

Oocyte Procurement for Research

A Background Paper for the Bioethics Advisory Committee of Singapore

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Summary

The purpose of this Background Paper is to describe the main ethical issues that arise in regard to procuring oocytes for research. These issues are part of a current debate informed by recent controversies surrounding the conditions of oocyte donation from women, the market in oocytes in some jurisdictions, and the scarcity of oocytes specifically for stem cell research.

In Part One, I discuss the reasons why oocytes are needed for research at this current time, and describe the potential sources of oocytes for these purposes. In Part Two, I focus on the immediate concerns of sourcing oocytes for research purposes from consenting donors, which are issues of payment, compensation, and incentives. To illustrate the various jurisprudential strategies that have developed in this regard, I look at a number of current legislative frameworks. In Part Three, I discuss in detail three ethical issues that have come to the fore in oocyte procurement debates: payment and compensation, commodification, and autonomy and risk. I close this section – and conclude overall – that various interpretations of the ‘public interest’ are central to understanding this present debate.

Introduction

In 2006, investigations into alleged scientific fraud by the South Korean stem cell scientist, Woo Suk Hwang, revealed that there were, among other concerns, contentious circumstances surrounding procurement of oocytes for research.¹ Specifically, in the attempt to be the first to successfully clone a human embryo, Hwang had obtained oocytes from paid donors and junior members of his own research team, and he had lied about the conditions under which the oocytes had been obtained.² This controversy emphasised the ethical concerns surrounding the degree to which incentives may be a

¹ Cyranoski, D. 2006. Blow Follows Blow for Stem-Cell Work. *Nature* 439: 8.

² Steinbrook, R. 2006. Egg Donation and Human Embryonic Stem-Cell Research. *New England Journal of Medicine* 354: 324-326.

part in the procurement of oocytes. While this apparently isolated incident was alleged by some to be a result of economic and political influences upon scientific independence and integrity,³ the case for inducements or incentives for consensual donation of cells, tissues and organs from healthy ‘donors’ remains a challenging ethical problem.

The issue has again come to the fore because of the claims that there may not be enough human oocytes to facilitate the advance of embryonic stem cell research. In response to this, various jurisdictions are considering whether it is ethically (and to what degree) appropriate to obtain oocytes from human donors and non-human sources. In this Paper, commissioned by the Bioethics Advisory Committee of Singapore, I will outline the main ethical issues that arise as a consequence of this pressure to obtain oocytes for research. The Paper is in three parts. Part One looks at the scientific background of oocyte procurement. Part Two discusses various legislative strategies that have been employed to regulate the procurement of oocytes. In Part Three, I discuss some of the main ethical issues that arise from oocyte procurement for research. The purpose is to provide a background for future policy discussions.

PART ONE: THE SCIENTIFIC BACKGROUND

I. Why Are Oocytes Needed for Research?

One of the outcomes of biotechnological progress is that human cells, tissues and organs have become valuable as commodities which can be bought and sold. For this reason, when certain human body parts become desirable – and by their nature are normally of limited availability – there are market pressures that turn them into (potential – if policy will allow it) premium commodities.

Human oocytes are valuable, because they are necessary for human reproduction – and therefore can become a commodity in the reproductive ‘business’, which is currently driven by higher levels of infertility and women choosing to have children later in life – but they are also valuable as a research resource. These dual demands, plus other issues such as health risks in donation and the removal of donor anonymity, mean that oocytes are in short supply. The two main areas of research that require oocytes are fertility-related research⁴ and stem cell (SC) research. It is the latter research – driven by both hype and hope – that will predictably create the greatest demand for oocytes in research.

³ Editorial. 2006. Ethics and Fraud. *Nature* 439: 117-118.

⁴ Embryonic and developmental research are important in light of continued low success rates for IVF pregnancies, the potential for harm occurring as a result of current clinical practice, and reports of ill health in IVF children. Barri, P. 2005. Multiple Pregnancies: A Plea for Informed Caution. *Human Reproduction Update* 11:1-2; Klemetti, R., Sevón, T., Gissler, M. and Hemminki, E. 2006. Health of Children Born as a Result of In Vitro Fertilization. *PEDIATRICS* 118: 1819-1827.

SCs provide an intriguing and potentially promising solution to many avenues of medical enquiry. These include questions of basic developmental science, the repair of *in situ* tissues and organs – which are often untreatable, either because of unattainable internal access or cellular and aetiological complexity – and the generation of whole organs *in vitro*, addressing problems of organ shortage and immunological rejection.⁵ Results in animal models have encouraged optimistic speculation about early human clinical applications in advanced generation and regeneration of organs and tissues.⁶ However, no SC applications of this type have entered clinical trial stages at the current time, and most believe that such therapeutic applications, if possible at all, are some years ahead.⁷

Much of the ethical debate about SCs to date has been concerned with the moral status of the embryo and the contested merits of alternative SC sources.⁸ While most jurisdictions are no closer to resolving the former question, there is general scientific agreement that progress does depend on isolating human embryonic stem (ES) cells from embryos, and that currently postulated (uncontroversial) alternatives – such as somatic SCs – have not reduced this need.⁹

ES cell research requires a source of oocytes to produce the embryos needed; and while animal models and animal oocytes have been employed in basic science and proof-of-theory research, human oocyte-derived embryos will inevitably be required for the transition into human clinical applications.¹⁰ Alleged solutions to the *embryo research*

⁵ Solter, D., Beyleveld, D., Friele, M., Hołówka, J., Lilie, H., Lovell-Badge, R., Mandla, C., Martin, U. and Pardo Avellaneda, R. 2003. *Embryo Research in Pluralistic Europe*. Berlin Heidelberg. Springer-Verlag.

⁶ SC from cord blood have been used for some time in the treatment of childhood blood disorders; however, the ‘advanced SC therapies’ which are envisaged take the science to a new level of medical-biotechnological innovation; see: Sousa, P., Galea, G., and Turner, M. 2006. *The Road to Providing Human Embryo Stem Cells for Therapeutic Use: The UK Experience*. *Reproduction* 132: 681-689; European Parliament-Committee on the Environment, Public Health and Food Safety (‘Mikolášek’ Report). 2006. *Draft Report on the Proposal for a Regulation of the European Parliament and the Council on Advanced Therapy Medicinal Products* [short title]. Provisional 2005/0227(COD) November. Strasbourg. available at: http://www.europarl.europa.eu/meetdocs/2004_2009/documents/pr/636/636826/636826en.pdf

⁷ Thomson, J. 2001. *Human Embryonic Stem Cells*. In: Holland, S., Lebacqz, K. and Zoloth, L. eds. *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy*. Cambridge, Massachusetts. Massachusetts Institute of Technology. pp. 15-26.

⁸ Capps, B. 2007. *Bioethics and Misrepresentation in the Stem Cell Debate*. In: Gunning, J. and Holm, S. eds. *Ethics, Law and Society*, Volume 3. Aldershot. Ashgate Publishing Ltd.

⁹ House of Lords Select Committee. 2002. *Stem Cell Research*. HL Paper 83(i) London. HMSO.

¹⁰ For example, most SC lines are currently grown on animal feeder layers, raising concerns of cross-species viral contamination if used in humans. Furthermore, there are important biological and chemical differences between the characteristics of SCs from human and other animal species; Bishop, A., Buttery, L. and Polak, J. 2002. *Embryonic Stem Cells*. *Journal of Pathology* 197: 424-429; Evans, M. and Hunter, S. 2002. *Source and Nature of Embryonic Stem Cells*. *C. R. Biologies* 325: 1-5; Reubinoff, B., Pera, M., Fong, C., Trounson, A. and Bongso, A. 2000. *Embryonic Stem Cell Lines from Human Blastocysts: Somatic Differentiation In Vitro*. *Nature Biotechnology* 18: 399-404; and Rossant, J. 2001. *Stem Cells from the Mammalian Blastocyst*. *Stem Cells* 19: 477-482.

debate – such as the creation of ‘embryo-like artefacts’¹¹ and parthenotes¹² – will not alleviate the demand for human oocytes because they are dependent on a source of eggs to be ‘genetically-altered’ or ‘activated’.¹³

One of the predicted advantages of ES cell therapies is that it may be possible to immunogenetically-tailor cells, tissues and organs to the patient by using Cell Nuclear Replacement (CNR) techniques.¹⁴ The pressure to embark on CNR strategies may increase if alternative sources of genetically-matched SCs do not yield expected results;¹⁵ and it is well known that CNR is currently inefficient and wasteful, requiring large numbers of oocytes for successful animal cloning techniques.¹⁶ In the future, SC banks may become valuable resources of immunologically-matched SCs which can be used in regenerative medicine, without resorting to CNR; but establishing such collections is a long-term effort, and probably will require large-scale regional collaboration (e.g. European or Asian) to be a clinically useful representation of a given population.

A major factor influencing the demand for oocytes will be whether national regulation allows the creation of human embryos specifically for research, either by IVF or CNR techniques. If the creation of research embryos is permitted, then oocytes – either human or animal – will become a necessary component of this type of research. Thus it is likely that the expansion of national and international SC research efforts,¹⁷ paired

¹¹ Embryo-like artifacts are bioengineered ‘entities’ that can produce pluripotent SCs, but without having the biological potential to develop into a foetus; Hurlbut, W. 2005. Altered Nuclear Transfer: A Way Forward for Embryonic Stem Cell Research. *Stem Cell Reviews* 1: 293-300. So-called ‘dead’ embryos are considered as those which are not suitable for IVF treatment because they stop dividing spontaneously. The selection of criteria for death in an embryo with none of the characteristics that would indicate normal death is clearly controversial.

¹² Parthenogenesis is a reproductive mechanism that is common in lower organisms and produces a live birth from an oocyte activated in the absence of sperm. Human parthenogenetic embryos have been shown to develop to the blastocyst stage and so can speculatively serve as a source of ES cells. This mechanism for generating SCs (it is alleged) has the ethical advantage of not involving the destruction of viable embryos. Moreover, the SCs do not involve the union of male and female and so genetic material will be derived exclusively from the female oocyte donor (with the attendant potential immunological advantages); Cibelli, J., Cunniff, K. and Vrana, K. 2006. Embryonic Stem Cells from Parthenotes. *Methods in Enzymology* 418:117-35.

¹³ Murray, T. 2005. Will New Ways of Creating Stem Cells Dodge the Objections? *Hastings Center Report* 35: 8-9.

¹⁴ Colman, A. and Kind, A. 2000. Therapeutic Cloning: Concepts and Practicalities. *Trends in Biotechnology* 18: 192-153.

¹⁵ Mertes, H., Pennings, G. and Van Steirteghem, A. 2006. An Ethical Analysis of Alternative Methods to Obtain Pluripotent Stem Cells Without Destroying Embryos. *Human Reproduction* 11: 2749-2755; Schulman, A. 2005. The Search for Alternative Sources of Human Pluripotent Stem Cells. *Stem Cell Review* 4: 291-292.

¹⁶ Hall, V., Stojkovic, P. and Stojkovic, M. 2006. Using Therapeutic Cloning to Fight Human Disease: A Conundrum or Reality? *Stem Cells* 24: 1628-1637.

¹⁷ Capps, B. 2005. The Human Embryo, Stem Cell Research, and the European Union. In: Bender, W., Hauskeller, C. and Manzei A. eds. *Crossing Borders: Cultural, Religious, and Political Differences Concerning Stem Cell Research: A Global Approach*. Münster. Agenda Verlag. pp. 435-467.

with the growing trend towards liberalising embryo research laws to allow the creation of embryos specifically for research,¹⁸ will have the inevitable effect of increasing the demand for human oocytes.

II. Sources of Oocytes for Research

Various types of donors may be identified as sources of oocytes for research: (1) IVF patients; (2) healthy providers (who volunteer to donate or are paid to provide oocytes specifically for research); (3) women applying for specific gynaecological interventions; (4) women applying for an experimental reproductive technology for their own benefit; (5) posthumous donors; (6) aborted foetal gonadal tissue; (7) non-human animal sources; and (8) SC-derived gametes. I will discuss these in turn, concentrating on the scientific and procedural implications.

(1) In Vito Fertilisation Treatment Patients

Along with (2), the procurement of oocytes from IVF patients offers the most immediate solution to the shortage of oocytes for research,¹⁹ although it is unlikely that this strategy alone will provide enough oocytes for clinically effective research. Within the clinical context there may be leftover oocytes after treatment which may be donated for research;²⁰ but the failure of many IVF cycles, the burdens of time and inconvenience, and the risks to health, will mean that many patients will prefer to go through as few cycles of controlled ovarian hyperstimulation (COH) as possible, and therefore store oocytes and IVF embryos for future personal use, thus taking many oocytes out of circulation.

One of the main issues with regard to oocyte procurement from living providers is the risk involved in COH and oocyte retrieval procedures involving the insertion of a needle through the vagina. Stimulating the ovaries in COH to produce more than the usual single monthly egg is an invasive procedure, requiring drug treatment. Ovarian hyperstimulation in IVF treatment is not without risks, and may cause ovarian

¹⁸ Capps, B. 2002. The European Union and Stem Cell Research: A Turnaround on Policy Regarding Human Embryo Research? *Legal Ethics*. 5: 18-23.

¹⁹ The numbers of women donating oocytes from (3), (5) and (6) are likely to remain small in comparison. Oocyte nuclear replacement therapy (4) is experimental at this stage, and therefore itself is a drain on available oocytes; Mayor, S. 2005. UK Team Hopes to Create a Human Embryo from Three Donors. *BMJ* 331: 359.

²⁰ These oocytes may also be donated for therapy to women who are seeking to become pregnant and are unable to produce their own oocytes. However, it is reported that in countries where there are strict controls on payment for gametes, such as the UK and Singapore, there are currently insufficient oocytes to meet clinical needs because demand currently far outstrips supply. Further options are therefore for the women to participate in egg sharing schemes (the 'donor' shares her eggs for subsidised IVF treatment), payment to healthy donors, or, where payment is prohibited, to seek treatment abroad where they can pay for oocytes; Murray, C. and Golombok, S. 2000. Oocyte and Semen Donation: A Survey of UK Licensed Centres. *Human Reproduction* 15: 2133-2139; Ahuja, K., Mostyn, B. and Simons, E. 1997. Egg Sharing and Egg Donation: Attitudes of British Egg Donors and Recipients. *Human Reproduction* 12: 2845-2852.

hyperstimulation syndrome (OHSS) in some women.²¹ This is a sudden and severe iatrogenic disorder which can result in morbidity. Fatalities linked to the syndrome have been reported.²² There appear to be differences between women with regard to the risk of developing OHSS.²³ Short-term health risks of needle aspiration include bleeding, infection, and the risks associated with anaesthesia.²⁴ Pain and psychological problems have also been studied.²⁵ There are also limited data to suggest that COH affects the woman's future health, such as a lifetime risk of ovarian and non-gynecologic tumours and malignancies, as well as other health conditions.²⁶

(2) Healthy Providers

Previously, scientists have relied on women already undergoing fertility treatment donating their extra eggs for research; but, as noted above, this supply is limited by clinical need, and relies on the donation of oocytes by patients who are likely to have reproductive reasons to withhold them from research. Researchers have therefore started to consider the opportunities for healthy women to donate (altruistically) or provide (a 'vendor' or 'broker' where a fee is offered) oocytes for research. Increasingly, financial rewards and incentives are claimed to be the best means to deal with the demand for research oocytes.

²¹ Three categories of OHSS have been determined by clinicians: mild, moderate and severe. Estimates vary widely as to the incidence of OHSS in all its forms, but it has been stated that up to 10% of all cycles result in some form of OHSS. Severe forms (0.2–1.0%) often require hospitalisation to avert potentially lethal effects, and many moderate cases are also hospitalized; Aboulghar, R. and Mansour, M. 2003. Ovarian Hyperstimulation Syndrome: Classifications and Critical Analysis of Preventive Measures. *Human Reproduction Update* 9: 275-289; Fauser, B., Devroey, P., Yen, S., Gosden, R., Crowley Jr., W., Baird, D. and Bouchard, P. 1999. Minimal Ovarian Stimulation for IVF: Appraisal of Potential Benefits and Drawbacks. *Human Reproduction* 14: 2681-2686.

²² Lazar, K. 1999. Wonder Drug for Men Alleged to Cause Harm in Women. *Boston Herald*, August 22.

²³ The aetiology of OHSS remains unknown and no strategy has yet been shown to completely prevent occurrence of severe OHSS, short of cancelling the cycle. There are certain molecular markers associated with the onset of OHSS and these may be predictive of the syndrome; Chen, D., Burmeister, L., Goldschlag, D., and Rosenwaks, Z. 2003. Ovarian Hyperstimulation Syndrome: Strategies for Prevention. *Reproductive Biomedicine Online* 7: 43-49; Shanbhag, S. and Bhattacharya, S. 2002. Current Management of Ovarian Hyperstimulation Syndrome. *Hospital Medicine* 63: 528-532; Orvieto, R. 2005. Can We Eliminate Severe Ovarian Hyperstimulation Syndrome? *Human Reproduction* 20: 320-322. There is some evidence that certain genes may provide important predicative information about individual responses to the drugs used; Greb, R., Behre, H. and Simoni, M. 2005. Pharmacogenetics in Ovarian Stimulation. *Reproductive Biomedicine Online* 11: 589-600.

²⁴ Sauer, M. 2001. Egg Donor Solicitation: Problems Exist, but do Abuses? *American Journal of Obstetrics and Gynecology* 1: 1-2.

²⁵ Jordan, C., Belar, C. and Williams, R. 2004. Anonymous Oocyte Donation: A Follow-up Analysis of Donors' Experiences. *Journal of Psychomotor Obstetrics and Gynecology* 25: 145-151.

²⁶ Brinton, L., Moghissi, K., Scoccia, B., Westhoff, C. and Lamb, E. 2005. Ovulation Induction and Cancer Risk. *Cancer Cause Control* 12: 875-880; Healy, D. 1998. Ovarian Cancer, Infertility and Infertility Therapy. In Kempers, R., Cohen, J., Haney, A. and Younger, J. eds. *Fertility and Reproductive Medicine*. New York. Elsevier Science. pp. 1-14.

In healthy providers (i.e. woman undergoing COH to provide oocytes only and not as part of IVF treatment), there is a reported lower incidence of OHSS.²⁷ However, they are exposed to the same risks with regard to the drugs used;²⁸ and some specialists in reproductive medicine are concerned that there is insufficient information about the long-term effects of these drugs to encourage healthy volunteers to undergo such procedures when there is no reproductive benefit to balance against the risks.²⁹ A major concern for healthy donors is that oocyte aspiration may lead to infection, and infertility. There are also particular psychological concerns for the healthy provider;³⁰ and they are also at risk of unintended pregnancy, because hormonal contraceptives must be discontinued.

(3) Donation in Relation to Specific Gynaecological Interventions

Ovarian tissue can be donated after surgery involved in sterilisation and hysterectomy.³¹ (It is unlikely that it will be possible for the woman to sell the tissue due to laws prohibiting the sale of organs and tissues.) The existing literature tends to focus on the ethics of donating such tissue for reproductive purposes (i.e. the resulting child's relationship to the donor).

An issue that may be considered in the context of this Paper is the question of whether tissue removed after surgery is considered as 'waste', and as such the property of the hospital to be used in research. This argument has been deployed in the context of cord blood (CB) collected during birth.³² Previously, placental tissues and CB have been routinely destroyed, unless specific instructions had been given for it to be donated for

²⁷ This is linked to the hormones released as a result of the implantation of IVF embryos; Sauer, M., Paulson, R. and Lobo, R. 1996. Rare Occurrence of Ovarian Hyperstimulation Syndrome in Oocyte Donors. *International Journal of Obstetrics and Gynecology* 52: 259-262.

²⁸ The full extent of the damage to the health of the Korean women who provided the eggs used by Dr. Hwang is not known, but it is apparent that a coalition of 35 women's groups is suing the South Korean government on behalf of women who have been harmed in the process of egg extraction. Reports are that about 20 percent of the donors have experienced side-effects; Hwa-young, T. 2006. Ova Donors Demand Compensation from Government. *AsiaNews.it*. 2 July; available at: www.asianews.it/view_p.php?l=en&art=5322. Assessed March 2007.

²⁹ Pearson, H. 2006. Health Effects of Egg Donation May Take Decades to Emerge. *Nature* 442: 607-608.

³⁰ The possible psychological and medical stress for the oocyte broker was vividly captured by the traumas of an American Ivy League student. She described how after invasive probing of her persona, the recipient couple rejected her as an egg donor because of, as she described it, the perceived inadequacies in her gene pool; *Sunday Telegraph* (London), 5 January 2003. A (limited) study of women providing oocytes for research reported that they felt like and were treated like a commodity; '[t]hey used terms like "prostitute" and "livestock" to describe how they felt, and they described the medical care as cold and impersonal. Specific actions such as being referred to by a number or pseudonym rather than their names, being segregated into a separate waiting room, and being instructed not to speak to other patients contributed to this feeling'; Kalfoglou, A. 2001. Navigating Conflict of Interest in Oocyte Donation. *American Journal of Bioethics* 1: W1-W2.

³¹ Bromwich, P. 1990. Oocyte donation. *British Medical Journal* 300: 1671-1672.

³² Zhao Y, Mazzone T. 2006. Turning 'Waste' into Gold: Identification of Novel Stem Cells from Human Umbilical Cord Blood. *Discovery Medicine* 6: 87-89.

research, and in the case of CB, in treatment for childhood blood disorders.³³ However, a sudden increase in value of the latter has now been confirmed because of its SC content, and thus potential use in research.³⁴ In the context of oocyte procurement, the following issues arise: (a) informing the patient of the option to donate cells for research; (b) avoiding commitments to collect the cells in the event of clinical difficulties; and (c) obtaining consent to use this important resource, rather than routinely discarding it. In the UK, these issues have been brought into sharp relief by the controversy over retained organs without consent.³⁵

(4) Donors in Experimental Reproductive Technology

A parallel development to regenerative SC medicine has been the possibility of oocyte nuclear replacement (ONR) to ‘repair’ oocytes by replacing damaged mitochondria residing in the oocyte cytoplasm. The use of ONR technology – which is technically similar to CNR – may provide the solution to many mitochondrial-associated diseases.³⁶ It is possible that oocytes collected for ONR research and therapy may be donated to other research projects. However, as well as the ethical dilemmas, societal concerns, and recent controversies regarding ‘therapeutic cloning’,³⁷ there are issues of participation in experimental clinical research (discussed further, below) and germ line genetic modification.³⁸ In the current context, it is important to consider whether the need for oocytes for SC research (which in this case is a subsidiary intention in regard to the reproductive-clinical research in treating mitochondrial disease) will detrimentally affect the normal rules of research participation. For example, whether withdrawing from an ONR project also entitles a woman to recall her oocytes, if they are being used in research elsewhere.

³³ Hows, J. 2001. Status of Umbilical Cord Blood Transplantation in the Year 2001. *Journal of Clinical Pathology* 54: 428-434.

³⁴ Wagner, J. and Verfaillie, C. 2004. Ex Vivo Expansion of Umbilical Cord Blood Hemopoietic Stem and Progenitor Cells. *Experimental Hematology* 32: 412-413. Future therapy is increasingly considered as an option via CB banks offering (questionable) autologous (self) treatments; Kmietowicz, Z. 2001. Doctors Object to Companies Offering to Store Cord Blood. *British Medical Journal* 323: 1203.

³⁵ In the context of CB, see: Armson, B. 2005. Umbilical Cord Blood Banking: Implications for Perinatal Care Providers. *Canadian Journal of Obstetrics and Gynecology* 27: 673. Regarding the issue of retained organs, see: Campbell, A. V. and Willis, M. 2006. They Stole My Baby’s Sole: Narratives of Embodiment and Loss. In *The Self in Health and Illness: patients, Professionals and the Narrative Identity*. Rapport, F and Wainwright, P. eds. Oxford. Radcliffe. pp. 123-129.

³⁶ Hall, V., Stojkovic, P. and Stojkovic, M. 2006. Using Therapeutic Cloning to Fight Human Disease: A Conundrum or Reality? *Stem Cells* 24: 1628-1637.

³⁷ The theoretical treatment in this case is oocyte nuclear replacement, which differs from the ‘Dolly’ technique (CNR) in that an oocyte, rather than a somatic cell, is used as the recipient of donor nuclear DNA.

³⁸ Department of Health 2000. *Stem Cell Research: Medical Progress with Responsibility - A Report from the Chief Medical Officer’s Expert Group Reviewing the Potential of Developments in Stem Cell research and Cell Nuclear Replacement to Benefit Human Health*. London. DoH.

(5) Posthumous Donation

The issues regarding posthumous donation involve the importance of the opportunity to specify personal wishes regarding the removal of specific organs, and in this particular case, reproductive tissue, which may have special symbolic and procreative status.³⁹ This raises many issues regarding organ donation in general, but with reproductive tissues there are the complexities of potentially creating new life from a deceased donor (and the possible implications for the familial relationships between living relatives). The important issue with regard to research however, are the pre-stated wishes of the person to involve her oocytes in research after her death, and the means to obtain consent through specific research pro-active policies.

(6) Aborted Foetal Tissue

Using eggs from aborted fetuses is possible due to advances in *in vitro* ovarian maturation and cryopreservation techniques. Some of the arguments against using foetal tissue in research reflect anti-abortion arguments, which are outside the scope of this paper.

One objection to the use of foetal tissue is that this demand will lead to coercion, devious pressures and financial incentives to terminate pregnancies. The common solution to such arguments is to separate the choice to have an abortion, the carrying out of the abortion, and any subsequent use of the tissue from the abortus. It is argued that the researcher should not have any influence on the clinical needs and decisions of women undergoing a termination of pregnancy, and consent for the use foetal tissue in research should be sought only after a woman has given her consent to the termination.⁴⁰ However, concerns about using oocytes or ovarian tissue from aborted female fetuses may also reflect more nuanced arguments regarding the relationships between the person undergoing an abortion and the researcher.

There is an argument that excluding clinical investigators from the clinical care of women undergoing termination codifies distrust of clinicians who undertake research, and so, according to the Royal College of Obstetricians and Gynaecologists (UK), inhibits the progress of research.⁴¹ A second argument concerns the conditions of consent. In most jurisdictions, a woman's consent to the use of the foetus in research is general: she is not given the opportunity to specify how her foetal tissue may or may not be used. However, the use of non-specific consent is suggested to be 'increasingly

³⁹ Mizukami, A., Peterson, M., Huang, I., Cook, C., Boyack, L., Emery, B. and Carrell, D. 2005. The Acceptability of Posthumous Human Ovarian Tissue Donation in Utah. *Human Reproduction* 20: 3560-3565.

⁴⁰ Polkinghorne, J. 1989. *Review of the Guidance on the Research Use of Fetuses and Fetal Material*. London. HMSO.

⁴¹ Royal College of Obstetricians and Gynaecologists. 2004. Response to MRC Consultation on the Code of Practice for the Use of Human Stem Cell Lines. www.rcog.org.uk. Accessed June 2005.

out of step with modern expectations’;⁴² thus, for example, making decisions on an *informed* basis may require details of the *purpose* of the intended research and feedback on whether the oocytes have been used at all. Others have argued that we should do away with considerations of research-specific consent, and instead allow blanket consent to free up the purposes of research.⁴³ Finally, there is an argument that clinical practice and research need not be in conflict. Therefore it may be ethically acceptable to modify the termination procedure according to the needs of the latter (to ensure that the foetal reproductive tissue is collected with due care, indicating its future use in research), without this being to the detriment of the woman’s health.⁴⁴

(7) *Non-Human Sources*

In the future, the use of animal oocytes to create human-animal chimeras for research may significantly relieve the demand for oocytes (if permitted in regulations). Using animal oocytes as a ‘shell’ for human nuclear DNA for the purpose of creating genetically human SCs for research is a possible solution to the scarcity of human oocytes and the ethical concerns linked to some human sources.⁴⁵ However, this may not be a long term solution, unless (controversially) the use of animal oocytes in *therapy* is also permitted.⁴⁶ The ethics of ‘Stem Cell Research and Interspecies Fusion’ has been discussed in detail in a separate Background Paper prepared for the Bioethics Advisory Committee.⁴⁷

(8) *Stem Cell-Derived Oocytes*

A further possible (and promising) solution to the demand for oocytes in research is the creation of female gametes directly from SCs. This proposal raises few new ethical concerns with regard to *research* (but may be controversial with regard to reproduction), but it is still at the experimental stage, and research will continue to require a source of conventionally created embryos using sourced oocytes to pursue this possibility.⁴⁸

⁴² Department of Health. 2002. Human Bodies, Human Choices: The Law on Human Organs and Tissue in England and Wales. A Consultation Report. London. DoH. sec 15.13.

⁴³ Burley, J. 2005. Stem Cells and Translational Medicine: Ethics, Law and Policy. In Bongso, A. and Lee E. H. eds. Stem Cells: From Bench to Bedside. Singapore. World Scientific. pp. 186-211.

⁴⁴ Department of Health, op. cit. note 42, sec. 15.9-15.11.

⁴⁵ Robert, J. 2006. The Science and Ethics of Making Part-Human Animals in Stem Cell Biology. The Journal of the Federation of the American Societies for Experimental Biology FASEB J 20: 838-845.

⁴⁶ The creation of chimeras is possible in some countries, such as (currently) in the UK, for research purposes only; Karpowicz, P., Cohen, C. and Van der Kooy, D. 2005. Developing Human-Nonhuman Chimeras in Human Stem Cell Research: Ethical Issues and Boundaries. Kennedy Institute of Ethics Journal 15: 107-134.

⁴⁷ By Nuyen, A.T. Department of Philosophy, National University of Singapore. 2006.

⁴⁸ Master, Z. 2006. Embryonic Stem-Cell Gametes: The New Frontier in Human Reproduction. Human Reproduction 21:857-863.

PART TWO: CURRENT LEGISLATIVE FRAMEWORKS REGARDING MONETARY EXCHANGE AND OOCYTE PROVISION FOR RESEARCH

In this section and subsequent sections I will concentrate solely on the issues arising out of monetary exchanges when sourcing oocytes for *research purposes* from consenting women is permitted.⁴⁹ Other legal issues to consider, but which (due to space) cannot be discussed in this Paper, are those concerning contractual arrangements, including those of medical obligation (for example in the provision of treatment and negligence in cases of OHSS).

(1) *Payment for Human Oocytes*

It is widely established in jurisprudential regions,⁵⁰ though more disputed in the ethics literature,⁵¹ that direct payments should be prohibited with regard to human tissues and organs. Therefore, it is unlikely that this restriction would be (legally) challenged with regard to the donation of ovarian tissue in (3), (4), (5) and (6), above. Many countries also expressly prohibit the purchase of human oocytes.⁵²

However, in the USA a market in oocytes is not illegal, since gametes are excluded from Federal law prohibiting the sale of organs. Interestingly, there are some States which permit payment for oocyte providers if the purpose is IVF treatment, but prohibit payment if the eggs are to be used in research. In States such as Massachusetts and California, compensation for reasonable expenses is permitted only.⁵³ (This may be an ‘ethical’ response to the large amounts of money invested in SC research and the continuing political requirement for public support.)

Strictly speaking, the US federal policy is one of *laissez faire*, rather than a deliberate decision to authorise an oocyte market. It probably developed out of the concurrent demand for IVF treatment and means of storing one's own oocytes for own use. This led

⁴⁹ See, for example: Gunning, J. 1997. Oocyte Donation: The Legislative Framework in Western Europe. *Bioethics* 11: 98-102.

⁵⁰ E.g. see the World Health Organisation's Resolution WHA57.18 on Human Organ and Tissue Transplantation; Fifty-Seventh World Health Assembly 22 May 2004. WHO. Geneva. For example, Singapore, the UK and the USA are fairly typical in prohibiting payment for organs through specific legislation; all three allow reimbursement for expenses associated with the donation; Human Organ Transplant Act 1987 (Singapore); Human Tissue Act 2004 (UK); and National Organ Transplant Act, 98-507 (1984) (USA).

⁵¹ Friedman, A. 2006. Payment for Living Organ Donation Should be Legalised. *British Medical Journal* 333: 746-748; Savulescu, J. 2003. Is the Sale of Body Parts Wrong? *Journal of Medical Ethics* 29: 138-139; Benatar, S. 2004. Blinkered Bioethics. *Journal of Medical Ethics* 20: 291-292; Campbell, A. V. In press. Why the Body Matters: Reflections on John Harris's Account of Organ Procurement. In Holm, S., Hayry, M., and Takala, T. eds. *Life of Value*. Amsterdam and New York. Rodopi.

⁵² E.g. Ministry of Health (Singapore), 1990; 6th Update 2006. Directives for Private Healthcare Institutions Providing Assisted Reproduction Services: Regulation 4 of the Private Hospitals and Medical Clinics Regulations (CAP 248, REG 1), sec. 4.11.2; Human Fertilisation and Embryology Act 1990 (UK), sec. 12(i).

⁵³ Spar, D. 2007. The Egg Trade – Making Sense of the Market for Human Oocytes. *New England Journal of Medicine* 356: 1289-1291.

to raising payment to the level of what the market will bear.⁵⁴ Thus, demand for oocytes determines whether, and how much, ‘donors’ are paid,⁵⁵ with some clinics offering up to \$10,000 and more for oocyte provision.⁵⁶ (Online and media advertisements can offer significantly more.)⁵⁷ The payment of ‘private egg brokers’ is seen by many as ‘compensation for time and trouble’.⁵⁸ The rationale given for this is that in addition to the risks assumed by the provider, oocyte procurement is a significant burden for women in terms of time. The American Society for Reproductive Medicine (ASRM) cites an estimate that egg providers spend ‘56 hours in the medical setting, undergoing interviews, counseling, and medical procedures related to the process’.⁵⁹

(2) Compensation for Living Oocyte Providers

Strict Compensation

Different levels of compensation exist in various countries. The least beneficial to personal profit – in terms of financial reward – is strict compensation, as found in Singapore. Here, the current position is that oocyte donation for research is permitted both for IVF patients and for healthy volunteers not undergoing fertility treatment. However, no inducement, financial or otherwise, is allowed under the *Human Cloning and Other Prohibited Practices Act 2004*,⁶⁰ although payment of ‘reasonable expenses’ is permitted for direct ‘out-of-pocket’ monetary loss.⁶¹ In this model, it is possible that the donor will be financially worse off, if, for example, she has to take time away from work to participate in the donation or because of illness linked to the COH procedure.

Cost Neutral Compensation

The cost neutral model, adopted by a number of countries, prevents providers from making any profit from the donation, but also attempts to ensure that they are not financially worse off. As of early 2007, women in the UK are able to donate their eggs to research projects.⁶² Women had previously been able to donate only spare eggs

⁵⁴ Sauer, op. cit. note 24.

⁵⁵ Sapr, D. 2006. *The Baby Business: How Money, Science and Politics Drive the Commerce of Conception*. Massachusetts. Harvard Business School Press.

⁵⁶ Ethics Committee of the ASRM. 2000. Financial Incentives in Recruitment of Oocyte Donors. *Fertility and Sterility* 74: 216-220.

⁵⁷ Kolata, G. 1999. \$50,000 Offer For Egg Donor Sharpens the Debate. *New York Times*, 3 March. p. A10

⁵⁸ Ethics Committee of ASRM, op. cit. note 56; ASRM. 2000. Financial Incentives in Recruitment of Oocyte Donors. *Fertility and Sterility* 74: 216-220.

⁵⁹ Ethics Committee of ASRM. 2004. Financial Incentives in Recruitment of Oocyte Donors. *Fertility and Sterility* 82 Suppl. 1: S240-S244.

⁶⁰ Chapter 131B; sec. 13; also see: Ministry of Health, op. cit. note 52.

⁶¹ Ibid. sec. (5)(a).

⁶² HFEA Statement on Donating Eggs for Research. 21 February 2007. Available at: <http://www.hfea.gov.uk/cps/rde/xchg/SID-3F57D79B-9CF63D2F/hfea/hs.xsl/1491.html>. Accessed March 2007; HFEA. 2006. Donating Eggs for Research: Safeguarding Donors – Consultation Document. London. HFEA. p. 9.

produced through IVF or in connection with gynaecological treatment such as sterilisation. Limited expenses can be provided to gamete donors as ‘reimbursement’ for any ‘out-of-pocket’ costs incurred *and* loss of earnings;⁶³ these are considered as reasonable expenses only if they are incurred within UK in direct connection with the donation.⁶⁴ Informal ‘payment’ may also be given to oocyte donors at the discretion of fertility clinics.⁶⁵ Compensation is therefore ‘expense neutral’, and the donor is left no worse off as a result of providing her oocytes.⁶⁶ It is not clear whether ‘loss of wages’ would include time away from work as a result of illness directly associated to the procedure.

Fixed Compensation

Some countries allow for fixed pecuniary compensation. This is set by policy rather than by market forces or the evidence of actual expenditure (as in the previous two schemes). The level of compensation may take into account any costs of the donor, but since it is a fixed amount, it does not specify what these ‘costs’ may be for each potential donor (i.e. direct costs, time, risk or loss of earnings). Thus the amount may constitute a positive benefit to the donor, since what is only reimbursement for one woman, may constitute payment for another.⁶⁷

(3) *Benefits in Kind*

In addition to the ‘cost neutral’ compensation available in the UK, there are no legal restrictions on the value of *other benefits* which may be given to the donor. However,

⁶³ Capped at £55.19 a day, but with an absolute limit for each cycle of oocyte donation of £250; HFEA. 2006. 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. Ref. D.2006/1. London. HFEA.

⁶⁴ To dissuade ‘fully funded’ visits from abroad; HFEA. 2005. SEED Report: A Report on the Human Fertilisation and Embryology Authority’s Review of Sperm, Egg and Embryo Donation in the United Kingdom. London. HFEA. (hereafter SEED). sec. 4.5.

⁶⁵ Capped at fifteen pounds plus expenses, this is permitted as an incentive to recruit donors for IVF treatment; HFEA. 2003. Code of Practice 6th Edition. London. HFEA. sec. 4.26. Although it has previously been considered whether any payment at all is ethical; see: HFEA. 1998. Consultation on the Implementation of Withdrawal of Payments to Donors. London. HFEA. The current payment is set at a level which does not ‘...induce research participants to take risks that they would otherwise take, or to volunteer more frequently than is advisable or against their better interests or judgments’; quoted in: HFEA. 2006, op. cit. note 62, p. 23.

⁶⁶ SEED, op. cit. note 64, sec. 4.

⁶⁷ The danger is that poor countries will be the targets for donation, because compensation in one country may amount to payment in another. In reference to Romanians in particular donating in the UK, an HFEA spokesperson stated: ‘We have to ask why there appear to be so many more altruistic donors in other countries’; Derbyshire, D. 2004. Law on Anonymity Drives Would-Be Parents Abroad. Daily Telegraph (UK), 3 July. Available at: <http://www.telegraph.co.uk/news/main.jhtml?xml=/news/2004/07/03/nivf03.xml>. Accessed April 2007.

the only ones which may be offered for this purpose are ‘treatment services’, and so, in practice, this means subsidised IVF treatment.⁶⁸

A justification for such schemes is that OHSS and other risks may be acceptable for successful IVF outcomes (and which are not altered by the donation of spare oocytes for research),⁶⁹ but not for healthy volunteers involved in research only. Therefore, since patients are already exposed to these drugs, there is no need to differentiate the subsequent use of oocytes; and if there are spare oocytes remaining after treatment they may be donated for research (I will return to this issue, below).

A further issue is that this scheme exposes the tension (and blurring of boundaries) between IVF-clinical goals⁷⁰ and the drive for research progress. On the one hand, a policy of collecting large numbers of oocytes driven by clinical need may result in spare oocytes which can be donated for research. On the other hand, there is the view that lower numbers of oocytes – and therefore lower levels of drugs which may decisively reduce clinical complications –⁷¹ may provide an equal probability of successful pregnancy.⁷² Obviously, fewer oocytes will thereby be available for research. It is also not clear what the contractual consequences are, if no oocytes are available for donation for research subsequent to treatment.

(4) Other Conditions for Oocyte Donation

There are countries which allow the donation of oocytes only from those undergoing IVF treatment, and in South Korea, since the Hwang scandal, egg donors cannot receive any financial reward or personal benefit. However, where oocyte donation from healthy woman is permitted by regulations, there are some common provisions associated with any recompense.⁷³

⁶⁸ HFEA, op cit. note 63, para. 5. This clause relates to a Direction, issued in 1992, in which the HFEA permitted the provision of ‘treatment services and sterilization in exchange for ovum donation’ or ‘egg sharing’; see: Blyth, E. 2002. Subsidized IVF: The Development of ‘Egg Sharing’ in the United Kingdom. *Human Reproduction* 17: 3254-3259.

⁶⁹ This is partly driven by a policy in many clinics to obtain a large number of eggs which can be frozen and retained for later use by the clients if the initial round of treatment fails. However, others have cautioned against the unchecked drive for achieving a successful pregnancy; see: Abramov, Y., Elchalal, U. and Schenker, J. 1999. Severe OHSS: An ‘Epidemic’ Of Severe OHSS: A Price We Have To Pay? *Human Reproduction* 14: 2181–2183; Empeaire, J. and Edwards, R. 2004. Time to Revolutionize the Triggering of Ovulation. *Reproductive BioMedicine Online* 9: 480–483.

⁷⁰ Ferber, S. 2007. As Sure As Eggs? Responses to an Ethical Question Posed by Abramov, Elchalal, and Schenker. *Journal of Clinical Ethics* 18: 35-48.

⁷¹ Aboulghar, R. and Mansour, M. 2003. Ovarian Hyperstimulation Syndrome: Classifications and Critical Analysis of Preventive Measures. *Human Reproduction Update* 9: 275–289.

⁷² Inge, G., Brinsden, P. and Elder, K. 2005. Oocyte Number Per Live Birth in IVF: Were Steptoe and Edwards Less Wasteful? *Human Reproduction* 20: 588–592; Edwards, R., Lobo, R. and Bouchard, P. 1996. Time to Revolutionize Ovarian Stimulation. *Human Reproduction* 11: 917–919.

⁷³ For example, some countries, such as Denmark, allow donation of oocytes for IVF treatment from IVF patients only; Andersen A., Larsen J., Hornnes P., Starup J., Andersen C., Westergaard L., Rasmussen P., Ingerslev H. and Maigaard, S. 1993. Ovum donation: A Review

Underlying much of the justification for allowing women to provide oocytes for research are measures to ensure that information is openly and freely made available regarding the risks and that she is well aware of the consequences of her decision.⁷⁴ Importantly, any compensation or payment should not cloud her judgment. However, there are some reports that the full implications of the risks of oocyte donation are not always made available to donors.⁷⁵ To avoid this occurring, a detailed procedure to ensure proper information and to look for evidence of coercion (financial or emotional) is needed. In Singapore, for example, a scheme operated by the Ministry of Health includes provisions for the review of all prospective healthy donors by a panel to ensure that consent for donation is informed and voluntary.⁷⁶ In assessing each donation, the panel must give additional consideration to the ‘public interest’ and ‘community values’.⁷⁷ Furthermore, often donors are screened in general medical evaluations, and specific screening for sexually transmitted diseases, genetic screening and a psychological assessment.⁷⁸ (Often these are more relevant to oocyte donation for reproductive purposes.)

(5) The International Demand for in Oocytes

of and a Suggestion to Unified Guidelines for Treatment at Public Fertility Clinics in Denmark. *Ugeskr Laeger* 155: 2515-2519. Most countries have research ethics frameworks to establish the ethical and scientific credibility of research projects involving human participants. In this regard, such committees will probably want to ensure that the condition of oocyte procurement (consent and justified incentives) are in line with local regulations and ethical norms.

⁷⁴ Ethics Committee of the ASRM, *op. cit.* note 56. The implications for future health and risks for an IVF patient as a result of ovarian hyperstimulation are quite different from a healthy donor, and IVF patients go through no unnecessary or unrelated treatment to procure oocytes should they decide to donate them for research.

⁷⁵ Magnus, D. and Cho, M. 2005. Issues in Oocyte Donation for Stem Cell Research. *Science* 308: 1747-1748.

⁷⁶ Ministry of Health, *op. cit.* note 52; see section 8 on ‘Research’.

⁷⁷ *Ibid.* sec. 8.6. ‘Public interest’ lacks a concise definition in many legislatures. In Singapore, for example, Justice VK Rajah stated: ‘...it is also pertinent to reiterate that public interest is not a static concept fossilized by time or space, but rather a dynamic one, shaped and coloured by the circumstances and mores of a particular society’; *Public Prosecutor v Law Aik Meng* [2007] SGHC 33. I will return to this question later in the paper. ‘Community values’ may indicate the recognition of the plurality of established cultural norms in Singapore; Heng, B. 2006. *Alternative Solutions to the Current Situation of Oocyte Donation in Singapore*. *Reproductive BioMedicine Online* 12: 286–291.

⁷⁸ It should also be noted that often the health and medical information required from the potential donor are significant, including health history, microbiological testing, genetic information and data on lifestyle choices. This is often not trivial information, and requires careful management on behalf of the donor by the collector, repository, and the researcher, and which must be consented to by the donor. Furthermore, rules on traceability are likely to become more significant, as the EU Tissue Directive demonstrates; Sousa et al., *op. cit.* note 6. See: ASRM. 2002. *Guidelines for Oocyte Donation*. *Fertility and Sterility* 77: S6–S8; ASRM. 2002. *Psychological Assessment of Gamete Donors and Recipients*. *Fertility and Sterility* 77: S11–S12. However, the problem in the USA is that the ASRM’s recommendations are optional and therefore (evidently) ineffectual.

The wide range of national policies on oocyte provision means that the international aspects of human body markets are significant; and the globalization of medicine has a significant impact on market positive arguments. One of the arguments offered to support markets is that they prevent potential providers from heading overseas, and so limit the incentive for overseas providers to leave their country.⁷⁹ Erin and Harris claim that an open market in body parts can be ethical if it is regionally specific.⁸⁰ However, while creating more convenient and rewarding ways to procure oocytes may reduce the demand for overseas oocytes, it will not eliminate the demand as long as those overseas oocytes remain significantly cheaper to procure than home based ones. Controlling an 'ethical' market on the lines described by Erin and Harris would require a well defined and regulatory advanced region; but it is unlikely that such a state could ever be achieved without strict policing, and this raises its own concerns.⁸¹ In Europe, where there is a developed regulatory framework in the procurement of organs, tissues and cells at the Community and Member State level, 'medical tourism' to procure various clinical services is evident; and it is clear that potential donors are willing to travel to receive payment for their oocytes.⁸² With regard to SC science this raises a specific concern for the 'invisible donor':⁸³ the purchase of oocytes from brokers in de-regulated havens where there is no traceability, or evidence of, for example, informed consent.⁸⁴

PART THREE: ETHICAL ISSUES

As stated at the outset of this Paper, current patterns in research will probably increase the demand on human oocytes. As a consequence there is likely to be an increased use of incentives or rewards to recruit potential donors and the possible emergence of a 'black market' in oocytes. In the following sections, I will address three issues that are at the forefront of the current debate regarding oocyte procurement from women able to consent. It will become clear that a theme to this debate is the actual choice which potential donors have when possible coercion and undue incentives are in the background. Reaching an ethical solution to the scarcity of human oocytes in public policy will therefore require an assessment of public interest as a guide to balancing altruistic and incentive-driven motivations.

⁷⁹ Sauer, M. 1997. Reproductive Prohibition: Restricting Donor Payment will lead to Medical Tourism. *Human Reproduction* 12: 1844-1845; the stories of two British students who traveled to the USA to donate their eggs for financial reward can be found in: *Sunday Times* (London), 24 November 2002.

⁸⁰ Erin, C. and Harris, J. 2003. An Ethical Market in Human Organs. *Journal of Medical Ethics* 29: 137-138.

⁸¹ Pennings, G. 2002. Reproductive Tourism as Moral Pluralism in Motion. *Journal of Medical Ethics* 28: 337-341.

⁸² It is alleged that a large number of Romanian women donate to UK and USA clinics, where 'reasonable expenses' of 100-250 Euros (or 6,400 Euros by one US company) provide a significant income for them in their home country; *Daily Telegraph* (London), 14th June 2005.

⁸³ Delmonico, F. and Dew, M. 2007. Living Donor Kidney Transplantation in a Global Environment. *Kidney International* advance online publication, 7th February. doi: 10.1038/sj.ki.5002125.

⁸⁴ Aldhous, P. 2000. Panacea, or Pandora's Box? *Nature* 408: 897-898.

I. Payment and Compensation

It is often pointed out that the problem of oocyte availability (and for that matter, organ availability) is comparatively less in countries where commercialisation is tolerated.⁸⁵ Therefore, it is argued that governmental restraints placed on payment may restrict woman from providing oocytes either for IVF treatment or for research.⁸⁶ Many see an appeal to healthy providers as a solution to the shortage of oocytes for research; but how one makes altruistic donation an attractive choice, or failing that, persuades women to donate oocytes, are crucial questions. It is argued that women are unlikely to donate oocytes for research when there is little, if any, direct benefit for them. Thus, payment is claimed to be a justified incentive to attract potential providers. However, others argue that this will merely lead to an uncontrollable market in oocytes, and once this happens, commodification and exploitation are significant risks (discussed in the next section). Thus, they believe that research must rely on altruistic and limited incentive-driven donation.

Proponents of oocyte payment schemes often question even the possibility of truly altruistic donation; some argue that, with the risks and inconvenience set so high, a culture of altruistic donation will never be achieved.⁸⁷ Thus, many turn to consistency arguments to allow universal payment for ‘donors’. Presently, payment for organ donation is generally prohibited, but payment *is* permitted for participation in clinical research, where volunteers are recompensed for their time and effort, as well as for expenses incurred.⁸⁸ Often, risks are also factored into the amount paid.⁸⁹ It is argued that ‘financially positive’ compensation, whether it is for research, organ or oocyte donation, constitutes a fair recognition of the contribution of the individual. It is further claimed that this in no way diminishes altruistic motives or the generosity of the donor, rather that it is an appropriate gesture of thanks for the time spent and inconvenience (willingly) experienced.⁹⁰ Payment or comprehensive compensation for living donors

⁸⁵ Sidebotham, M. 2003. Egg and Sperm Donation: An Issue for Health Care Professionals? *Journal of Family Health Care* 13: 134-136.

⁸⁶ The other possibility is that the lack of regulation in the USA (for example) disproportionately encourages oocyte donation; Sauer, M. 2005. Further HFEA Restrictions on Egg Donation in the UK: Two Strikes and You’re Out. *Reproductive BioMedicine Online* 10: 431-433.

⁸⁷ Ironically, prior to the Hwang controversy, it was commented that: ‘South Korea has a culture of egg donation for research, which enabled the scientists to obtain good-quality eggs’; Cookson, C. 2005. *The Cloning Connections*. In: *The Future of Stem Cells*. Financial Times & Scientific American Special Report. p. A11.

⁸⁸ Woo, K. 1999. *Conducting Clinical Trials in Singapore*. Singapore Medical Journal 40: no page number (Singapore); General Medical Council (GMC). 2002. *Research: The Role and Responsibility of Doctors*. London. GMC (UK); and National Institutes of Health. *Modification of GCRC Guidelines Regarding Payment to Research Subjects*; June 2002. Available at: <http://www.ncrr.nih.gov/clinical/crguide2001/gcrguidelinemodify062002.pdf> (USA).

⁸⁹ The distinction between payment for donating for profit in IVF and compensation for donation for research in some US states is likewise criticised; Spar, op. cit. note 51.

⁹⁰ Ethics Committee of ASRM, op. cit. note 56.

should therefore be made ethically consistent, and exploitation and equitable treatment of donor and recipient can be managed through a controlled market, so it is argued.⁹¹ Others emphasise the difference between the donation of different body parts. Objection to the sale of parts like kidneys, they claim, ‘lacks punch in the case of gametes, which are replaceable, and non-essential to health’.⁹² So, the degree of risk for oocyte donors does not warrant the same paternalistic protection; and oocytes, since they lack characteristics that confer ‘interests’ (or a ‘dignity’ status, discussed below), can be bought and sold as property.⁹³

In light of the concerns about markets in human body parts, policies have evolved that attempt to provide incentives without leading to direct payment to the donor. As we saw above, one solution, preferred in the UK, is to make the proposition of donation attractive to a limited population by offering ‘benefits in kind’ to IVF patients. Proponents of this scheme point out that, working with donors who are using ovulation-stimulating drugs anyway, avoids exposing otherwise healthy women to any risks associated with them.⁹⁴ The most recent study concerning egg-sharing in IVF exchanges provided evidence that such practices do not affect the success of IVF treatment;⁹⁵ therefore, it is possible that donating oocytes for research *as part of the IVF treatment* would also not affect the clinical outcome. Furthermore, it is argued, subsidised IVF treatment services do not represent payment in monetary terms. These ‘other benefits’ reflect services which cannot normally be measured in money. (One can pay for a service, but the service itself – once used – has no monetary value).⁹⁶ However, in addition to a number of clinical concerns of clinical practice to be arising,⁹⁷ some critics view subsidised IVF treatment as essentially a commodity exchange – redefining the interaction to avoid any reference to payment –, and so perilously close to a financial inducement.⁹⁸

Compensation for expenses is therefore the most common incentive for oocyte donation. But even here there are concerns. Since the primary motivation of having a child is no longer present, any incentive treads very close to what may be considered as

⁹¹ Friedman, op. cit. note 51.

⁹² Burley, op. cit. note 43, p. 193.

⁹³ Ibid. p. 194.

⁹⁴ Ahuja, K., Simons, E., Rimington, M., Nair, S., Gill, A., Evbuomwan, I. and Bowen-Simpkins, P. 2000. One Hundred and Three Concurrent IVF Successes for Donors and Recipients Who Shared Eggs: Ethical and Practical Benefits of Egg Sharing to Society. *Reproductive Biomedicine Online* 1: 101-105.

⁹⁵ Thum, M., Gafar, A., Wren, M., Faris, R., Ogunyemi, B., Korea, L., Scott, L. and Abdalla, H. 2003. Does Egg-Sharing Compromise the Chance of Donors or Recipients Achieving a Live Birth? *Human Reproduction* 18: 2363-2367.

⁹⁶ SEED, op. cit. note 64, sec. 10.

⁹⁷ There are a number of established rules that should be followed surrounding the separation of the clinician and research, so as to ensure that, for example, there is no risk of over-stimulation to produce more oocytes for treatment and research. A problem is that pressure to donate by IVF patients is inherent in any subsidy agreement, since without the arrangement, the woman is under no pressure to donate. Furthermore, what should happen if the woman withdraws her consent to donate embryos while undergoing treatment?

⁹⁸ Johnson, M. 1997. Payments to Gamete Donors: Position of the Human Fertilisation and Embryology Authority. *Human Reproduction* 12: 1839-1846.

‘undue’, especially if the decision to participate rests solely on monetary recompense.⁹⁹ If incentives are undue, it is normally to the detriment of the individual’s ability to provide free and voluntary consent.¹⁰⁰ Therefore, compensation schemes, however they are presented, do provide an incentive which selectively attracts a certain – often financially less well off – person; and for some, this amounts to little more than subtle coercion and exploitation.

The fundamental question is where the point lies at which compensation becomes an undue incentive or reward, since a sum that will be merely compensation for one woman could be enticement for another. The recent drug trials in the UK and the recent research-related deaths in the USA illustrate the significant risks of harm in some classes of medical research.¹⁰¹ This had lead to questions regarding the appropriateness of incentives in inherently risky clinical research, and indeed all activities in which the ‘donor’ exposes herself to significant risk.¹⁰² If consistency is a criterion for regulating risky practices, then it might be argued that what is permitted for volunteers in one area should be applicable to all forms of volunteering, such as oocyte and organ donation. But the argument can cut the other way: perhaps the stricter controls on the latter should be applied to the former. This would mean that many current aspects of clinical research participation by healthy volunteers may be exposed as coercive. (How many would have participated – and what ‘payment’ would have been reasonable – in the TeGenero trial if they knew of the risks?).

II. Commodification

Commodification is the transformation of what is normally a non-commodity into a commodity, or, in other words, to assign monetary value. Once something has a value,

⁹⁹ Tishler, C. and Bartholomae, S. 2002. The Recruitment of Normal Healthy Volunteers: A Review of the Literature on the Use of Financial Incentives. *Journal of Clinical Pharmacology* 42: 365-375.

¹⁰⁰ Macklin, R. 1981. On Paying Money to Research Subjects: ‘Due’ and ‘Undue’ Inducements. *IRB* 3: 1-6. There are numerous concerns regarding consent in this specific context, for example, the comprehension of present risk and future health implications (such as healthy donors who are pre-motherhood and potential infertility through COH), especially in the present uncertainty and the paucity of meaningful statistics. In attaining consent, the oocyte collectors have the concern of the non-disclosure of information if incentives are too high. This not only risks the health of the patient, but also may invalidate research; Bentley, J. and Thacker, P. 2004. The Influence of Risk and Monetary Payment on the Research Participation Decision Making Process. *Journal of Medical Ethics* 30: 293-298.

¹⁰¹ Steinbrook, R. 2002. Protecting Research Subjects: The Crisis at Johns Hopkins. *New England Journal of Medicine*. 346: 716-720.

¹⁰² Indeed, oocyte donors have been classified as ‘research donors’ to distinguish them from research participants, while acknowledging that they are part of a wider research – rather than therapy – programme; Magnus, D. and Cho, M. 2005. Issues in Oocyte Donation for Stem Cell Research. *Science* 308: 1747-1748. That is not to say that all human research is as risky as giving up a kidney or going through ovarian hyperstimulation, but there may be cases in which ‘special scrutiny’ of certain types of research is needed; Levine, C., Faden, R., Grady, C., Hammerschmidt, D., Eckenwiler, L., Sugarman J. and Consortium to Examine Clinical Research Ethics. 2004. ‘Special Scrutiny’: A Targeted Form of Research Protocol Review. *Annals of Internal Medicine* 140: 220-224.

it can be bought and sold, and for some, this betrays the ‘dignity’ status of human beings.¹⁰³ For others, commodification leads to processes through which social relations are reduced to an exchange relation; thus the interests, health, wellbeing, and ‘worth’ of the individual come second to monetary interests, and there is an inevitable disregard of human rights and the encouragement of exploitive practices. In practical terms, commodification in human body parts leads to the inducement for economically vulnerable people to sell their organs, tissues and cells, since they are the only ones who stand to benefit by addressing financial burdens in this way. Therefore, a common argument against payment for human parts focuses on the concept of ‘gift’.¹⁰⁴ It is argued that receiving ‘valuable consideration’ or ‘money’s worth’ in exchange for organs contradicts the normal understanding of a gift as something that is given without the expectation of payment or reward; and by emphasising the altruistic nature of giving human parts, one is better able to avoid the risks of an open market.

A problem here is that donors may ‘gift’ their oocytes to research, but the relationship is really one of exploitation: ‘If donors believe they are demonstrating altruism, but biotechnology firms and researchers use the discourse of commodity and profit, we have not ‘incomplete commodification’ but complete commodification with a plausibly human face’.¹⁰⁵ Solving this problem, according to some, would require making the transaction transparent – and therefore making it subject to *public* payment. Choice therefore becomes paramount; but we are left with the familiar problem that “‘choice’ appeals to those who have options, but it is relatively meaningless to those who do not, it is politically divisive’.¹⁰⁶ The European Parliament (of the European Union) therefore conclude that any trade – public or not – should be prohibited, and that ‘egg cell donation, like organ donation generally, [should be] strictly regulated in order to protect both donors and recipients and to tackle all forms of human exploitation; [and] ...any woman forced to sell any part of her body, including reproductive cells, becomes prey to organised crime networks that traffic in people and organs’.¹⁰⁷

Another way to avoid commodification, so it is argued, is to prohibit payment altogether, and this is justified on the grounds that while there is some form of rights over the control of one’s body parts (i.e. to be able to donate oocytes regardless of the risks),¹⁰⁸ there are no rights to exploit the commercial value of the same. This is similar

¹⁰³ See: Brownsword, R. 2003. Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the ‘Dignitarian Alliance’. Notre Dame Journal of Law, Ethics and Public Policy 17: 15-57.

¹⁰⁴ Titmuss, R. 1970. The Gift Relationship. London. Allen and Unwin.

¹⁰⁵ Dickenson, D. 2002. Commodification of Human Tissue: Implications for Feminist and Development Ethics. Developing World Bioethics 2: 55-63, p. 62.

¹⁰⁶ Fried, G. 2005. The Politics of Abortion and Reproductive Justice: Strategies for a Stronger Movement’. In: DIFFERENTAKES Series of the Hampshire College Population and Development Programme. No. 38, Fall. Available at: <http://popdev.hampshire.edu/projects/dt/dt38.php>.

¹⁰⁷ European Parliament. 2005. Resolution on the Trade in Human Egg Cells. P6_TA(2005)0074 Thursday, 10 March. Strasbourg.

¹⁰⁸ This point is similar to that made by Andrew Grubb, in which ‘English law has developed ...to provide significant protection to individuals’ self-determination by recognizing a ‘right to bodily integrity’ Grubb, A. 1998. ‘I, Me, Mine’: Bodies, Parts and Property. Medical Law International 3: 299-317.

to Ronald Dworkin's argument that a right, by definition, must trump *some* collective goal, but it does not follow that it must trump *all* such goals.¹⁰⁹ Thus, the deployment of individual rights may be limited by exceptions which uphold the rights and freedoms of others in general or of a specific group. I will discuss this further regarding public interest, below.

III. Autonomy and Risk

Those who support paid oocyte donation focus upon the desirable ends of SC therapies, and justify the solution to the current shortage of oocytes by openly paying for them. Taking this argument further, some maintain that it is ethically imperative for human oocytes to be readily available for SC research so that progress is not held up. The solution is therefore to protect individuals in the process of provision of oocytes, and to avoid the (not inevitable) pitfalls of 'black markets'. The key, some have argued, is to strengthen the rights of vulnerable individuals and populations by improving autonomy through consent procedures; as long as women give their free and informed consent, it is up to them to take the risks of egg donation. Others have called for a more cautious – but permissive – approach which may permit such donation, but requires the monitoring of all women who undergo COH either for research or therapy.¹¹⁰ However, the concern here is that the future health problems for COH are currently unknown, and therefore consent is not truly informed, and donors may appear as research subjects in finding out the long-term effects.¹¹¹

The possible future health risks have led some to reject entirely the suitability of healthy woman as oocyte donors for research. This is driven by the concern that research has not yet produced results which are convincing enough to justify the risks to some donors. They additionally point out that the reported 'emergency' in the lack of human oocytes for research may be unfounded or at least overblown, since currently there are relatively few SC research projects involving human oocytes or embryos;¹¹² and in the UK, careful oversight and control of 'compensated' and 'benefits in kind' donations in a recent project has achieved the requisite numbers of oocytes necessary.¹¹³ SC research is barely past basic scientific scrutiny; and cloning

¹⁰⁹ Dworkin, R. 2004. *Taking Rights Seriously (New Impression)*. London. Duckworth. pp. 184-205.

¹¹⁰ Mertes, H. and Pennings, G. 2007. Oocyte Donation for Stem Cell Research. *Human Reproduction* 22: 629-634. The Royal College of Obstetrics and Gynecology (UK) endorse the establishment of an oversight committee to monitor the health of oocyte donors; RCOG Statement on HFEA's Discussions on Altruistic Human Egg Donations for Research. 21st February 2007.

¹¹¹ Capps, B. and Campbell, A. V. 2007. Why (only some) Compensation for Oocyte Donation for Research Makes Ethical Sense. *Journal of International Biotechnology Law* 4: 89-102.

¹¹² In the UK, as of March 2007, there were 34 current projects licenced by the HFEA, involving 25 UK Centres. Available at: <http://www.hfea.gov.uk/en/374.html>. We were unable to find a record of research using human embryos in the Singapore or the USA.

¹¹³ But with certain caveats; see: Choudhary, M., Nesbitt, M., Leary, C. and Murdoch, A. 2006. Donation of Fresh Oocytes for Nuclear Transfer Research – A New Approach. *Reproductive Medicine Online* 13: 301-302.

experiments, which seem to make the most demands of oocyte donation, have yet to pass animal-research stages, so that clinical applications are necessarily hypothetical.¹¹⁴

IV. The Public Interest and Policies of Oocyte Procurement

This current debate, I believe, can be better understood through the concept of public interest. The ‘public interest’ is a fundamental criterion in many medical and reproductive policies, placing constraints upon individual rights,¹¹⁵ and in this regard it has an important role in determining the nature of national and global policies.¹¹⁶ However, the careless deployment of the concept has created a number of confusions and has tended to mask differences in national policies. With such different opinions on the acceptability of a market in oocytes, clearly there must be more than one concept of ‘the public interest’ at work,¹¹⁷ one which promotes autonomous self-interest – and therefore payment –, and another that values altruism as conducive to communitarianism. These are two common, but quite different accounts of the concept which are evident in oocyte procurement policies:

(1) The Public Interest as the Sum of Individual Interests

Market models, such as that found in the USA, consider the donation of oocytes from the perspective of meeting market demands. Since oocytes are in short supply, it is not unreasonable, the argument goes, for carefully controlled but positive incentives to persuade IVF patients and healthy individuals to donate oocytes by ‘rewarding’ their

¹¹⁴ Snyder, E. and Loring, J. 2006. Beyond Fraud: Stem-Cell Research Continues. *New England Journal of Medicine* 354: 321-324.

¹¹⁵ For example, it is implicit in case law; for the UK, see: Beyleveld, D. 1995. The Concept of a Human Right and Incorporation of the European Convention on Human Rights. *Public Law Winter*: 577-598; for USA, see: Dworkin, op. cit. note 109; and Sorauf, F. 1957. The Public Interest Reconsidered. *Journal of Politics* 19: 616-639. Indeed, arguably public interest is integral to any jurisdiction whose jurisprudential underpinnings rely on human rights; see: Rawls, J. 2005. *Political Liberalism* (Expanded Edition). New York. Columbia University Press; Gewirth, A. 1978. *Reason and Morality*. Chicago. Chicago University Press. In Singapore, where there is no human rights legislation, the public interest is expressly mentioned; supra. note 77.

¹¹⁶ The European Convention of Human Rights 1950 (which is incorporated into UK domestic law by the Human Rights Act 1998) construes public interest in ‘health’ (in Articles 8, 9, 10, & 11) as the ‘...interference by a public authority ...as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others’ (from Article 8 Right to Respect of Private and Family Life, but is similarly stated in the subsequent Articles). In the US, the importance of the public interest can be inferred from case law. For example, the payment for organs was described as ‘...clearly repulsive to public policy and federal law’; Opinion by Judge Crabtree, *Wilson v. Adkins*. Court of Appeals of Arkansas, Division 1 941 S.W.2d 440 (Ark. Ct. App. 1997), quoted in Menikoff, J. 2001. *Law and Bioethics: An Introduction*. Washington, D.C. Georgetown University Press. p. 484.

¹¹⁷ McHarg, A. 1999. Reconciling Human Rights and the Public Interests: Conceptual Problems and the Doctrinal Uncertainty in the Jurisprudence of the European Court of Human Rights. *Modern Law Review* 62: 671-696.

altruistic actions.¹¹⁸ Notwithstanding the public interest in procreation, medical, and specifically SC research represents benefits which are ‘long-term’ and reflect a ‘relative value’ that ‘benefit many people within society’.¹¹⁹ This defence of oocyte procurement therefore depends on the evaluation that current research can appeal to the public interest (i.e. it is not in the public’s interest to stop this kind of compensated or paid oocyte provision).¹²⁰

Market models built upon this idea promote the liberty interests or autonomy of donors and recipients on the grounds that most of our free choices presuppose some control over our own bodies – implying that people may sell parts of their body, while also benefiting others in society.¹²¹ Indeed, some writers question whether we should even *allow*, let alone *encourage*, non-patient volunteers to donate eggs as an altruistic act.¹²² Thus the US model reflects (in theory) a balance between empowering self-determination, providing fair incentives, and dissuading undue inducements, which could lead donors to discount risks and make ill-considered judgments.

The problem with this interpretation of the ‘sum-of-particular interests’ is that it restricts central (government) politics to only those goals held unanimously by members of society, such as the almost universal political condemnation and resulting prohibition of reproductive cloning. Moreover, many of these private interests are specific ‘special’ interests, leaving us with no way of assessing the advantage that gives *this* interest a prior claim to support in public policy.¹²³ Therefore, it has little moral depth, and so, according to Gunn, it is easy to criticize this position as a subjective collection of individual interests that ‘...do not ‘add up’’.¹²⁴ In the context of oocyte donation, many are quick to point out the implication of diminished, rather than augmented good, for vulnerable populations. Therefore, a decentralised market in oocyte procurement, of the kind evident in the USA, cannot produce collective outcomes and cannot protect vulnerable members of society from instrumentalism, or even enslavement and impoverishment. Regulations that minimally ensure that the potential donor is informed of the risks, and that no inducement or coercion is evident, primarily protect those well able to look after their own interests already. Therefore, it

¹¹⁸ Ethics Committee of the ASRM, op. cit. note 56, p. 218.

¹¹⁹ HFEA. 2006, op. cit. note 62, p. 9.

¹²⁰ There remain questions as to how far reproductive autonomy can be permitted to go, and some acts should regardless be outright banned. Likewise, compensation for the physical inconvenience and risks may encourage some people to donate without thinking sufficiently about the consequences; payment therefore risks coercion and undue incentives which places undesirable burdens on women; SEED op. cit. note 64, sec. 5.9.

¹²¹ Resnik, D. 2001. Regulating the Market for Human Eggs. *Bioethics* 15: 1-26.

¹²² Lockwood, G. 1997. Donating Life: Practical and Ethical Issues in Gamete Donation. In: Shenfield, F. and Sureau, C. eds. *Ethical Dilemmas in Assisted Reproduction*. New York: Parthenon Publishing Group. pp. 23-30.

¹²³ Sorauf, op. cit. note 115, pp. 620-621.

¹²⁴ Gunn, J. 1968. Jeremy Bentham and the Public Interest. *Canadian Journal of Political Science* 1: 398-413, p. 398.

is argued, aggregating interest is bound to fail some members of the community when the ‘sum’ of conflicting interests represents no common unity.¹²⁵

(2) The Public Interest as Sharing Agreed Goals

The ‘common-interest theory’ of public interests focuses on what sort of society we want to live in, and how best we can achieve these shared social goals. By considering these questions, it is possible to create a picture of a community in which every individual is equally recognised as a cooperative and social entity.¹²⁶ Therefore, the public interest supports ethical standards which apply to every member of the community as collective goals, benefiting all members of society. Public interest values can be distinguished from something which is advantageous to one person but disadvantageous to another.¹²⁷

If public interest is viewed in this way, it is possible to direct attention towards often ignored interests, such as equal treatment, avoidance of exploitation and the fostering of opportunity, thus emphasising the importance of private achievements that contribute to the ‘public’ experience. This version of the public interest lends support to policies of altruism (as implicitly expressed in expense reimbursement only policies). In this sense, public interest equates to a justifiably paternalistic attitude which aims to protect certain worthwhile values of the *community*.¹²⁸ Without such protections and limits on individual autonomy, the concern is that community cohesiveness would be eroded. Ensuring that oocytes are donated for the benefit of others in the community and not for personal profit and that vulnerable populations are protected from potentially unscrupulous buyers are the priorities for this version of the public interest.

The common counter-argument here is that this approach removes part of our ‘reproductive autonomy’,¹²⁹ and which leads one back to public interest as the sum of individual interest. Provided that such choices are entirely free from coercion – and *regardless* of the possibility of intentional and foreseeable harm – why shouldn’t women choose – and be paid as for any other legal public service – to use their oocytes to achieve their own, or someone else’s pregnancy, or to donate them for research?

Conclusion

This Paper was commissioned by the Bioethics Advisory Committee of Singapore and completed in the period between January and April 2007. In this Paper, I do not offer

¹²⁵ Lyons, D. 1994. Utility and Rights. In Waldron, J. ed. Theories of Rights. Oxford. Oxford University Press. pp. 110-136.

¹²⁶ Rawls, J. 1973. A Theory of Justice. Oxford. Oxford University Press. pp. 522-525.

¹²⁷ Cassinelli, C. 1958. Some Reflections on the Concept of the Public Interests. *Ethics* 69: 48-61.

¹²⁸ Capps, B., Campbell, A. and ter Meulen, R. Forthcoming, 2007. Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good. Commissioned paper for the UK Biobank Ethics and Governance Council.

¹²⁹ For a discussion on this, see: O’Neill, O. *Autonomy and Trust in Bioethics*. Cambridge. Cambridge University Press. pp. 55-72.

an opinion or support to any particular policy, and instead I offer an overview of the arguments offered for various strategies to procure oocytes for research.

The issues that arise in oocyte procurement are part of a current debate informed by recent controversies surrounding the conditions of oocyte donation from women, the market in oocytes in some jurisdictions, and the scarcity of oocytes specifically for stem cell research. In this Paper I have identified three ethical issues which should be considered in any future ethical policy on oocyte procurement: payment and compensation, commodification, and autonomy and risk. These issues are predominated by the demand for oocytes in stem cell research, and the available and potential alternative sources of oocytes. Resolving these issues requires a debate regarding the definition of ‘public interest’ in oocyte procurement policies, and the balance that one wishes to set between self-interest and communitarian ethics. Central to this balance is the degree to which consensual donation of human parts should be incentivised – to encourage the self-interested to donate oocytes – or predominantly motivated by altruism.

The ‘politics’ of egg donation is not merely a question of identifying and mitigating risks to donors’ health, it is also an issue of scientific ‘promise’, society’s interest in bio-medical progress, and protecting the vulnerable in our community.

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