available by the HFEA in accordance with the Cabinet Office Code of Practice on Written Consultation. In addition the society will be making this response available on its website (<http://www.fertility.org.uk>).

Section A - General Views on Egg Donation for Research

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

a) as non-patient donors?

Yes

REASON: *Donation of eggs is likely to be required to further medical research in this area and non-patient donation is one of only two ways of obtaining high quality fresh eggs for this purpose. Women have the right as autonomous individuals to give informed consent for procedures which may yield great benefit to society.*

b) through egg sharing arrangements?

No (with minority dissenting view)

REASON: *Egg sharing for research is regarded by many BFS members as ethically unacceptable as it compromises the patient's chance of conception, especially as the numbers of embryos available for freezing will be reduced. In addition, compensated egg sharing is coercive and some members feel that this is ethically unacceptable. This is a controversial area and the BFS recognises that compensated egg sharing is currently licensed by HFEA for reproductive purposes and was supported by BFS during the SEED review. However, some members see a distinction between the sharing of eggs for a therapeutic purpose (i.e. the creation of a baby) and for research. In addition, embryonic stem cell lines derived from eggs from compensated egg sharing may not be accepted for use internationally, greatly reducing their potential application.*

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

No

REASON: *Risks are similar to those involved in IVF treatment, now available to millions of couples all over the world in the last 25+ years, with an estimated 3 million resulting babies. The accepted risks associated with ovarian hyperstimulation and egg retrieval are relatively low and readily quantified to allow informed consent by egg donors. The potential risks e.g. ovarian cancer, are unproven and are not sufficient in themselves to compromise informed consent. Women must be fully counselled as to actual and potential risks and enter the procedure for no financial gain. The safeguards as outlined in the consultation seem to be adequate.*

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?

No

REASON: *We do not feel that there are any ethical concerns other than those associated with medical risk, discussed in (2) above. The safeguards as outlined in the consultation seem to be adequate.*

b) for egg sharing donors?

Yes (with minority dissenting view).

REASON: *Many members of the BFS have profound objection to egg sharing de facto in view of concerns about potential coercion and compromise of treatment outcome, as in 1 (b) above. Others have taken the view that while compensated egg sharing raises ethical concerns it should be allowed as much for research as it is allowed for reproduction. Still others hold the view that reproduction is fundamentally different to research, and egg sharing may be acceptable for the former but not the latter. Non-compensated egg sharing (i.e. for purely altruistic reasons) is ethically more acceptable provided full information is given on the reduced success rates arising from the reduced number of eggs available for treatment.*

It would seem logical that the HFEA's position on the use of egg sharing for research should ultimately be consistent with its position on egg sharing for treatment as the ethical concerns re coercion/coercion of treatment outcome are similar. However if the HFEA concludes that egg donation for research and treatment are significantly different (see [4] below), then it is possible to allow egg sharing for one purpose but not both..

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

There were a number of views expressed with no majority consensus.

REASON: *Some members took the view that the motivation of patients donating for a reproductive purpose (i.e. the creation of a baby) is very different to that for research, as is the outcome of course. Some members see a further ethical and moral distinction between the two, being uncomfortable with the creation of embryos purely for research purposes, and expressing concerns over the destruction of such embryos. Other members took the view that the principle is the same: eggs are being provided either without compensation, which may compromise treatment, or with compensation, which is arguably coercive. This applies regardless of the intended use or fate of the eggs.*

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

Yes

REASON: *As described above, there are medical risks to non-patient donation, which do not apply to egg sharing as the patient is already undergoing those risks for her own treatment. Egg sharing gives rise to ethical concerns about coercion and the nature of the consent. This is not the case with non-patient egg donation where fully informed consent can be freely given.*

Section B - If Egg Donation for Research were to take place

The following measures are already in place. Do you agree that these measures should be applied to egg sharing and non-patient donation for research?

6. Safeguards in place to ensure informed consent.

a) Donors should be approached about the possibility of donating to research by someone independent and not involved in the research project that the eggs would be used in?

- for non-patient donors

Agree. This is standard procedure under current COREC guidelines and would be equally applicable under this setting.

- for egg sharing donors

Agree. This is standard procedure under current COREC guidelines and would be equally applicable under this setting.

b) Patients are expected to be provided with detailed information relating to the project, the likely outcomes and how the eggs donated to the project will impact on the work. e.g. for CNR and stem cell research, the chance of their eggs resulting in the development of an embryo, a stem cell line and a treatment for a particular condition.

Agree. This is standard procedure under current COREC guidelines and would be equally applicable under this setting.

c) Potential donors should have the option to talk to researchers about the work that they are carrying out.

Agree. This is standard procedure under current COREC guidelines and would be equally applicable under this setting.

d) Before consent is given, potential donors should be given information on the personal and financial benefits that the researchers may receive as an indirect result of the donation.

- for non-patient donors

Agree. This is standard procedure under current COREC guidelines and would be equally applicable under this setting.

- for egg sharing donors

Agree. This is standard procedure under current COREC guidelines and would be equally applicable under this setting.

Please use this space to give reasons or comment on any answers in this section referring to which answer your comment relates.

We are not sure why these questions are part of the consultation as they are standard in existing informed consenting in this field (a), and/or required under COREC (b, c, d) and surely unlikely to be inappropriate for egg donation to research?

A dissenting view from one BFS respondent was as follows:

By insisting that consent is taken by someone uninvolved in the research, it will become increasingly difficult for researchers to find individuals who can fulfil this function because (1) they could not be paid for on research grants (eg, research nurse/clinical fellow), (2) there is not sufficient spare time in most settings for clinical staff to do this and (3) it is normal to recognise someone's contribution to the research (eg, recruiting patients, gaining consent) through publications, which would presumably not be accepted because those named on publications have to have had involvement in the research and take responsibility for their involvement.

7. Safeguards in place to prevent potential conflicts of interest.

a) For egg sharing, the eggs should be divided into those for research and those for treatment by an embryologist who is not involved in the research project.

Agree

b) For egg sharing, prior to egg collection there should be an arrangement in place detailing which eggs will go to the research project and which to the patient.

Agree

c) Where donors are involved in an egg sharing agreement for research the centre should not have any policy or make any decisions that could impact adversely on the patient's chance of successful treatment.

Agree

Please use this space to give reasons or comment on any answers in this section referring to which question your comment relates.

For 7c, although highly desirable in principle, it is in fact impossible for egg sharing NOT to impact adversely on the patient's chance of successful treatment.

Section C - If Egg Donation for Research were to take place

The following additional safeguards could be introduced for donation to research. Do you agree with the following measures?

8. Possible additional safeguards to ensure informed consent.

a) Every donor should have a cooling-off period wherein she can withdraw her initial consent and wherein no effective treatment or donation can take place.

- for non-patient donors

Agree. This is standard procedure under current COREC guidelines and would be equally applicable under this setting.

- for egg sharing donors

Agree. This is standard procedure under current COREC guidelines and would be equally applicable under this setting.

b) Before consent is given, individual assessors should evaluate potential donors to ensure that they have not been coerced or pressured into donating eggs for research.

- for non-patient donors

Disagree

- for egg sharing donors

Disagree

c) Potential donors would be expected to see independent counsellors - that are not associated with the research group - to ensure that they have fully understood the implications of donation.

- for non-patients donors

Disagree

- for egg sharing donors

Disagree

d) Potential donors to research should have to answer a set of questions to ensure that they fully understand the research, the risks and the implications of donation.

- for non-patient donors

Disagree

- for egg sharing donors

Disagree

e) A licensed project should not obtain eggs from women involved in research or associated with the research institution.

Agree

f) Relatives of people who suffer from a condition that could potentially be cured as a result of research following egg donation should be subject to additional restrictions e.g. extra counselling or limitations on the specific projects to which they can donate.

- for non-patient donors

Disagree

- for egg sharing donors

Disagree

Please use this space to give reasons or comment on any answers in this section referring to which question your comment relates.

- a. *A short period of a few days would be reasonable and practical as consent is normally taken significantly earlier than the day of egg collection when the decision is made. A longer period might compromise treatment outcome further.*
- b. *This might be desirable in an ideal world but would be unworkable. It would be expensive to employ independent assessors, and patients would be deterred from consenting by the additional time and invasive nature of the assessment.*
- c. *Independent counsellors should be AVAILABLE, as in all licensed clinics, but donors who consent should not be obliged to see independent counsellors. Those undertaking egg sharing for research as part of their own treatment should be particularly encouraged to avail themselves of counselling opportunities.*
- d. *No, this would be unworkable and is highly invasive not to say insulting to patients, who would be deterred from consenting.*
- e. *It would be virtually impossible to obtain eggs from research workers with a guaranteed absence of coercion or conflict of interest.*
- f. *This again is rather insulting to the donors (see (b) and (d) above), and suffers from the further problem that embryonic stem cell technologies have a wide range of practical therapeutic applications. It would be impossible to isolate particular conditions that might impact on the donor's decision. Counselling on offer should be appropriate to the needs of the situation rather than of proscriptive nature.*

9. Possible additional safeguards to prevent potential conflicts of interest.

a) Formal consent to donation to research should be taken by someone not directly involved in the research project?

- for non-patient donors

Disagree

- for egg sharing donors

Disagree

b) Members of staff that may be considered to have conflict of interest regarding the research project should not be allowed contact with potential donors, or eggs until the eggs are passed into the research project.

- for non-patient donors

Agree

- for egg sharing donors

Agree

c) The medical treatment should be overseen by someone who is not involved in the research.

- for non-patient donors

Agree

- for egg sharing donors

Agree

Please use this space to give reasons or comment on any answers in this section referring to which question your comment relates.

- a. *It is more important to separate the consenting process from clinical treatment, as patients may feel coerced to give consent to those providing treatment services. This is clear in embryo donation to embryonic stem cell research and is the basis for the formation of the UK-wide human embryonic stem cell co-ordinators group (hESCCO). Ideally the consent should not be taken by a researcher, but this is not always practical and is less important as the researcher is not in a position to put the patient under pressure.*
- b. *This seems reasonable, except that the nature of any conflict of interest is not made clear?*
- c. *There is a clear need to separate clinical treatment from research, as in (a) above.*

10. The HFEA currently deals with whistleblowers from licensed clinics under its confidential complaints procedures. Do you think any additional measures should be put in place?

No

REASON: *The BFS feels that the existing system is adequate.*

Section D

11a. If all the measures to which you have agreed above were put in place by the HFEA, would you feel that women wishing to donate to research would be adequately protected?

Agree, for non-patient donation. It would be difficult to safeguard egg sharing patients completely as the fundamental nature of the coercion cannot be altered.

11b. What additional safeguards do you think would be required to ensure the safety of the donors?

If egg sharing donation is allowed, there would need to be strict safeguards covering the number of eggs which could be donated (for non-compensated egg sharing) and the amount of compensation available (for compensated egg sharing).

12. Please use this space to make any further comments on egg donation or egg sharing for research.

The BFS is disappointed that the consultation was not framed in a wider context, to include the fact that eggs are also available for research and embryonic stem cell derivation following IVF treatment cycles, when they are immature or have not fertilised. This is mentioned only as a single bullet point early in the document. The public should have been made aware that many tens of thousands of eggs are available from this source every year, and that at least one licensed project is using these to generate embryos for research and ES cell derivation. This context may have altered responses to a number of the questions as the case has not been made convincingly that fresh (as opposed to failed fertilise) eggs are REQUIRED for embryo research or ES cell derivation. At the moment this stands as an unproven hypothesis.

Other comments from members include the opinion that use of human oocytes for cell nuclear replacement is premature as the efficacy and potential benefits of this are not clear. Arguably the top priority for eggs donated to research should be research into reproduction, including fertilisation, meiosis and contraception.

Adequate resource of IVF in the state sector would obviate much of the need for egg sharing arrangements. The NICE recommendations for 3 cycles of treatment to be made available for appropriate patients should be fully implemented. The link between “demand from patients for egg sharing” and inadequate resource allocation is at the heart of the debate and the HFEA should acknowledge this in coming to its conclusions and make representation to the Department of Health accordingly.