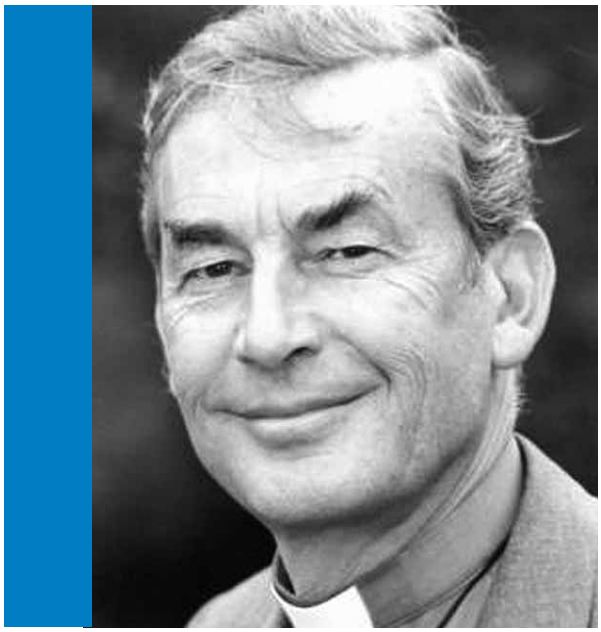
Donating eggs for research: safeguarding donors

Should egg donation for research take place and, if so, how can donors be best protected?

HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY

00 Chair's Foreward



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'Donating eggs for research: safeguarding donors' addresses concerns around the safety and interests of people wishing to donate eggs to research. New research is essential for the progression of science. However, where the research poses potential risks to donors, we should ensure that they are adequately safeguarded. The purpose of this consultation is to address the question of whether women should be allowed to donate eggs to research projects and, if so, how to ensure that their interests are best protected.

Embryo research using donated eggs must be licensed by the Human Fertilisation and Embryology Authority (HFEA). For embryo research to be licensed it must fulfil certain criteria. The research activity has to be necessary or desirable for one of eight research purposes, for example, to promote advances in the treatment of infertility or to increase knowledge about serious disease. It must also be necessary to use embryos in the project.

A further check that is made before licensing projects is how any material, such as eggs, to be used in the research is obtained. There are medical risks associated with the process of egg donation and some concerns have been expressed about women undertaking these risks for the sole purpose of scientific research. Women can donate eggs for treatment of infertile women and some people argue that if it is appropriate for women to donate for treatment then they should also be allowed to donate to research. In other words, it is for the person donating to decide how her eggs should be used – either for the treatment of others or for research.

As the HFEA may be asked to consider more applications for research projects that acquire eggs through donation in the near future, it is important that we consider the issues including having a wider public consultation. The purpose of this consultation is to give people an opportunity to comment on where they think the balance lies between protecting people from the risks of egg donation for research and the right to choose whether to donate and how the eggs that they donate should be used.

Please take the time to consider these issues and send us your views so that the Authority can make their decision based on as many views as possible. I look forward to receiving your opinions on this important issue.

Lord Harries of Pentregarth
Chair, HFEA, September 06

September 06

01 Introduction

This document sets out to identify the issues and gather the views of the public and interested parties on the issue of egg donation for embryo research. It will address the current situation around donation, including safeguards already in place to protect donors, current Human Fertilisation and Embryology Authority (HFEA) guidance around embryo research and some of the issues that we have identified in relation to egg donation specifically for research. Finally, we will identify potential problems associated with donation of eggs for embryo research and what possible additional safeguards could be introduced to ensure that donors are adequately protected if egg donation for research is to take place.

The questionnaire at the end of this document will allow you to tell us what you think about egg donation for research and whether it should take place, to comment on existing safeguards and suggest additional measures that you think should be in place to protect women donating eggs to embryo research. This information will help inform the HFEA's decision on egg donation for use in research projects.

02 General Information

The HFEA is responsible for regulating and licensing centres that carry out IVF treatments or embryo research. This includes the donation of sperm, eggs and embryos for use in the treatment of other people and the donation of, and use, of sperm, eggs and embryos in licensed research projects[1]. Before addressing some of the specific issues around donation for research, the existing practices of egg donation and HFEA guidance need to be considered.

Egg Donation for treatment

Eggs can be donated for use in treatment:

- as non-patient donors (all eggs are donated to the treatment of others)
- through compensated egg sharing arrangements (women undergoing IVF treatment choose to donate a proportion of their eggs for the treatment of others and in return receive reduced treatment costs).

The SEED review

The HFEA recently carried out a review of sperm, egg and embryo donation (the SEED review). This addressed issues around payment of donors, the appropriateness of egg sharing in general, screening of donors and import and export of gametes. Following the SEED review, new guidance was produced and some of this guidance could be applicable to the issue of egg donation for research, in particular guidance on payments for donors (Annex A) and egg sharing (Annex B). We are not reconsidering any of the issues that were addressed in the SEED review in this consultation, instead we will be focussing on those issues unique to egg donation for research, using the existing guidance as the framework within which the issues will be discussed.

[1] An HFEA licence is only required if embryos are to be created and / or used in research. Donation of egg and sperm for research that does not result in the creation of an embryo would not be regulated by the HFEA and therefore would not necessarily be subject to the same guidance and conditions.

Payment for donors

One issue addressed by the SEED review was that of payment for donation. The HFEA decided donors should not be paid for their donation but they should also not be out-of-pocket after donation – so the donation is 'expense neutral'. Accordingly, the decision was taken that donors can be compensated for all reasonable expenses occurred within the UK in connection with their donation. In addition to these expenses, it was agreed that donors should also be compensated for loss of earnings up to a predetermined limit. Some European countries offer donors inconvenience payment for donation as is permitted in the European Union Tissues and Cells Directive. The HFEA decided that inconvenience payments were inconsistent with the principle of donation being 'expense neutral' and therefore decided not to allow compensation for personal inconvenience for donors in the UK. This would also apply to donors wishing to donate specifically to licensed research projects (for the guidance, please see Annex A).

Egg sharing guidance

Egg sharing is when women undergoing IVF treatment choose to donate a proportion of their eggs for the treatment of others and in return receive reduced treatment costs. The practice of egg sharing was considered as part of the SEED review and the Authority decided that it could continue and new guidance was produced (Annex B). This guidance relates to the information that should be provided to donors and recipients, consent, counselling and the arrangement that should be in place for those involved in an egg sharing agreement. As part of the agreement, it is expected that the donor will be provided with information on the number of cycles covered by the agreement, the minimum number of eggs required for sharing and how these eggs will be allocated between donor and recipient. By having an agreement in place prior to egg collection, all participants will be fully informed of the arrangement prior to initiation of treatment.

02 General Information (continued)

Donation for Research

The HFEA currently licenses 33 embryo research projects. Of these, 15 licensed projects are to derive human embryonic stem cell lines. It has been proposed that these human embryonic stem cells could be used in research into treatments for conditions such as Alzheimer's, Parkinson's, Spinal Cord injuries and diabetes. The HFEA has also licensed projects to derive stem cells following cell nuclear replacement[2] and parthenogenesis[3].

Embryos and research

Currently licensed research groups obtain embryos for use in research through donation of embryos that are leftover after patients have undergone IVF (surplus embryos). Sometimes this is because the embryos are not suitable for use in treatment, in which case they can be allowed to perish or be donated to research. Or if a couple no longer requires their embryos they can allow them to perish, choose to donate them to research projects or donate them to the treatment of others.

Sperm and research

Sperm used in research can be obtained in several ways:

- From patients undergoing fertility treatment who donate sperm surplus to their requirements,
- From donors who have reached the limit of families to be born from their donation, or
- From donors that are specifically recruited to donate to research.

We are not aware of there being a shortage of sperm for research at present and the risks associated with sperm donation are considerably less than those associated with egg donation. For these reasons, the focus of this consultation will be on the donation of eggs for research but it is likely that any guidance developed as a result of this consultation would also apply to donation of sperm to research.

2 Cell nuclear replacement (CNR) is also known as cloning. It was using this technique that Dolly the Sheep was created.

3 Parthenogenesis is a process that occurs spontaneously or can be induced and is when an embryo initiates development without fertilisation.

Eggs and research

Eggs are currently made available to research projects from several sources:

- women undergoing gynaecological procedures e.g. sterilisation
- women undergoing follicle reduction (if too many follicles develop following ovulation induction, some of the eggs are removed prior to insemination to reduce the risk of multiple pregnancies)
- women having IVF treatment can opt to donate some eggs (usually 2) to research if more than 12 are collected
- eggs that did not fertilise following IVF (failed to fertilise eggs)

As well as the above sources, the HFEA have recently issued a licence to one research group to allow them to acquire eggs for research projects through an egg sharing arrangement. A Licence Committee 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. If, after due consideration, the Authority decides that egg sharing for research is not appropriate, it will be possible for the Licence Committee to review their decision for the egg sharing licence based on the new policy.

All women who donate eggs or embryos, created from their eggs, to research are told about the research projects carried out at their clinic or an associated fertility clinic prior to commencing treatment. If they express an interest in donating eggs and / or embryos they are given more detailed information and after having the opportunity to receive counselling and a detailed discussion with a qualified member of staff, often a research nurse, the donor is asked to sign the appropriate consent forms. As part of the HFEA inspection process we ensure that the woman's clinical treatment takes priority. We ensure that the doctor responsible for overseeing the woman's IVF treatment is not involved in the research project and, where possible, the embryologist who chooses the embryos to be used in treatment or frozen for later use is not involved in the research project.

02 General Information (continued)

Research guidance and licensing

A research licence can only be issued by the HFEA Licence Committee if it meets certain specific criteria. The research must be 'necessary or desirable' for one of the following purposes:

- To promote advances in the treatment of infertility
- To increase knowledge about the causes of congenital diseases
- To increase knowledge about the causes of miscarriage
- To enhance knowledge in the development of more effective contraception
- Detection of genetic or chromosomal abnormalities before implantation
- To increase knowledge about the development of embryos
- To increase knowledge about serious disease or
- To enable any such knowledge to be applied in developing treatment for serious disease[4]

After being shown to be necessary or desirable for one of the above purposes, the Licence Committee would also have to be satisfied that the proposed creation or use of an embryo is necessary for the research and that the patient information and consent forms are appropriate and adequate.

In addition to the guidance relating to licensing of research projects (Annex C), the *Code of Practice* also contains guidance relating to absolute prohibitions, as stated in the Human Fertilisation and Embryology Act 1990 (HFE Act 1990). These prohibitions include keeping an embryo for longer than 14 days and placing a human embryo in an animal. The guidance also states that before being approved by the HFEA, the application has to be approved by a research ethics committee. The full guidance for research is available at Annex C

The *Code of Practice* also contains details on providing information for research donors (Annex C). This includes guidance ensuring that the donor is provided with information so they are aware that donation would not affect or compromise any treatment, that they will have an opportunity to ask questions and discuss the research project and importantly that the donor can withdraw their consent at any time up until the gametes are used in research. This guidance also states that *'Only those fresh or frozen gametes (eggs and sperm) and embryos that are surplus to treatment will be used for research'*.[5] This would need to be considered further if it were decided that non-patient donation or egg sharing for research should take place as these types of donation could be considered to fall outside this guidance.

Stem cell research

For embryo research that results in the derivation of human embryonic stem cell lines, there are specific licence conditions (Annex D). These licence conditions ensure standards on information and consent specifically for patients whose donated sperm and eggs are used to create the embryos used for stem cell research. There are conditions that aim to remove potential conflicts of interest between acquiring material for research and patient care. Although these are currently applicable to stem cell research, some of the same principles could be applied to all research projects using material donated from patients. For example *'Your centre must ensure that clinical and research roles are separated, so that individuals involved in advising patients regarding clinical decisions about their licensed treatment are not involved in the research projects to which patients are considering donating.'* The full set of standard conditions can be found in Annex D.

4 *Schedule 2 to the HFE Act 1990 and HFE (Research purposes) Regulations 2001*

5 *Code of Practice 6th Edition 5.8ii*

02 General Information (continued)

Consent
For any medical treatment or examination every person has the right to give or withdraw consent. This is a legal requirement that is mentioned in the HFE Act 1990[6] and this is reflected in the HFEA guidance. The *Code of Practice* stresses the need for informed and voluntary consent to be obtained for the use, storage and donation of sperm, eggs and embryos. As well as consenting generally to the medical treatment, all people donating or storing sperm, eggs or embryos will also have to sign specific consent forms as detailed in the *Code of Practice* (Annex E). The Human Embryonic Stem Cell Coordinators (HESCCO) is made up of representatives from stem cell research groups and they have developed a set of standard consent forms for use in embryo research that could result in the derivation of human embryonic stem cell lines.

Medical law
As well as specific guidance issued by the HFEA on research and consent, there are also other important national and international guidelines and regulations, such as the Helsinki Declaration and the General Medical Council's (GMC) guidance that protect the rights of patients involved in research.

The Helsinki Declaration was introduced to protect people involved in medical research. The declaration states that people need to be adequately informed of the potential risks and the possible conflicts of interests to ensure that informed consent is obtained (text box). A similar provision is also found in the GMC's guidelines[7].

The Helsinki Declaration also makes reference to vulnerable donors by saying that the consent of these donors should be obtained by independent physicians who are not involved in the research program (text box) and this is again similarly reflected in the GMC's guidance.

The Helsinki declaration[8]
Consent
In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing.

Vulnerable donors
When obtaining informed consent for the research project, the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

Autonomy
A fundamental principle common to all the guidance discussed above is that of patient autonomy. Autonomy literally means self-rule and refers to a person's ability to make decisions – free from controlling influences – about things that will affect them. To make an autonomous decision a person must be:

- free from coercion, pressure or manipulation so that any decision taken is entirely voluntary;
- provided with adequate and accurate information including details of all the risks;
- able to (have the capacity to) make the decision.

6 Human Fertilisation and Embryology Act 1990 Schedule 3 (Consents to the use of gametes or embryos)
7 The GMC's "Seeking patient's consent: the ethical guidelines" 1998
8 World Medical Association declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects

03 What is involved in donating eggs?

Potential non-patient donors who are considering donating eggs would approach a clinic for information about donation. It is an HFEA requirement that all people considering donation are given the opportunity to receive counselling to discuss donation. This will include counselling on the medical risks and the psychosocial and ethical implications of donation. Patients will also be provided with written information about donation. Before donating, the donor will register and also sign consent to the use of the eggs following donation. For egg sharers, there will also be a specific agreement with details about consent, benefits in kind and arrangements for distributing the eggs (see Annex B).

After being given the opportunity to receive counselling and giving consent, the donor would begin the medical steps involved in donation.

1. The donor is given drugs, usually as a nasal spray, to stop their normal cycle. Once this has been achieved they are given another drug to stimulate super ovulation (the development of more than one egg). This drug is often injected and can sometimes be self administered.
2. The donor is monitored for the number of follicles that are developing and for any symptoms of ovarian hyperstimulation syndrome (OHSS – more information below). This is usually done by ultrasound analysis and/or blood tests.
3. When eggs are almost ready to be collected, another drug is injected to prepare for collection.
4. During egg collection the donor is usually given a sedative or anaesthetic.
5. The eggs are collected, most commonly using a thin tube and ultrasound guidance. The tube is inserted through the vagina into follicles containing eggs, and fluid including the eggs is drawn out through the tube.
6. Once collected the eggs are sorted by an embryologist and placed into culture dishes ready for further use.
7. If eggs are being donated to treatment, the eggs would then be used by the recipient/s for IVF. For egg sharers, a proportion of the collected eggs would be donated; the remainder would be used for the egg sharer's own treatment.

What are the medical risks involved in egg donation?
The long term consequences of taking the fertility drugs that are used when women donate are not known and there have been concerns expressed that exposure to these drugs may increase the chance of certain types of cancer developing later in life although to date there has been no conclusive evidence that would suggest that this is the case.

In the short-term, the fertility drugs that are used can cause donors to experience discomfort, mood swings, infections or bleeding as well as the risk of developing OHSS. Mild OHSS is relatively common (occurring in between 1-10% of treatment) and can be treated and controlled. Severe OHSS is rarer (occurring in around 1% of cases) and very rarely severe OHSS can be fatal. There are also risks associated with the type of anaesthetic or sedation that is used when the eggs are collected.

04 Why are we considering egg donation for research now?

Researchers say that they require good quality eggs, particularly – but not exclusively – for research involving CNR (therapeutic cloning). They suggest that the efficiency of the CNR technique could be improved by using recently collected eggs (rather than failed to fertilise eggs following IVF - which is the main source of donated eggs for research currently). Because of the desire for recently collected eggs, researchers have proposed obtaining eggs by donation specifically for use in research either through non-patient donation or through egg sharing schemes.

The CNR work carried out by Hwang and colleagues in South Korea – later shown to be falsified – has increased concerns about practices in this area. In the subsequent investigation into Hwang's work, it was shown that some of the eggs used in the project were donated by researchers in the laboratory (which might raise questions about the donor's consent) and there was significant underreporting of the number of eggs used in the project.

Because of concerns stemming from the incident in South Korea and because the HFEA is likely to be asked to approve more research projects that require eggs from non-patient donation or egg sharing schemes, we felt it was appropriate to carry out a consultation to give members of the public an opportunity to share their views on the issues raised by the donation of eggs for research.

Scientists indicate that CNR and stem cell research would benefit from increased availability of eggs and some of the discussion in this document will be focussed on this issue. However, it is important to remember that this is not the only research that could benefit from egg donation and it is likely that any output as a result of this consultation will apply to other types of research as well as to the donation of sperm for research.

September 06

05 What are we asking you?

This consultation is an opportunity for you to tell us what you think about egg donation (either through egg sharing or non-patient donation) for the purposes of embryo research. We want to gather the views of as many people as possible on the following issues:

- The appropriateness of non-patient donation for research
- The appropriateness of egg sharing for research (one centre has already been licensed for this)
- The safeguards and measure that should be in place to protect donors if egg donation for research was introduced
- Any additional comments on eggs being donated specifically for use in research

In the following section we address some issues that may affect your decision on the appropriateness of non-patient donation and egg sharing for research.

Non-patient donation - when a woman not having IVF treatment herself undergoes stimulation and donates all the eggs collected.

Egg sharing - when a woman undergoing IVF treatment donates a proportion of her eggs and in return receives reduced treatment costs.

06 Issues relating to egg donation for research

We have identified the following issues that may influence your decision on the appropriateness of donation of eggs for research.

Relative 'value' of donating for research
The value of donating eggs for someone else's treatment is that the recipient could become pregnant as a result of the donation. This benefit would be directly enjoyed by the parent/s of the child born as a result of donation. The chance of a pregnancy occurring as a result of one donation is relatively high (given that an average of 8-10 eggs are collected per donation and success rates with donor eggs are 25 to 40 per cent).

The value associated with donation for research resulting in embryonic stem cell derivation (discounting the benefit for the researcher in getting eggs) is likely to be more long-term. Egg donation for stem cell research could result in the possible development of treatments for conditions such as Alzheimer's, Parkinson's or for people affected by heart disease or spinal cord injuries. The value of these treatments will not be enjoyed immediately or even necessarily within the lifetime of those that donate (other research may have more immediate benefits). There is also no guarantee that this research will actually result in any treatment. On the other hand, if such treatments are developed, they would benefit many people within society. So, although there is a relatively small chance that any individual donation to stem cell research will result in the development of a specific treatment, any research that comes out of this work will potentially be of great value to society.

Inappropriate influence and egg sharing
By donating eggs to research or the treatment of others, egg sharers receive discounted treatment costs which could be viewed as equivalent to a substantial payment. Some people argue that this could act as an incentive for women to donate and is why some people believe that this is the same thing as donors being coerced into donation. If this were the case, the consent might be considered to be invalid because consent needs to be given free from coercion.

There are also concerns that egg sharing could result in injustice because less well-off women would be more likely to participate because they could not afford treatment if they did not. While the Authority would welcome greater National Health Service (NHS) provision of fertility treatment, currently it is clear that egg sharing enables women, who might not otherwise be able to afford it, to have access to fertility treatment. The Authority has decided that 'egg sharing does not amount to coercion, and that any alleged harms are not proximate, likely or significant enough to amount to a sufficient or compelling reason to prohibit egg sharing'[9]

Conflicts of interest and egg sharing
Conflicts of interest could occur when a patient is considering egg sharing for the purposes of research. The conflict could occur because a member of staff is involved both in a patient's (the donor's) care and in the research project which would use donated eggs. A conflict could arise, for example, if the member of staff discussing the research project with the potential donor overstates the potential benefits of the research so that the patient is more likely to donate. There are already safeguards in place that protect against these sorts of conflicts of interest. These will be addressed in the next section of the document.

9 *SEED Report – A report on the Human Fertilisation and Embryology Authority's review of sperm, egg and embryo donation in the United Kingdom (October 2005) www.hfea.gov.uk/consultations*

06 Issues relating to egg donation for research (continued)

Availability of eggs for treatment

Some women need to use donor eggs to get pregnant because they are unable to produce eggs, perhaps because of a premature menopause or cancer treatment. People may also wish to use donor eggs in assisted reproduction if a woman has had repeated miscarriages or if she has a medical condition that she wishes to avoid passing on. There is a shortage of donor eggs for use in treatment and therefore there are concerns that by allowing women to donate eggs to research, shortages of donor eggs for treatment could be compounded. It is likely that non-patient egg donation and egg donation through egg sharing would be differentially affected by donation for research and therefore each situation will be considered separately.

Non-patient donors

Non-patient egg donors that would donate to research might be a different group, with different motivations, to those non-patient donors that would donate to treatment. People who donate for research projects may be motivated by the development of medical treatments from the research for certain conditions because they have a relative affected by such a condition, or because they feel strongly about the moral obligation to participate in medical research. Non-patient donors that donate eggs for the treatment of others may have different motivations, for example, they may be motivated primarily by the possibility that they will help another woman to get pregnant, perhaps because they have had to use donor sperm or had difficulties getting pregnant themselves, because they know the recipient or because of the great value they associate with being a parent.

Egg sharers

It is possible that the donation of eggs to research through egg sharing arrangements may have more of an impact on the availability of eggs for treatment than non-patient donation to research. Unlike non-patient donors, those that might choose to donate to research through egg-sharing arrangements would be from the same pool of women who may otherwise have chosen to egg share for treatment. The proportion of women that may chose to donate to research instead of treatment is unknown. Infertility Network UK (INUK) are currently carrying out a survey on egg sharing and the findings of this will help us to better understand the motivations of egg sharers and the impact that any policy on egg sharing for research will have.

International issues

Although the HFEA does not have an international remit, human embryonic stem cell research is an international matter. Stem cell banks are established in several countries including the UK (the UK stem cell bank). It is a condition of all human embryonic stem cell licences issued by the HFEA that a sample of any stem cell line produced will be deposited in this bank. Stem cell lines can then be shared with other researchers in order to prevent unnecessary repetition of experiments and waste of valuable material.

We are aware that some stem cell banks may not accept stem cell lines that were derived from eggs obtained through an egg sharing agreement because of the perceived financial inducement (women who participate in egg sharing arrangements receive reduced treatment costs for the cycle in which they donated). This may mean that the stem cell lines produced as a result of an egg sharing donation would not be able to be used internationally. Although this is primarily an issue for researchers working in this area, egg sharing donors may prefer their donation to be used as widely as possible to ensure the maximum benefit to be obtained from their individual donation.

07 Potential problems and safeguards

There are already measures in place to protect people considering non-patient donation or egg sharing. However there could be additional measures introduced to ensure that donors wishing to donate specifically to research are protected.

We have identified some problems that could occur during donation for research and listed the existing measure that safeguards against this. We have also listed some additional safeguards that could be introduced. (see next section)

Existing safeguards

Situation	Potential Problem	Existing Safeguard
A researcher talks to a woman about the possibility of donating her eggs to research.	The researcher can underplay the risks of donation while overemphasising the benefits of research.	Potential donors are usually approached about the possibility of donating to research by staff not involved in the research project e.g. by the nurse coordinator.
Consent is taken by a member of the research team.	The person taking consent could pressure the donor into donating eggs for treatment so that eggs are available for the project.	Consent to donation for research is taken by someone not directly involved in the research project.
A donor signs the consent form.	After donation, research carried out results in a patent earning the researchers / research group significant financial benefits which the donor feels they are entitled to a share of.	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.
In egg sharing, following collection the eggs are sorted and divided into those for treatment and those for research by an embryologist.	Not many eggs are collected and the donor receives less than she expected for her treatment. The 'best' eggs are reserved for the research project leaving lower quality eggs for treatment.	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 and the minimum number of eggs required for sharing.
A woman agrees to donate eggs to research having been provided with information on the research.	The donor may have misconceptions about their donation thinking that their donation is likely to result in the development of treatment.	Donors 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.
A potential donor gets standard information on donating her eggs to research by an independent person.	She has some further comments and unanswered questions.	Every donor should have the possibility to talk about donation to the researchers before deciding whether to donate or not.
After receiving information on donation to research by an independent person, the woman decides to donate.	After the donation or after time for reflection or consulting the literature, changes her mind about choosing to donate her eggs to research	A donor can withdraw consent up to the point that the eggs are used in research.

07 Potential problems and safeguards (continued)

This section suggests additional safeguards that could be introduced to protect non-patient donors or egg sharers that may wish to donate to research.

Possible additional safeguards

Situation	Problem	Potential additional safeguard
Someone employed by a research project donates her eggs to a research project.	There is a possibility that she was coerced into doing this because she felt that her career prospects may suffer if she did not.	A licensed project should not obtain eggs from women involved in the research or associated with the research institution where the research is taking place.
A woman donates her eggs to a research project because someone close to her suffers from a disease for which stem cell research could lead to a cure for.	There is a possibility that she was pressured by her loved-one to do this on the chance that it might result in treatment.	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.
After being informed about research the donor decides to donate eggs.	The consent is not properly acquired either because there was coercion or the donor was not fully informed.	Before they consent, donors should be evaluated by an independent assessor to ensure that proper information was given.
A potential donor is considering donating eggs to research.	There are concerns about conflicts of interest throughout the whole process.	Potential donors would be expected to see independent counsellors to ensure that they have fully understood the implications of donation.
After receiving information on donation to research, the woman decides to donate.	The donor has not fully understood the information that was provided to her.	Members of staff that could be considered to have a conflict of interest should not be allowed contact with potential donors or eggs until the eggs are passed to research.
After receiving information on donation to research by an independent person, the woman decides to donate.	After the donation or after time for reflection or consulting the literature, she changes her mind about choosing to donate her eggs to research.	The donor should formally answer a set of questions on donation and research before donation can be carried out. 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.

Questions

Personal Information

Name:

Organisation:

Email:

Address:

Position in organisation (if applicable):

Please indicate the nature of your interest in the Egg donation for research review.

In line with the Cabinet Office Code of Practice on written consultation, responses to this consultation may be made public unless specifically requested. Do you agree to the HFEA making your response publicly available?

YES / NO

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? ☐ YES ☐ NO

REASON

b) through egg sharing arrangements? ☐ YES ☐ NO

REASON

2. Do you consider the medical risks of egg donation too great to allow non-patients to choose to donate eggs to research? ☐ YES ☐ NO

REASON

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 ☐ YES ☐ NO

REASON

Questions (continued)

b) for egg sharing donors ☐ YES ☐ NO
REASON

4. Do you consider egg donation for research to be significantly different to donation for treatment? ☐ YES ☐ NO
REASON

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 ☐ NO
REASON

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 ☐ DISAGREE
- for egg sharing donors ☐ AGREE ☐ DISAGREE

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 ☐ DISAGREE

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

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 ☐ DISAGREE
- for egg sharing donors ☐ AGREE ☐ DISAGREE

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

Questions (continued)

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 ☐ DISAGREE

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 ☐ DISAGREE

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 ☐ DISAGREE

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

SECTION C - IF EGG DONATION FOR RESEARCH WERE TO TAKE PLACE

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

8. 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 ☐ DISAGREE
- for egg sharing donors ☐ AGREE ☐ DISAGREE

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

- for non-patient donors ☐ AGREE ☐ DISAGREE
- for egg sharing donors ☐ AGREE ☐ 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-patient donors ☐ AGREE ☐ DISAGREE
- for egg sharing donors ☐ AGREE ☐ 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 ☐ AGREE ☐ DISAGREE
- for egg sharing donors ☐ AGREE ☐ DISAGREE

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

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 ☐ AGREE ☐ DISAGREE
- for egg sharing donors ☐ AGREE ☐ DISAGREE

Questions (continued)

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

9. 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 ☐ AGREE ☐ DISAGREE
- for egg sharing donors ☐ AGREE ☐ DISAGREE

b) Members of staff that may be considered to have a 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 ☐ DISAGREE
- for egg sharing donors ☐ AGREE ☐ DISAGREE

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

- for non-patient donors ☐ AGREE ☐ DISAGREE
- for egg sharing donors ☐ AGREE ☐ DISAGREE

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

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?

☐ AGREE ☐ DISAGREE

REASON

Questions (continued)

SECTION D

11a. If all of 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?

☐ YES ☐ NO

(If no please answer 11b)

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

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

How to respond

This discussion is open to any organisation or individual who wishes to respond. We will continue to receive responses until the 8th December 2006.

On-line

If possible, please respond by answering the questions on the HFEA website at www.hfea.gov.uk/consultations

Email

Please follow the format of the questions of the questionnaire. Answer the questions in as much detail as is required and email to eggsforresearch@hfea.gov.uk

By post

If preferred, you may answer the questions on the questionnaire in the printed out document and send to the following address:

Donating eggs for research: Safeguarding donors
Human Fertilisation and Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

For further information

If you would like any further information please contact Dr Katy Berry, Policy Manager by post or email on the addresses given above.

Annex A

Donor Payment Guidance[10]

1. Individual donors of gametes

2. Individual donors of gametes may be given money or other benefits for the supply of their gametes, subject to the conditions of these Directions.

3. In money or money's worth, a donor may be reimbursed reasonable expenses which he or she has incurred, within the UK, in connection with the donation.

4. Donors may be compensated for loss of earnings (but not for other costs or inconveniences) up to a daily maximum of £55.19 but with an overall limit of £250 (or the equivalent in local currency) for each course of sperm donation or each cycle of egg donation.

5. There is no restriction on the value of other benefits which may be given to the donor, but the only benefits which may be offered for this purpose are treatment services. These services should be provided to the donor in the course of the donation cycle unless there is a medical reason why they cannot be provided at that time.

6. No establishment may accept as a donor any individual who is known by that establishment to have received or to be about to receive, or who is reasonably suspected by that establishment to have received or to be about to receive:

   a) money or money's worth in excess of reasonable expenses incurred in connection with the donation or compensation for loss of earnings permitted by these Directions;

   or

   b) other benefits of a kind not permitted to be given under these Directions, received through the means of and/or with the assistance of any agency or other intermediary.

Meaning of terms

10. In these Directions, the terms listed have the meaning shown:

- "money's worth" means anything which could be sold for money, or used to obtain goods or services, but does not include services themselves;
- "other benefits" include services and also include benefits which cannot be measured in money;
- "course of sperm donation" means the period beginning at the first consultation and ending once the sample has been released for use in treatment;
- "cycle of egg donation" means the period from the first consultation until the donor's recuperation is complete.

[10] *DIRECTIONS GIVEN UNDER THE HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990 (Giving and receiving money or other benefits in respect of any supply of gametes or embryos.)*

Annex B

EGG SHARING GUIDANCE (extract)

Terms used in this guidance

Egg sharing – an arrangement whereby a woman undergoing treatment agrees to provide a certain portion of the eggs collected during her treatment cycle to be used in the treatment of others

Compensated egg sharing – an egg sharing arrangement in which the egg provider receives her own treatment at a discounted price, in accordance with HFEA Directions[11]

Egg provider – a woman who agrees to supply a number of the eggs collected from her in the course of her own fertility treatment to be used for the treatment of others

Egg recipient – a woman who receives eggs supplied by the egg provider as part of an egg sharing arrangement

Egg sharing agreement – an agreement between either an egg provider or an egg recipient and the centre providing treatment. An egg sharing agreement is not enforceable between a centre and patient but failure on the part of the centre to abide by the terms of the agreement will constitute a failure of compliance with the Code of Practice which may be taken into account by a licence committee.

Procedure

In addition to standards and the procedures that centres are expected to adopt in treating egg donors and recipients of donated eggs:

Welfare of the child and the assessment of those seeking treatment

1. Treatment centres should provide the opportunity for the egg provider and egg recipient to receive counselling from different, independent counsellors.
2. Treatment centres are expected to make available additional impartial support (e.g. a member of the nursing staff not involved in the treatment of either egg provider or recipient) to all parties during the egg sharing cycle.

Information

3. Before the egg sharing cycle begins egg providers and recipients should be provided with separate written information which should include:
   (i) a description of the criteria used for the selection of women providing and receiving eggs in egg sharing arrangements
   (ii) a description of how the centre proposes to determine the allocation of eggs between provider and recipient(s)
   (iii) a description of the screening that a woman providing eggs in an egg sharing arrangement will undergo
   (iv) a description of the terms of the agreement to be entered into (see below)
   (v) a description of the law relating to consent, in particular the rights of a woman providing eggs to vary or withdraw her consent and the implications of her doing so
   (vi) a description of available alternative treatment options

Consent

4. The egg provider's consent should be recorded in such a way as to allow different conditions to be placed on the use of eggs and the use and storage of embryos created for the egg provider's own treatment, on the one hand, from conditions placed on the use of eggs and the use and storage of embryos created for the treatment of the recipient(s), on the other hand[12]

[11] *Directions D.2006/1*

[12] *This may be achieved using the current HFEA consent forms as follows:*
(ii) the egg provider should complete one 'HFEA (00) 7' form in respect of the use of her eggs and embryos created for her own use as she were an IVF patient
(ii) the egg provider should also complete a second 'HFEA (00) 7' form in respect of the use of her eggs and embryos created for the treatment of the recipient(s) as if she were an egg donor
(iii) each sperm provider (usually the husband or partner of, respectively, the egg provider and recipient(s)) should complete form 'HFEA (00) 6'

Annex B (continued)

EGG SHARING GUIDANCE (Continued)

5. Centres should emphasise to both the egg provider and recipient(s) that the egg provider may withdraw or vary her consent up to the time that an egg, or embryo created using her eggs, is transferred to a woman, used in a project of research or allowed to perish. The possible consequences of this should be made clear to both the egg provider and the recipient(s) before the egg sharing cycle begins and should be set out in the written patient information included with the egg sharing agreement.

Counselling

6. Independent counsellors should be aware of the medical procedures and the legal and social issues relevant to egg sharing arrangements.
7. Centres should encourage couples who intend to participate in an egg sharing arrangement to undergo implications counselling. Counselling should cover:
   (i) the implications of receiving information about the outcome of the treatment of the person(s) with whom the eggs are shared
   (ii) the implications of either the egg sharer or recipient(s), both the egg sharer and recipient(s), or neither the egg sharer nor recipient(s) having a live birth as a result of the treatment, in particular:
   (a) where both the provider and recipient(s) have a live birth, the implications of half-siblings who may not know each other being born and growing up as contemporaries
   (b) where a recipient has a live birth and the egg provider does not, the implications of a recipient having a live child whilst the egg provider might remain childless
   (iii) the implications for the recipient(s) of using the eggs of a woman who is herself undergoing treatment
8. [….]

Egg sharing agreements

9. Licensed treatment centres offering an egg sharing arrangement should draw up separate agreements with the egg provider and with the egg recipient(s). The centre's agreements with an egg provider and with those receiving eggs from that provider should be consistent with each other. Centres should abide by the terms of egg sharing agreements they have made.
10. Where benefits are offered to an egg provider those benefits should be given in connection with the cycle in which eggs are supplied for the treatment of a recipient unless there is a clinical reason to defer them. Where such a reason exists the egg provider may elect to donate all the eggs collected in the initial cycle and to take advantage of the benefits in a subsequent cycle.[13]
11. Eggs collected from an egg provider in a single cycle should not be shared among more than two other recipients.

[13] *See General Directions D.2006/1*

Annex B (continued)

EGG SHARING GUIDANCE (continued)

Agreement between a licensed centre and an egg provider

The agreement between the treatment centre and the egg provider is expected to set out the terms of the arrangement in full. It is expected to identify clearly the egg provider and the treatment centre, and to be signed by both parties. The agreement is expected to include:

(i) […]

(ii) Treatment

- A full description of the what the treatment is expected to involve, including:
  - (a) the number of cycles of treatment covered by the agreement
  - (b) the date upon which treatment will commence
  - (c) full details of the terms of the egg sharing arrangement
- A statement from the egg provider confirming that she has:
  - (a) had an opportunity to discuss the treatment procedures involved in providing her eggs as part of an egg sharing arrangement with a qualified member of the treatment centre's staff
  - (b) received both verbal and written information about the treatment to be provided
  - (c) received all the appropriate information listed in the relevant parts of the HFEA's Code of Practice (written information should be attached to the agreement)
  - (d) been offered counselling about the implications of the treatment

(iii) Consent

- A statement confirming:
  - (a) that the patient's consent to the treatment has been obtained
  - (b) that the egg provider's consent to the use of eggs/creation, use and storage of embryos has been recorded appropriately
  - (c) that the agreement does not override the terms of paragraph 4 of Schedule 3 to the HFE Act 1990 (i.e. that the egg provider may withdraw or vary her consent in respect of any embryo created using her egg at any time until that embryo is transferred to a woman, used in a project of research or allowed to perish)
  - (d) the consequences of any variation or withdrawal of consent, and the liability of the parties involved for any additional charges that may be applied

(iv) Charges

- A statement describing:
  - (a) what charges (if any) are expected to be paid to the treatment centre by the egg provider
  - (b) if the egg provider's treatment is provided at a discounted cost, the circumstances that would result in the egg provider being liable for the total cost of her treatment and the total sums she would have to pay[14]

(v) Arrangements for distributing eggs

- Full details of the proposed arrangements for distributing the eggs between the provider and recipient(s), including:
  - (a) the minimum number of eggs required for sharing
  - (b) the number of recipients among whom eggs will be shared[15]
  - (c) how these eggs will be allocated between the provider and recipient(s)

Full guidance can be found on the HFEA website www.hfea.gov.uk

[14] Where an insufficient number of eggs are collected for sharing the egg provider is expected to be given the option of using all the eggs at no additional cost to her.

[15] This should not exceed two, excluding the egg provider.

Annex C

RESEARCH GUIDANCE

Code of practice - chapter 10

10.1 Research involving the creation, keeping or use of human embryos outside the body must be licensed by the HFEA. Research centres must apply to the HFEA for separate licences in respect of each separate research project.

10.2 The HFEA may only grant licences for research projects if it appears to the HFEA that the activity to be authorised by the licence is necessary or desirable for one or more of the following purposes:

(i) To promote advances in the treatment of infertility

(ii) To increase knowledge about the causes of congenital disease

(iii) To increase knowledge about the causes of miscarriages

(iv) To develop more effective techniques of contraception

(v) To develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation

(vi) To increase knowledge about the development of embryos

(vii) To increase knowledge about serious disease

or

(viii) To enable such knowledge to be applied in the development of treatments to combat serious disease

10.3 The HFEA will not grant a research licence using human embryos unless it is fully satisfied that the use of human embryos is necessary for the purposes of the research.

10.4 The following activities are prohibited by the HFE Act:

(i) Placing animal gametes or embryo(s) in a woman

(ii) Keeping or using an embryo after the appearance of the primitive streak or after 14 days – whichever is the earlier

(iii) Placing a human embryo in an animal

(iv) Replacing a nucleus of a cell of an embryo with a nucleus taken from the cell of any person, another embryo or a subsequent development of an embryo

(v) Altering the genetic structure of any cell while it forms part of an embryo

10.5 Embryos which have been appropriated for a research project must not be used for any other purposes.

10.6 Before the HFEA approves a research license, it is expected that each research project will be referred to a properly constituted ethics committee for approval.

10.7 Research centres within the NHS are expected to refer research projects to the relevant Multiple Centre Research Ethic Committees and/or Local Research Ethics Committee (LREC).

10.8 Research centres outside the NHS may also refer research projects to the LREC by prior arrangement or may set up their own committees which are expected to be independent and consist of no fewer than five members. The chairman of this committee is expected to be independent of the centre concerned. No more than one third of the membership of such a committee is expected to be employed by or have a financial interest in the research centre.

10.9 Membership of the Ethics Committee is expected to be approved by the HFEA. For further information concerning the creation and operation of a research ethics committee, research centres are expected to contact the Department of Health.

10.10 Proposals for research projects involving the use of embryos will be submitted to appropriate academic referees chosen by the HFEA for peer review.

10.11 Medical practitioners are bound to follow the General Medical Council's guidance set out in Research: the Role and Responsibilities of Doctors published in 2002. In particular in relation to funding and payments:

(i) All financial interests and sums of money known or estimated to be paid for the research must be disclosed to a research ethics committee

Annex C (continued)

RESEARCH GUIDANCE (Continued)

(ii) Payments are expected not to be offered at a level which could induce research participants to take risks that they would otherwise not take, or to volunteer more frequently than is advisable or against their better interests or judgement

(iii) Participants must be given information on how the research is funded, including any benefits which would accrue to researchers and/or their departments

(iv) There must be honest and full responses to participants' questions, including enquiries about direct payments made and any financial interests in the research project or its sponsoring organisations

(v) Ensure that everyone in the research team, including nurses and non-medical staff, is informed about the way in which the research is being financed and managed

10.12 The attention of research centres is also drawn to those paragraphs of this *Code of Practice* dealing with:

(i) 6.5 – 6.24 consent to storage and use of gametes and embryos

and

(ii) 8.4 – 8.9 the use of gametes and embryos which have been subject to procedures that might prejudice their developmental potential and

(iii) 8.10 – 8.12 the termination and disposal of embryos which have been used for research

Information for research donors Code of practice – chapter 5

5.8 People consenting to the use of gametes or embryos for the purposes of a research project may specify conditions subject to which the gametes or embryos may be so used and are expected to be given the following information:

(i) Research is experimental and any gametes and embryos used and created for the purposes of any project of research will not be transferred for treatment and

(ii) Only those fresh or frozen gametes and embryos that are surplus to treatment will be used for research

and

(iii) Research will not affect the treatment cycle and

(iv) The donation of gametes or embryos for research will not compromise treatment and

(v) They are under no obligation to donate gametes and embryos for research and

(vi) They have the right to vary or withdraw their consent from any project of research at any time up until the gametes and embryos are used for the purposes of such research project and

(vii) They are expected to have an opportunity to ask questions and discuss the research project and

(viii) After the research has been completed, all donated gametes and embryos will be allowed to perish

5.9 If donated gametes and embryos could be used in secondary research, those consenting are expected to be so informed and given the following further information:

(i) The possibility that gametes and embryos, or embryo cell samples, may be fixed for future studies and that such research is called secondary research and

(ii) Secondary research could include genetic research (and the resulting implications) and

(iii) As a means of protecting confidentiality, gametes and embryos for secondary research may be anonymised but that this may be reversible and

(iv) If gametes and embryos are to be reversibly anonymised and if genetic research were to be proposed, those considering donation are expected to be offered counselling about the implications and

(v) If gametes and embryos were to be irreversibly anonymised, those considering donation are expected to be fully informed of the implications, that is to say, the inability to feed results back and

(vi) If embryos are to be used for stem cell research, it is expected that those considering donation are given thorough and appropriate information, including that any stem cell lines created may continue indefinitely and may be used in different research projects

5.10 Where any genetic research is to be carried out on identifiable samples, or those capable of being identified, it is expected that explicit consent will be obtained. This should be preceded by information about the research project and what, if any, information may be fed back to the donor.

Annex D

STANDARD LICENCE CONDITIONS APPLICABLE TO STEM CELL RESEARCH

Standard licence conditions applicable to stem cell research

With respect to any programme of research involving or with the intention of involving human embryonic stem cell creation the following conditions apply:

a. your Centre must ensure that a designated individual who is not directly involved in the patient's treatment is available to discuss with patients the project of research and the possibility of donating material to the project;

b. your Centre must ensure that clinical and research roles are separated, so that individuals involved in advising patients regarding clinical decisions about their licensed treatment are not involved in the research project to which patients are considering donating embryos;

c. your Centre must uniquely label each embryo donated to the research project in accordance with any directions and/ or guidance issued by the Authority;

d. before patients give consent to donation of their embryos for use in the research project, they must be given oral information supported by relevant written material which confirms:

   i. the specific research project, including any tests may be performed as part of the licensed research project on embryos or cells derived from the embryos;

   ii. that any stem cells lines created may continue indefinitely and be used in many different research projects;

   iii. that the decision whether to donate will not affect their treatment in any way;

   iv. whether the embryos will be reversibly or irreversibly anonymised, and the implications of this;

   v. whether any information will be fed back to the donors;

   vi. that the donors can vary or withdraw the terms of their consent until the point the embryos are used in the project of research;

   vii. that once an embryo has been used in the project of research the donors have no control over any future use of the embryonic cells and any stem cell lines derived;

   viii. that stem cell lines derived in this project will be deposited in the MRC Stem Cell Bank and the implications of this including that they may be used for other projects;

   ix. that stem cell lines must not be generated from donated embryos where the consent from the relevant donors, or one of them, places a constraint on future use;

   x. that cell lines may be used for commercial purposes, but that the donor will not benefit financially from this;

   xi. that any cell lines derived, or discoveries made using them, could be patented, but that the donor will not benefit financially from this;

   xii. how the research is funded, including any benefit which will accrue to researchers and/ or their departments.

e. your Centre must ensure:

   i. that a sample of all stem cell lines derived from embryos that are developed or used in the course of the research project be deposited in a stem cell bank in accordance with any relevant bank guidelines;

   ii. that the remainder of all stem cell lines (in so far as not used or destroyed as part of or in the course of the research project) be deposited in the stem cell bank in accordance with any relevant bank guidelines.

f. your Centre must submit a six monthly progress report of the research project to the HFEA. The report must include a complete audit of all embryos donated to research since the start date of the research project and such other information as the Authority may specify in directions.

Annex E

CONSENT GUIDANCE

6.1 All people generally have the right to withhold or give consent to examination and treatment3.

General guidance on this matter is given in the Department of Health's:

(i) Good Practice in Consent implementation Guide: consent to examination or treatment

(ii) Reference Guide to Consent for Examination or Treatment

(iii) The RCOG's "Gynaecological examinations: Guidelines for Specialist Practice" (July 2002) and

(iv) The GMC's "Seeking patient's consent: the ethical considerations" (1998).

6.2 Unless there are exceptional circumstances, treatment centres may not examine or treat people without first obtaining their consent. The only exceptional circumstances which are likely to arise in the course of infertility treatment services are:

(i) Where the procedure is necessary to save the patient's life and

(ii) The treatment cannot be postponed and

(iii) The patient is unconscious or mentally incapacitated and cannot indicate their wishes

6.3 For consent to be valid it must be:

(i) Given voluntarily (without pressure or undue influence being exerted to accept treatment)

(ii) By a person who has capacity to consent to such treatment and

(iii) Upon receipt of sufficient information to enable them to understand the nature, purpose and implications of the treatment treatment centres are expected to give patients sufficient time to consider this information before giving consent.

Consent to the presence of observers

6.4 If a member of the treatment centre's team wishes an observer to be present when an individual is being examined, treated or counselled, they are expected to explain, preferably beforehand, who the observer is and why this is desirable. The centre is expected to provide appropriate information and ask the individual whether or not there is an objection. If the individual objects, the observer is expected not to attend.

General Obligations

6.5 Treatment centres have an obligation to take all reasonable steps to ensure the valid identity of all persons accepted for treatment, including male partners who might not often be seen in the centre during treatment. Where there is doubt about a patient's identity, this is expected to include the examination of photographic identification evidence such as photo card driving licences and passports. Centres are expected to document this evidence in the patient records.

6.6 To avoid the possibility of misrepresentation or mistake (e.g. where patients present for treatment with new partners) centres are expected to check the identities of patients against identifying information held in the patient's file.

6.7 Treatment centres are expected to allow individuals seeking treatment, considering donation or storage sufficient time to reflect upon their decisions before obtaining their written consent. It is expected that a copy of the signed consent form will be provided for those who have given consent.

6.8 Individuals may specify additional conditions subject to which their gametes or embryos may be stored or used. Consent may be varied or withdrawn at any time providing that the gametes and embryos have not already been used in treatment services or research.

6.9 Gametes must not be taken from anyone who is incapable of giving a valid consent, or has not given a valid consent to examination and treatment and effective consent to the use or storage of those gametes.

Annex F

PARTIAL IMPACT ASSESSMENTS

Partial Regulatory Impact assessment (RIA)
A regulatory impact assessment addresses the possible impact that the options contained within this consultation could have on centres, patients, researchers or other stakeholders often paying particular attention to the financial impact on small businesses.

It is not anticipated that the options proposed in this document will have any negative impact on centres, patients or donors as they are largely only supplementing existing practices. It is not anticipated that any proposals would affect competition between licensed centres. However, we would welcome comments if you consider that any of the proposed measures would have a financial or competition impact on licensed centres. Please send any comments to eggsforresearch@hfea.gov.uk

Partial Equality Impact assessment (EIA)
Proposed policies must be subject to screening and those identified as having significant implications for equality of opportunity following such a review must be subject to full impact assessment. Each policy must be considered in relation to the seven equality categories. These are age, disability, ethnicity, faith, gender, human rights or sexual orientation.

Egg donation is an issue that primarily affects women and therefore it is impossible to address the question of whether it is appropriate to donate eggs for research without considering it solely on behalf of the woman (therefore any policy would affect women differently to men). There are medical risks associated with donation that are unique to women because sperm donation is a considerably less invasive process. In order to decide whether donation for research is appropriate, it is essential to consider egg donation and sperm donation as unique issues. Having said this, many of the safeguards that are proposed if egg donation to research is to go ahead, could be equally applicable to sperm donation and it is intended that any new guidance developed could apply to sperm donation for research.

A full equality impact assessment may not be required for this consultation because it is not anticipated that any of the policies or safeguards suggested in the consultation would impact differentially (positively or adversely) on any of the groups identified above. If you have any comments on this or can identify any measures that may impact differentially on any of the equality groups listed above, please send us your views to eggsforresearch@hfea.gov.uk

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