DONATION OF HUMAN EGGS FOR RESEARCH

A REPORT BY
THE BIOETHICS ADVISORY COMMITTEE

SINGAPORE

November 2008

FOREWORD

The use of human eggs in biomedical research is not new. For many years researchers have successfully used eggs to investigate the causes and treatment of infertility. However, new directions in research and a growing concern with the ethics of egg donation have prompted the present Report. Research with human eggs is no longer confined to research into infertility. Increasingly, it is part of a much wider inquiry into the properties of stem cells and their potential clinical applications. In addition, the ethics of egg donation have received recent attention and publicity because eggs are also a valuable fertility resource, and are sought after for use in fertility treatment. The demand for eggs for fertility treatment and for research raises the possibility of exploitation of women for their eggs.

The ethical aspects of egg donation also take on an added importance when it is recognised that donation is not without risk to the donor. In general, the ethics of donation of tissue raises issues of safety, informed consent and compensation. The BAC thus views it as timely to review the ethics of egg donation for research, and the regulatory implications that may follow from such a review.

This Report is the outcome of over a year of deliberation, in the course of which consultations were made with civic, religious, medical and scientific bodies, and international guidelines and best practice were reviewed. Local and international experts were consulted, and a public forum was organised. The result is a total of seven recommendations, dealing with consent, compensation and care of donors, the import and use of eggs in research, and the need for regulatory control.

I hope this Report and its recommendations will help support research whilst ensuring that it is done in an ethical way. I would like to thank all who have given the BAC their views. Comments from concerned organisations and individuals were all considered and have helped shape the eventual position the BAC has adopted. I would also like to thank Professor Lee Eng Hin, Chair of the Working Group that produced this report, and the members of the Group, for their time and effort.

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Chairman
Bioethics Advisory Committee
November 2008

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The Bioethics Advisory Committee (BAC) was established by the Singapore Cabinet in December 2000 to examine the ethical, legal and social issues arising from research in the biomedical sciences and to develop and recommend policies on these issues. It aims to protect the rights and welfare of individuals, while allowing the biomedical sciences to develop and realise their full potential for the benefit of mankind.

The BAC reports to the Steering Committee on Life Sciences (formerly the Life Sciences Ministerial Committee).

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   Centre for Biomedical Ethics, National University of Singapore; and Centre for Ethics in Medicine, University of Bristol, UK

DONATION OF HUMAN EGGS FOR RESEARCH

EXECUTIVE SUMMARY

1. This Report addresses the ethical, legal and social issues raised when human eggs are donated for research and highlights the importance of ensuring that the eggs are obtained ethically. The Report follows a public consultation conducted by the BAC from 7 November 2007 to 7 January 2008.

2. The procedure by which eggs are obtained is invasive and carries some risk and inconvenience, which are accepted by women seeking fertility treatment, but probably deter altruistic donation by women not undergoing any treatment. Women donating eggs for treatment or research are exposed to this risk as part of the process of obtaining their eggs. The main risk lies in the development of ovarian hyperstimulation syndrome, a condition which may be life-threatening if severe, although such cases are rare.

3. The informed consent of the donor is a fundamental requirement when any human tissues, including eggs, are donated for research purposes. It is important that this requirement is met in the case of women considering donation of eggs for research.

4. In the case of a donor undergoing fertility treatment, it is also important that her consent be taken independently of the treatment team. Consent should be taken only if she has indicated a willingness to donate her surplus eggs for research after discussing the fate of such eggs with her physician. She must be certain that she will not require these eggs for future use and must also have decided that she does not want to donate them for the fertility treatment of others.

5. The Report considers the issue of compensation for egg donation, and the associated risk of exploitation through commercialisation of eggs, either as an explicit policy or as an unintended consequence of substantial compensation amounting to an inducement. Recent developments in relation to compensation of egg donors in Europe and North America highlight continuing concerns over the potential trade of eggs across national boundaries and the exploitation of women.

6. It is the view of the Bioethics Advisory Committee (BAC) that altruism should be the basis of egg donation, as is already reflected in legal prohibitions on commercial transactions in eggs. Women should not be compensated for the donation of eggs for research when these are surplus to fertility treatment or obtained as a result of other medical treatments. It does, however, consider that women not undergoing any treatment, who donate eggs specifically for research, should be compensated for loss of time and earnings in addition to reimbursement of expenses directly incurred in donating. Such compensation must not amount to an inducement, and should not be tied to the actual number or quality of eggs provided.

7. The BAC is of the view that all research with human eggs should be regulated, and that the standards applicable to the donation of eggs for research in Singapore should also apply to eggs obtained abroad and used in Singapore.

LIST OF RECOMMENDATIONS

Recommendation 1
The procurement and use of human eggs for research should be regulated.

Recommendation 2
Consent for the donation of human eggs for research should be obtained without any coercion or inducement. Potential donors must be provided with sufficient information in an understandable form, and given adequate time to make an informed decision.

Recommendation 3
Donors should be informed that they have the right to withdraw consent or vary the terms of consent any time before their eggs are actually used in research.

Recommendation 4
Consent for the donation of eggs for research from women undergoing fertility treatment should be taken independently of the treatment team. The donors should confirm in writing that they do not require these eggs for future reproductive use.

Recommendation 5
Women undergoing ovarian stimulation specifically for research should be provided with prompt and full medical care when complications occur as a direct and proximate result of the donation. Responsibility for this provision should rest with the researchers and their institutions.

Recommendation 6
Egg donors should be compensated only for loss of time and earnings as a result of the procedures required to obtain the eggs, and only if the eggs were obtained specifically for research purposes, and not as a result of clinical treatment. Such compensation should be in addition to any reimbursement of expenses incurred. The relevant regulatory authority should determine the appropriate amount of such compensation.

Recommendation 7
The procurement or use of human eggs from any source by procedures not consistent with the recommendations in this Report should be prohibited.

DONATION OF HUMAN EGGS FOR RESEARCH

I. Introduction

1.1 The Bioethics Advisory Committee (BAC) was established in December 2000, to examine the ethical, legal and social issues arising from biomedical research and development in Singapore, and to recommend policies to the Steering Committee on Life Sciences (formerly called the Life Sciences Ministerial Committee).

1.2 Donating eggs for fertility treatment has been practiced for more than two decades and is considered a well-established method for helping women who have problems conceiving. In contrast, the donation of eggs for research is more recent, and mainly follows from advances in embryonic stem cell research. Such research is important in contributing to our basic knowledge of the nature and potential of stem cells. This understanding is generally viewed as the key to unlocking the potential of stem cell therapy for serious and currently untreatable diseases, such as diabetes, Alzheimer's disease and Parkinson's disease.

1.3 However, the availability of human eggs for research is limited as donors are almost invariably women undergoing fertility treatment, which naturally takes priority over any donation of eggs for research. Moreover, the invasiveness of the medical procedures involved in obtaining the eggs entails some risk to the donors. Thus safety and ethical concerns arise, the most important being the possibility that vulnerable women may be exploited, through various forms of inducement to provide eggs for research. Associated with this is also the risk of commercialisation of the body.

1.4 At a practical level, the difficulty lies in determining whether any payment or compensation should be given to egg donors, and if so, the appropriate form or amount, and how to regulate it. It is also necessary to consider if it is ethically acceptable for researchers to obtain eggs from women who are not undergoing fertility treatment, in which case similar concerns arise.

1.5 The need for guidance on the donation of eggs for research, and ethical issues of equity, compensation and the welfare of donors, formed the basis of a public consultation conducted by the BAC from 7 November 2007 to 7 January 2008. A Consultation Paper,[1] set out in Annex A, was sent to 94 research, governmental and healthcare institutions (including 21 fertility clinics), and professional and religious organisations for comment. A list of these institutions

1 Bioethics Advisory Committee, Singapore, *Donation of Human Eggs for Research: A Consultation Paper,* 7 November 2007.

and organisations is given in Annex B. Feedback was also received from members of the public through various means including email, and an online discussion forum and e-consultation managed by REACH.[2] A public talk on the subject was held on 22 November 2007.

1.6 Opinion on the following issues was solicited:

(a) Whether healthy women not undergoing fertility treatment should be allowed to donate eggs for research, and if so, under what conditions;

(b) Whether egg donors for research should be compensated for time, inconvenience and risk, and if so, what type of compensation or monetary amount would be acceptable, and not amount to an inducement;

(c) Whether there are circumstances in which the compensation for eggs could amount to a sale, and if so, whether such a sale should ever be contemplated; and

(d) Any prohibitions, limits or regulatory mechanisms that should govern the supply and use of human eggs for research in Singapore.

Respondents were also invited to raise any other matters of concern related to the donation of human eggs for research.

1.7 Written responses from 23 organisations, institutions and individuals were received and are set out in Annex C. A summary of the views received through the online discussion forum and e-consultation is provided in Annex D. This Report was finalised after careful consideration of the feedback and suggestions from the various organisations as well as the public. The recommendations take into account advice, comments and suggestions from local experts and the members of the BAC's International Panel of Experts. The BAC also considered two background papers on this subject prepared by experts in this area. Annex E consists of these two papers.

2 REACH (Reaching Everyone for Active Citizenry @ Home) is an agency set up by the Singapore Government to engage and connect with its citizens. http://www.reach.gov.sg/

II. Human Eggs in Research

2.1 Human eggs are required for embryonic stem cell research, and research into human fertility. The eggs can be used without being fertilised, for example, in studies into methods of egg maturation and preservation, or they can be used to create embryos.

2.2 An embryo can be created from an egg through *in vitro* fertilisation (IVF) by a sperm or through technologies such as somatic cell nuclear transfer (SCNT)[3] and parthenogenesis.[4] Stem cells can be derived from embryos thus created, and are useful for research that has the potential of understanding disease processes and finding cures for them. SCNT has the advantage of producing patient-specific cells that would not be rejected, when used for treatment.

2.3 Recently, several research groups have demonstrated that human skin cells can be transformed into cells with properties similar to those of embryonic stem cells through the introduction of specific genes into the cells.[5] Such cells are called induced pluripotent stem cells or iPS cells. This could lead to the creation of disease-specific or patient-specific cells, which are useful for further research into understanding the disease process or for clinical applications. However, it is still too early to decide whether this technology can replace the derivation of stem cells from embryos through IVF or cloning technology.

2.4 Human eggs are not readily available, and currently, most eggs for research are from women who have undergone fertility treatment. These could be surplus eggs which were not used for treatment, eggs that had failed to fertilise, or they could be immature eggs that were unsuitable for fertilisation. Other sources of eggs for research include cadavers, aborted foetuses and women undergoing medical procedures such as the removal of their ovaries.

2.5 Theoretically, it might also be possible to create eggs from embryonic stem cells, and eggs created this way could then be used in research. In 2005, researchers in the UK demonstrated that human embryonic stem cells displayed a capacity to generate immature gametes.[6] However, while it has been possible

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3 Also sometimes referred to as research cloning or therapeutic cloning. SCNT involves the transfer of the nucleus of a somatic (differentiated) cell into an egg cell, the nucleus of which has been removed.

4 The process whereby the development of an organism starts in an egg that has not been fertilised.

5 Takahashi K et al, Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors, *Cell*, 131 (2007): 1-12; and Yu J et al, Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells, *Science*, 318 (2007): 1917-1920.

6 Aflatoonian B and Moore H, Germ cells from mouse and human embryo embryonic stem cells, *Reproduction*, 132 (2006): 669-707.

to create mouse eggs from mouse embryonic stem cells,[7] research on creating human eggs from human embryonic stem cells is still in the preliminary stages.

2.6 As eggs from fertility treatment are often all fertilised *in vitro* to ensure sufficient embryos for implantation, or are retained for future use by the woman herself or donated to other couples undergoing fertility treatment, insufficient eggs are available for research. Indeed, scientists have indicated that the scarcity of human eggs is a major limiting factor in stem cell research. In some leading scientific nations, the possibility of obtaining eggs from women not undergoing any form of medical treatment (i.e. healthy women) has been considered. There are however significant ethical questions to be considered if this is done. These questions are discussed in Part IV below.

7 Hubner K et al, Derivation of oocytes from mouse embryonic stem cells, *Science*, 300 (2003): 1251-1256.

III. Procedures and Risks Involved in Egg Donation

3.1 The procedures which a woman has to undergo in order to obtain eggs for fertility treatment or for research are essentially the same, and it is important that she understands the procedures and risks involved.

3.2 Donating eggs is a time-consuming process, associated with a certain degree of discomfort and possible health risks. A woman has to undergo stimulation of her ovaries through multiple hormone injections, followed by close monitoring of the development of her eggs through ultrasound scans and blood tests. Thereafter, the eggs are collected under mild anaesthesia via a special needle attached to an ultrasound vaginal probe. One can expect an average of between 20 to 40 injections under the usual regimes of ovarian stimulation.

3.3 Ovarian stimulation carries some health risks, because it can lead to a condition called ovarian hyperstimulation syndrome (OHSS). In addition, egg retrieval may cause excessive bleeding or infection. As the procedure of egg retrieval is done under mild anaesthesia, there are also risks associated with the type of anaesthesia administered. However, the risks in egg retrieval are relatively low. In a review of more than 4000 cases in an egg donation programme over a period of about seven years, it was found that the incidence of moderate to severe OHSS was 0.54% and that of complications related to egg retrieval was 0.4%.[8]

3.4 Mild OHSS is relatively common, affecting up to 10% of women undergoing ovarian stimulation, usually between five to nine days after egg retrieval. The condition can be easily managed without hospitalisation and usually resolves spontaneously within several days. Severe OHSS is rare but will require urgent medical attention. It is of late-onset (occurring between ten days to three weeks after egg retrieval) and is often associated with pregnancy. Women undergoing ovarian stimulation specifically for the purpose of donating eggs for research are unlikely to develop severe OHSS, as pregnancy is not expected to follow the retrieval of eggs. More details on the clinical aspects of ovarian stimulation are provided in the background paper (1) in Annex E.

3.5 There is some documented evidence that ovarian stimulation, which exposes women to increased concentrations of hormones, may lead to an increased risk of future cancers of the breast, ovary and uterus, although the risk appears low.[9] While the possibility of long term effects still needs further study, and current findings are not consistent or conclusive, it is not possible to rule out such effects. In view of possible health risks, the American Society for Reproductive

8 Bodri D, Complications related to ovarian stimulation and oocyte retrieval in 4052 oocyte donor cycles, *Reproductive Biomedicine Online,* 17, no. 2 (2008): 237-243.

9 Brinton L, Long-term effects of ovulation-stimulating drugs on cancer risk, *Reproductive Biomedicine Online*, 15, no. 1 (2007): 38-44.

Medicine has recommended limiting the number of stimulated cycles that a donor should undergo to about six.[10]

3.6 Women who are less than 30 years of age, with low body weight, irregular menstrual cycles, or polycystic ovaries are at increased risk of developing OHSS. OHSS can be prevented by careful exclusion of such less suitable egg donors, judiciously minimised use of the drugs given for ovarian stimulation, and close monitoring of the individual's response to the drugs. It is the responsibility of the attending physician to advise on whether a woman should undergo ovarian stimulation and to ensure that the risk of OHSS is reduced as much as possible in every case.

10 American Society for Reproductive Medicine, Practice Committee Opinion, Repetitive oocyte donation, *Fertility and Sterility*, 86 Suppl 4 (2006): S216-217.

IV. Ethical, Legal and Social Considerations

General Ethical Principles

4.1 Certain ethical principles have formed the basis of the BAC's recommendations in its various reports. These can be summarised as follows:

(a) *Respect for individuals*. The autonomy of individuals is to be respected, and their welfare and interests are to be protected, especially when their ability to exercise their autonomy is impaired or lacking. This principle underscores the importance of informed consent, respect for privacy, safeguarding confidentiality, and it also entails a proper regard for religious and cultural diversity;

(b) *Reciprocity*. The BAC has interpreted the idea of reciprocity between the individual and the wider society as an expression of the well established idea that there is some implicit recognition of mutual obligation that regulates the relationship between the individual and society. In biomedical research, agreed social benefits – as a public good – carry an implication that, if accepted, they inherently reflect an in-principle willingness to consider participation in research of the kind yielding the accepted benefits. This means that there is a balance to be struck between the interests of the public and the rights of individual participants, and that incompatible and irreconcilable ethical perspectives should be resolved with regards to the public interest;

(c) *Proportionality*. The regulation of research should be in proportion to the possible threats to autonomy, welfare or public good;

(d) *Justice*. The idea of justice as applied to research includes the general principle of fairness and equality under the law. This implies that access to the benefits of publicly funded research, and the burden of supporting it, should be equitably shared in society. It also implies that researchers incur a responsibility for the welfare of participants and their possible compensation or treatment in the event of adverse outcomes arising directly from their participation; and

(e) *Sustainability*. The research process should be sustainable, in the sense that it should not jeopardise or prejudice the welfare of later generations. For example, research leading to permanent change to the human genome would not be considered ethical, on the grounds that the long term implications are unforeseeable and might not be beneficial.

Ethical Governance of Research Involving Human Eggs

4.2 It is important to ensure that human eggs for research are obtained in a manner based on internationally accepted ethical principles and practices. The general principles for research involving human participants will ordinarily apply, although there are certain issues, such as informed consent and compensation, that need special consideration. In addition, caution must be taken to ensure that no one is exploited, especially vulnerable individuals who are financially disadvantaged or in dependent relationships.

4.3 The BAC notes that the International Society for Stem Cell Research (ISSCR)[11] and the California Institute for Regenerative Medicine (CIRM)[12] have provided details on the informed consent process, which includes information to be provided to prospective donors, monitoring of recruitment practices, rigorous review to ensure that reimbursements or financial considerations of any kind do not constitute an inducement, and the requirement that egg procurement procedures be done by medically qualified and experienced physicians, using carefully controlled ovarian stimulation to reduce the risk of OHSS and ensure that women do not undergo excessive ovarian stimulation for research.

4.4 These requirements are consistent with the framework for ethical governance recommended by the BAC, whereby any biomedical research in Singapore that involves a human subject, personal information or human tissue will need to undergo a process of ethics review by an institutional review board (IRB) prior to the commencement of the research. Ethics review ensures, among other things, that participation in research, whether in person or through the contribution of biological tissue or information, presents minimal harm, is voluntary and on an informed basis.

4.5 In addition, research that involves human eggs and embryos is subject to legal regulation and scrutiny by the Ministry of Health (MOH). The MOH regulates hospitals and clinics that provide assisted reproduction services under the Private Hospitals and Medical Clinics Act. The Assisted Reproduction (AR) Directives promulgated under the Act require all research on human eggs (including those obtained from excised ovarian tissue) or on human embryos to be subject to prior written approval from the MOH.[13] While it is already a requirement for the procurement of eggs for research to be performed by medically qualified physicians in licensed institutions, the BAC is of the view that all research with eggs, and all procurement of eggs, in any premises whatsoever, should be regulated.

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11 International Society for Stem Cell Research, *Guidelines for the Conduct of Human Embryonic Stem Cell Research*, December 2006.

12 California Institute for Regenerative Medicine, *The CIRM Medical and Ethical Standards Regulations*, 2007, chapter 2.

13 Ministry of Health, Singapore, Licensing & Accreditation Branch, *Directives for Private Healthcare Institutions Providing Assisted Reproductive Services: Regulation 4 of the Private Hospitals and Medical Clinics Regulations* (Cap 248, Reg 1), March 2006, paragraph 8.1.

Recommendation 1
The procurement and use of human eggs for research should be regulated.

Privacy

4.6 A number of respondents to the BAC's public consultation emphasised that researchers should respect the privacy concerns of donors and safeguard any confidential information that has been entrusted to them. The BAC is in agreement and reiterates its view that personal information that is used in research should be de-identified as far and as early as possible, and should be stored or transferred as de-identified information.[14]

Informed Consent

4.7 Intrinsic to the principle of respect for individuals is the requirement that potential egg donors should freely decide whether or not to contribute eggs for research. Their consent must be given without coercion or inducement, and on the basis of information that is sufficient and appropriately presented. Potential donors should also be provided with adequate time to make an informed decision. In addition, they should be informed that they have the right to withdraw consent or vary the terms of consent at any time before their eggs are actually used in research.

4.8 To ensure that a potential donor is fully informed before making a decision to donate eggs for research, the consent taking process should include the following information, insofar as applicable:

(a) the purpose and nature of the research;

(b) the procedures and possible health risks;

(c) the possibility of a reduced chance of achieving pregnancy;

(d) that the research may not have any direct benefit to her, as any potential benefit can only be realised in the future and is for the public good;

(e) the ways in which her privacy and the confidentiality of her personal information will be safeguarded;

(f) whether the donated eggs may be used to create embryos for research, which will thus be destroyed during the process;

(g) whether the derived cells will be kept for future research that is not predictable at the present time;

14 Bioethics Advisory Committee, Singapore, *Personal Information in Biomedical Research,* 2007, Recommendation 2, page 20.

(h) whether she may be re-contacted regarding the future use of her eggs, eg. for the creation of gametes, or for research into therapeutic applications where the personal information of the donor needs to be retained;

(i) whether the eggs or derived cells may be used for research involving genetic manipulation;

(j) that eggs used for stem cell research will not be used to produce a pregnancy, and will not be allowed to develop *in vitro* for more than 14 days;

(k) whether the results of the research will be conveyed to her;

(l) the disclosure of any expected possible commercial benefit;

(m) that she has the right to withdraw consent or vary the terms of her consent at any time before her eggs are actually used in research, how she may withdraw consent and the implications of any withdrawal; and

(n) whether and how she will be compensated for her donation.

4.9 A potential donor needs to be reassured that any current or prospective benefit, or medical care will not be affected if she decides not to consent. This is especially true if she is in a dependent relationship, where caution may be necessary. In a situation where the risk of coercion, inducement or undue influence cannot be avoided, the donation should not be accepted. For instance, it would be ethically inappropriate for principal investigators to accept the donation of eggs by members of their research team, due to a serious risk of undue influence.

4.10 The voluntary nature of contributing tissue for research mandates that there should be no pressure on women undergoing IVF treatment to donate eggs out of a sense of obligation to their attending physicians. The free and informed nature of consent should be ensured, and this entails avoiding any conflicts of interest in the process of taking consent. In this regard, the ISSCR has indicated that, "wherever possible, the treating physician should not also be the investigator who is proposing to perform research on the donated materials."[15] The BAC is of the view that consent from women undergoing fertility treatment should be taken independently of the treatment team. In addition, donors should be sure that they do not require the eggs for future reproductive use and confirm this in writing.

15 International Society for Stem Cell Research, *Guidelines for the Conduct of Human Embryonic Stem Cell Research*, December 2006, paragraph 11.4.

4.11 In research involving eggs from fertility treatment, the time of consent taking is an important consideration in ensuring that reproductive choice remains free of any influence by researchers. Referring to embryos, a number of organisations have made ethical recommendations on this point. The American Society for Reproductive Medicine (ASRM)[16] and the Australian National Health and Medical Research Council (NHMRC)[17] have recommended that consent for the use of embryos in research should be taken only after the couple have decided not to continue storing their embryos, or have confirmed that the embryos are truly surplus embryos.

4.12 Certain policy bodies have also considered the need to allow donors the opportunity to reconsider whether their gametes or embryos should be used in research if consent was taken prior to the treatment. This is to ensure that they are given the opportunity to change their minds if they so wish. For instance, the Canadian Institutes of Health Research (CIHR) indicates that consent should be re-taken at the time when the embryos are to be used in research, even if consent has been given before the collection of the gametes, unless appropriate consent has been given for unrestricted research use.[18] Similarly, the Indian Council of Medical Research (ICMR)[19] and the ISSCR[20] have indicated that consent should only be given near or at the point that surplus embryos are to be transferred for research use. Given the gravity of the decision for donors, the HFEA requires that they be "given sufficient time to consider the implications of their donation" before their embryos or gametes may be used for research.[21] The NHMRC has specified an interval of at least two weeks before donated embryos may be used for research.[22]

4.13 The BAC does not consider there to be a material distinction between consent taking for the donation of embryos and that for the donation of eggs by women undergoing fertility treatment. As a matter of good practice, the disposal of surplus eggs should be discussed with the woman at the start of her fertility treatment, including the option of contribution for research. Provided that the woman at this stage indicates of her own accord an interest in donating eggs for

16 American Society for Reproductive Medicine, Ethics Committee, Donating spare embryos for embryonic stem cell research, *Fertility and* Sterility, 78 (2002): 957-960, page 959.

17 National Health and Medical Research Council, Australia, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*, June 2007, paragraph 17.13.

18 Canadian Institutes of Health Research, *Updated Guidelines for Human Pluripotent Stem Cell Research,* June 2007, paragraph 8.3.2.

19 Indian Council of Medical Research, *National Guidelines for Stem Cell Research and Therapy,* 2006, paragraph 11.2.

20 International Society for Stem Cell Research, *Guidelines for the Conduct of Human Embryonic Stem Cell Research,* December 2006, paragraph 11.2.

21 Human Fertilisation and Embryology Authority, UK, *Code of Practice*, 7th Edition, revised September 2008, Section S.8.4.2 (c).

22 National Health and Medical Research Council, Australia, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*, June 2007, paragraph 17.19.

research, confirms in writing that she does not require these eggs for future reproductive use and conflicts of interest are avoided, the BAC sees no objection to the woman giving specific informed consent for the use of her eggs for research, and this consent, because it is informed, can be given before the start of treatment.

Recommendation 2
Consent for the donation of human eggs for research should be obtained without any coercion or inducement. Potential donors must be provided with sufficient information in an understandable form, and given adequate time to make an informed decision.

Recommendation 3
Donors should be informed that they have the right to withdraw consent or vary the terms of consent any time before their eggs are actually used in research.

Recommendation 4
Consent for the donation of eggs for research from women undergoing fertility treatment should be taken independently of the treatment team. The donors should confirm in writing that they do not require these eggs for future reproductive use.

Egg Donation by Healthy Women

4.14 It is ethically acceptable for informed and consenting healthy women not undergoing fertility treatment to donate eggs for research. The principle of respect for individuals (and their autonomy in decision-making) supports this, and it is already the legal position in Singapore. The public consultation that was recently conducted by the BAC indicated that the general public is mostly supportive of this position, provided that donors are counselled to ensure their donation is genuinely informed and voluntary, and that there are effective safeguards against exploitation.

4.15 One safeguard against exploitation is the requirement by the MOH for all prospective egg donors for research to be provided with comprehensive information and be interviewed by a three-member panel before ovarian stimulation begins. The panel, which may be from the hospital's ethics committee, consists of a lay person and 2 medical practitioners, one of whom must be an authorised assisted reproduction practitioner. The panel must be satisfied that the prospective donor is of sound mind, clearly understands the nature and consequences of the donation, and has freely given explicit consent, without any inducement, coercion or undue influence.[23] Even with this process,

23 Ministry of Health, Singapore, Licensing & Accreditation Branch, *Directives for Private Healthcare Institutions Providing Assisted Reproductive Services: Regulation 4 of the Private Hospitals and Medical Clinics Regulations* (Cap 248, Reg 1), March 2006, paragraphs 8.5 and 8.6.

much vigilance is required as there is no perfect safeguard against the threat of exploitation. Members of the public have raised a number of considerations during the public consultation which may be helpful. These include giving due regard to the donors' residential and financial status, and their age and educational level. It was proposed that the number of times that donation may be made should be set by the regulating authority. The BAC is of the view that safeguards in the consent taking process should be reviewed from time to time to ensure that they remain effective.

Non-Commercialisation of the Human Body

4.16 A central ethical concern arising from obtaining human eggs for research relates to the possible commercialisation of the human body. The current view in research and clinical practice alike, is that the commercialisation of human tissues is not desirable, as it conflicts with a principle of respect for individuals. It is for this reason that blood donors, for example, are not paid but make a voluntary contribution to the public good. An egg donor, on this view, should not be motivated by any financial incentive in making the donation, although reasonable reimbursement of expenses incurred may be given.

4.17 The Human Cloning and Other Prohibited Practices Act of 2005[24] gives legal effect to this ethical principle, specifying that a person is prohibited from giving or receiving valuable consideration for the supply of human eggs, or to otherwise make an offer to that effect. "Valuable consideration" includes "any inducement, discount or priority in the provision of a service to the person, but does not include the payment of reasonable expenses incurred by the person in connection with the supply."

4.18 The BAC maintains that when tissue is donated for research, it should be an outright gift. This implies that the donor does not retain rights over the donated tissue (including eggs) or the results of research done using it. However, a donor can express a view as to the type of research that may or may not be done with the donated material. Donors can always decline to donate if any restrictions they wish to place on the research are not acceded to, and this matter should be addressed during the process of consent taking.[25]

4.19 Respect for the human body has always been seen as fundamental to ethical thinking and conduct in both medical practice and biomedical research. Commercialisation of the human body, by treating it, or part of it, as a disposable economic asset is generally taken to be inconsistent with this principle. This view is not unchallenged, but insofar as it underpins current ethical thinking in Singapore, it supports a view that financial inducement to

24 *Human Cloning and Other Prohibited Practices Act* (Cap 131B), revised 2005, Singapore, section 13.

25 Bioethics Advisory Committee, Singapore, *Human Tissue Research,* 2002, paragraphs 13.1.8 to 13.1.10.

provide an organ or tissue, would amount to a form of commercialisation and is not acceptable. Furthermore, this view found strong public support during BAC's public consultation on the donation of human eggs for research. There is thus no compelling force in reason or public sentiment to depart from this view.

4.20 There are other social and cultural reasons for safeguarding against potential commercialisation of not only the human body, but also the entire process of procreation. The BAC notes that many countries have adopted a variety of legislative and regulatory policies to this effect. In Japan[26] and Norway[27] for instance, egg donation for reproductive purposes is prohibited. This would prevent a couple undergoing fertility treatment from seeking 'egg donors' with certain preferred characteristics (such as physical appearance or academic accomplishment). In Denmark,[28] egg donation for reproductive purposes is restricted to women receiving treatment themselves, so that while 'egg sharing' among these women is permissible, a woman is not allowed to undergo ovarian stimulation specifically to donate eggs for the infertility treatment of another woman. Table 1 provides a summary of the laws and guidelines of various countries on whether egg donation is allowed, and if so, whether compensation may be provided.

4.21 The BAC, similarly, is interested in ensuring that neither the human body, nor any aspect of the reproductive process, becomes the subject of commercialisation. It is sensitive to the great importance attributed to the institution of the family in Singaporean society, and reproduction is a key element of this institution. Reproductive choice should remain the prerogative of the couple and it should be free from undue influence from third parties such as researchers. For this reason, the BAC does not support the implementation of schemes whereby individuals may be financially induced to provide eggs for research. However, it considers ethically acceptable for women undergoing fertility treatment to donate eggs for research, provided that these are freely donated as gifts, without compensation, and if they are not required for future reproductive use.

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26 International Federation of Fertility Societies, IFFS Surveillance 07*, Fertility and Sterility*, April 2007, 87 Suppl 1 (2007): S1-67, page S31.

27 *Act on the Medical Use of Biotechnology*, Norway, 2003, sections 2-18.

28 *Order No 728 of 17 September 1997 on Artificial Fertilization,* Denmark, chapter 1, paragraph 9.

Table 1: Regulatory Approaches of Selected Countries to Human Egg Donation[1]

Country[2]	Egg Donation for Assisted Reproduction (AR)	Payment[3] (Egg donation for AR)	Egg Donation for research[4]	Payment[3] (Egg donation for research)
Austria	✗	na	✗	na
Australia (Commonwealth)	✓	R	✓	R
Belgium	✓	C	✓	NI
Brazil	✓	NI	✓	R
Canada	✓	R	✓	R
China	✗	na	✓	R
Czech Republic	✓	R	✓	R
Denmark	✓	C	✓	NI
Estonia	✓	R	✓	R
Finland	✓	R	✓	R
France	✓	R	✓	R
Germany	✗	na	NI	NI
Greece	✓	✗	✓	✗
Hong Kong	✓	C	✓	C
Hungary	✓	C	✓	C
India	✓	C	✓	R
Israel	✓	NI	NI	NI
Italy	✗	na	NI	NI
Japan	✗	na	✓	R
Korea (South)	✓	R	✓	R
Netherlands	✓	R	✓	R
New Zealand	✓	R	✓	R
Norway	✗	na	✗	na
Singapore	✓	R	✓	R
Slovenia	✓	R	NI	NI
South Africa	✓	R	✓	R
Spain	✓	C	✓	C
Sweden	✓	R	✓	R
Switzerland	✗	na	NI	NI
Taiwan	✓	C	NI	NI
Turkey	✗	na	NI	NI
United Kingdom	✓	C	✓	C
USA (Federal)	✓	C	✓	C

Legend:

✕	Prohibited
✓	Allowed
C	Compensation allowed
R	Reimbursement of expenses allowed
na	Not applicable
NI	No information that directly addressed the issue was found or the position on the issue was unclear

(1) The information set out in the table is indicative and not necessarily a complete representation of the regulatory approach of the specified country. In particular, the regulatory approach of each country presented has been interpreted in relation to that of Singapore and for the purposes of this Report.

(2) Countries are selected based on several factors including availability of information (in English), availability of legislation and guidelines (both legally binding and non-binding) on the issues considered, and the extent that these issues have been deliberated on and debated in those countries.

(3) In this Report, compensation is considered distinct from reimbursement. Reimbursement is defined as payment for incurred expenses. In contrast, compensation includes recompense for loss of time and earnings as a result of the procedures required to obtain the eggs. It is not intended to include any transaction for monetary gain.

(4) Many countries have specific provisions for certain types of research involving eggs, such as the creation of an embryo, and therapeutic or research cloning. These specific types of research are not considered here. Rather, this column indicates whether eggs may be contributed for research in general. Countries with legislation or guidelines on egg donation for assisted reproduction may not have made similar (or explicit) provisions for egg donation for research. However, many countries that allow egg donation for assisted reproduction would generally allow a similar donation to research that is concerned with reproduction.

Compensation for Donating Eggs for Research

4.22 Concerning the issue of compensation, it is instructive to consider the position in major jurisdictions elsewhere. In the UK, the Human Fertilisation and Embryology Authority (HFEA) allows donors providing eggs for fertility treatment to be compensated for loss of earnings (but not for other costs or inconveniences) up to a daily maximum of £55.19 (about S$168) and an overall limit of £250 (about S$760) for each cycle of egg donation. These sums are in addition to reimbursement of reasonable expenses incurred.[29] In February 2007, when the HFEA announced that women will be allowed to donate eggs for research whether or not in conjunction with their own fertility treatment, it stated that this system of compensation was to be adopted by researchers as well.[30] Similarly, the Ethics Committee of the American Society for Reproductive Medicine is of the view that egg donors, whether for fertility treatment or for research, should be compensated for their time, inconvenience and discomfort and decided that "at this time sums of $5,000 or more require justification and sums above $10,000 are not appropriate."[31] These sums seem considerable, and might easily amount to an inducement for less well to do (or actually impoverished) potential donors.

4.23 In addition, the HFEA indicates that other benefits in the form of treatment services, which are of unrestricted value, should be provided in the course of the donation cycle unless medical considerations dictate otherwise.[32] Some cost of fertility treatment might be offset, as compensation, in return for the provision of eggs for research, an arrangement known as 'compensated egg sharing'. The Medical Research Council has expressed support for compensated egg sharing by providing funds for subsidising the IVF treatment of women who choose to donate some of their eggs for a research project undertaken by the North East England Stem Cell Institute.[33] This scheme is the first of its kind in the world.[34]

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29 Human Fertilisation and Embryology Authority, UK, *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*, 2006, paragraphs 3 and 4. http://www.hfea.gov.uk/docs/D2006_1_Directions_on_giving_and_receiving_money.pdf (accessed 30 October 2008).

30 Human Fertility and Embryology Authority, UK, HFEA Statement on Donating Eggs for Research, 21 February 2007. http://www.hfea.gov.uk/en/1491.html (accessed 30 October 2008).

31 Ethics Committee of the American Society for Reproductive Medicine, Financial compensation of oocyte donors, *Fertility and Sterility*, 88 (2007): 305-309.

32 Human Fertilisation and Embryology Authority, UK, *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*, 2006, paragraph 5. http://www.hfea.gov.uk/docs/D2006_1_Directions_on_giving_and_receiving_money.pdf (accessed 30 October 2008).

33 Medical Research Council, UK, *Women undergoing IVF to donate eggs for stem cell research in return for reduced treatment costs*, 13 September 2007. http://www.mrc.ac.uk/consumption/groups/public/documents/content/mrc003971.pdf (accessed 30 October 2008).

4.24 The BAC remains doubtful about the acceptability of compensated egg sharing schemes for research, as it appears to amount to a financial inducement to have eggs for research, and such external pressure seems inappropriate. It is contrary to the principle of respect for individuals, and the BAC is seriously concerned with the possibility of exploitation of women, especially those of limited economic means. Furthermore, with research rapidly expanding beyond the borders of Singapore, the effectiveness of regulating any such scheme in ways that could avoid financial inducement and unnecessary risk to women is questionable.

4.25 Similarly, in a situation where eggs have been obtained from a woman who has specifically undergone ovarian stimulation for the fertility treatment of another woman, the donor will not be eligible for compensation if eggs that are surplus to the treatment are contributed for research. This is because the original giving of the eggs was directed at therapeutic use, and if compensation is allowed, there is a real risk that the commercialisation of eggs may result.

Compensation in the Case of Healthy Donors

4.26 If commercialisation of the body is unacceptable, and altruistic donation of tissue is to be the basis of research participation, it follows that inducement is unacceptable. The BAC is of the view that to induce an otherwise reluctant woman to donate eggs by offering money or services amounts to commercialisation. On the other hand, if a woman's reluctance arises from a hesitation to actually suffer financial or other loss, a case can be made for compensation in respect of such loss under the principle of justice. There are three general approaches to paying women for providing eggs for research:

(a) *No payment beyond reimbursement* of expenses incurred. This clearly implements a philosophy of altruistic donation that is free of any risk of inducement;

(b) *Payment as compensation* for loss of time and earnings, which loss may or may not be precisely quantifiable, in addition to reimbursement of incurred expenses. This is not inconsistent with a philosophy of altruistic donation provided the quantum of compensation is not disproportionate, and neither the quantity nor the quality of the donor's eggs affects the compensation; and

(c) *Substantial payment* for eggs as a commodity. In this case, the provider is in effect a vendor making a profit, and not a donor, especially if the

34 North East England Stem Cell Research Institute, *Egg sharing: Women to get help with IVF treatment costs for donating eggs to research*, 13 September 2007. http://www.nesci.ac.uk/news/item/egg-sharing-women-to-get-help-with-ivf-treatment-costs-for-donating-eggs-to-research (accessed 30 October 2008).

price paid is contingent on the quantity or presumed genetic quality of the eggs. The BAC is opposed to this option.

4.27 Only the first approach – no payment beyond reimbursement of expenses – is not affected by ethical concerns about inducement. Once the possibility of compensation is raised, it becomes much harder to compute a quantum that represents a fair compensation but does not amount to an inducement.

4.28 The procedures for obtaining eggs are invasive with certain health risks entailed. However, the risk, discomfort and lost time are an inherent part of fertility treatment. Thus women who donate eggs from their fertility treatment are at no increased risk and they do not undergo additional discomfort or inconvenience to donate these eggs for research. These women will undergo voluntary ovarian stimulation and retrieval of eggs anyway. It can therefore be argued that they are not appropriate candidates for compensation, following a general principle that does not compensate individuals for doing what they would do in any event.

4.29 On the other hand, in the case of healthy women who volunteer to donate specifically for research, loss of time and earnings are a real cost incurred by any decision to donate. In such cases, however, it is difficult to determine a level of compensation that will not amount to undue influence or inducement, as this would depend on a number of factors including the financial status of the women concerned. This is made even more difficult as biomedical research assumes an increasingly global character. Owing to differences in payment or compensation schemes among countries, women from a country that does not allow compensation for the donation of eggs for research may be induced to make the donation in another country that allows a large payout to be made. Furthermore, there is concern that researchers from wealthy countries may attempt to obtain eggs from women in poor countries, where the compensation, if required, would be financially less burdensome for these researchers. Even within the same country, instituting payment schemes that appeal only to the poorer members of society may be socially divisive and thus run counter to the ideal that medicine, as far as possible, should not do harm. There is no simple response to this concern, but many countries are mindful that globalisation has a bearing on what might be considered as reasonable compensation for egg provision.

4.30 The issue of compensation has been considered in a number of major jurisdictions. In the US and the UK, while compensatory payment beyond reimbursement of expenses incurred could be made to the donors of eggs for research, there is a general recognition of the need to guard against such payment becoming an inducement. As mentioned in paragraph 4.22 above, total compensation that may be paid to a donor in these countries is capped at a particular amount that is considered fair and not amounting to an inducement. The European Society on Human Reproduction and Embryology (ESHRE)

Task Force on Ethics and Law indicated that vulnerable groups such as illiterate and poor women, as well as women from abroad, may have to be excluded from donating in order to prevent them from being exploited.[35]

4.31 In the Hong Kong SAR, donors are not paid for the supply of eggs (whether for research or clinical use), but may be compensated for loss of earnings and expenses incurred.[36]

4.32 Based on the principle of justice, the BAC is of the view that compensation for loss of time and earnings should be provided to women not undergoing fertility treatment who donate eggs specifically for research. Such compensation should not be dependent on the quantity or the quality of the eggs obtained, as it is not payment for the eggs. The relevant governmental authority may wish to consider setting a limit on the amount of compensation in order to avoid any inducement. In the case of donors who are not employed, the relevant regulatory authority should determine an appropriate compensatory amount for these donors based on the time spent as a result of the procedures required to obtain the eggs for research. The authority may need to review current legislation to determine whether legislative amendments are required to implement any proposal for compensation.

4.33 As the process of ovarian stimulation needed to yield eggs is invasive, and carries a health risk, a number of respondents[37] have emphasised the need to provide egg donors with medical care should an adverse event occur as a consequence of the donation. The BAC agrees that such provisions should be made. Donors should be provided with prompt and full medical care when complications occur as a direct and proximate result of donating eggs specifically for research. If the supply of eggs was a commercial matter, one might expect the vendors to shoulder the risk, but since it is not a commercial proposition, as explained above, it is the responsibility of researchers and their institutions to provide the medical care when required.

Recommendation 5
Women undergoing ovarian stimulation specifically for research should be provided with prompt and full medical care when complications occur as a

35 European Society for Human Reproduction & Embryology, Task Force on Ethics and Law, Oocyte donation for non-reproductive purpose, *Human Reproduction*, 22 (2007): 1210–1213, page 1213.

36 The three categories of expenses that an egg donor in Hong Kong may claim are loss of earnings, specified accountable expenses (such as travel expenses and minding services), and medical expenses. There is no limit for claimable medical expenses but the maximum daily payment in respect of loss of earnings and specified accountable expenses cannot exceed HK$1,060 (S$184), and HK$1,360 (S$236) on the day of egg collection for each donation (i.e. the sum of loss of earnings and specified accountable expenses, but excluding medical expenses, which do not have a limit). Council on Human Reproductive Technology, Hong Kong SAR, *Code of Practice on Reproductive Technology & Embryo Research*, December 2002, Section 4.14 and Appendix II.

37 Such as the Graduates' Christian Fellowship and the Law Society of Singapore.

direct and proximate result of the donation. Responsibility for this provision should rest with the researchers and their institutions.

Recommendation 6
Egg donors should be compensated only for loss of time and earnings as a result of the procedures required to obtain the eggs, and only if the eggs were obtained specifically for research purposes, and not as a result of clinical treatment. Such compensation should be in addition to any reimbursement of expenses incurred. The relevant regulatory authority should determine the appropriate amount of such compensation.

Importation of Human Eggs

4.34 The BAC notes that importation of human eggs is not subject to regulatory control. This notwithstanding, the BAC is of the view that any research use of human eggs in Singapore, whether imported or not, should be confined to eggs that have been obtained in accordance with the recommendations in this Report. They should also conform to all earlier relevant recommendations, such as those mandating ethics review. Furthermore, in cross-border research collaborations, the requirements specified in this Report should be met if the project is to receive approval by any IRB in Singapore.

Recommendation 7
The procurement or use of human eggs from any source by procedures not consistent with the recommendations in this Report should be prohibited.

V. Conclusion

5.1 The BAC has considered international practices and guidelines on the donation of human eggs for research purposes, together with expert views on the subject. It has also carefully considered the feedback received from the public and the written responses from various organisations. It has reached the following conclusions, which form the basis of seven recommendations:

(a) The general ethical principles of research involving human participants should apply to the procurement and use of human eggs for research;

(b) It is ethically acceptable for fully informed and freely consenting healthy women, not undergoing any medical treatment, to donate eggs for research;

(c) Women who are not undergoing fertility treatment and who donate eggs specifically for research should be compensated for loss of time and earnings as a result of the procedures required to obtain the eggs. In addition, they should receive reimbursement of expenses incurred, and should also receive prompt and full medical care if complications arise as a direct and proximate result of the procedures; and

(d) Women donating surplus eggs from fertility treatment should not be compensated, as they do not incur additional loss of time and earnings to donate their eggs for research.

5.2 **List of Recommendations:**

Recommendation 1
The procurement and use of human eggs for research should be regulated.

Recommendation 2
Consent for the donation of human eggs for research should be obtained without any coercion or inducement. Potential donors must be provided with sufficient information in an understandable form, and given adequate time to make an informed decision.

Recommendation 3
Donors should be informed that they have the right to withdraw consent or vary the terms of consent any time before their eggs are actually used in research.

Recommendation 4
Consent for the donation of eggs for research from women undergoing fertility treatment should be taken independently of the treatment team. The donors should confirm in writing that they do not require these eggs for future reproductive use.

Recommendation 5
Women undergoing ovarian stimulation specifically for research should be provided with prompt and full medical care when complications occur as a direct and proximate result of the donation. Responsibility for this provision should rest with the researchers and their institutions.

Recommendation 6
Egg donors should be compensated only for loss of time and earnings as a result of the procedures required to obtain the eggs, and only if the eggs were obtained specifically for research purposes, and not as a result of clinical treatment. Such compensation should be in addition to any reimbursement of expenses incurred. The relevant regulatory authority should determine the appropriate amount of such compensation.

Recommendation 7
The procurement or use of human eggs from any source by procedures not consistent with the recommendations in this Report should be prohibited.

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