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## Payment of egg donors in stem cell research in the USA

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### Abstract

Arguments have been put forth as to whether women who donate oocytes for human embryonic stem cell (HESC) research should be compensated, but data regarding this issue have been scant. Recently in the United States, several States have begun funding HESC research, and patient recruitment efforts have begun. This paper lays out relevant arguments and presents data concerning this issue. Researchers are finding that women are unwilling to donate eggs altruistically, which is hampering the progress of research. These efforts are examined, and data on potential donors' views are presented. The absence of payment, rather than ethical concerns, appears to explain opposition to donation. Women also appear generally ignorant of policies in this area. It is suggested that policy discussions shift focus from whether to pay, to how much would be appropriate, and how to decide; and that research and professional education be increased to heighten understanding and awareness of these issues.

### Keywords

assisted reproductive technology; egg sharing; embryo; ethics; IVF; moral

### Introduction

Whether women who donate eggs for human embryonic stem cell (HESC) research should be paid remains hotly debated in both Europe and the United States (USA), but scant relevant data have been available. HESC research (see definitions in Materials and methods for all abbreviations) more broadly has been one of the most controversial topics in contemporary medical science, capturing the attention of scientists, physicians, politicians, theologians and the lay public, all of whom struggle for consensus on how best to proceed in the development and proper use of this research. Following early advancements with various mammalian stem cell lines, concerns arose over the potential for misuse of stem cell research, prompted particularly by questions of reproductive cloning. The lack of safeguards led to governmental prohibitions that severely restricted or banned research outright. In the USA, President Obama on March 9, 2009 reversed President George W Bush's ban on the use of federal monies to develop new cell lines beyond those already existing, which had forced most researchers to pursue avenues outside traditional federal grants. Philanthropically obtained funds and, recently, individual state grants, have in the meantime secured the necessary capital for further development of this important research.

The start of state funding of stem cell research in New York, California, Massachusetts and elsewhere has strengthened the promise of establishing a successful research programme in this area. However, clinical material available to researchers remains scarce. Somatic cell nuclear transfer (SCNT) is best performed using fresh eggs that are enucleated so that a desired somatic cell nucleus can be fused to create a unique cell line carrying the specific traits desired for study. Although egg donation has been commonly used as an infertility treatment in Europe and the USA for over 20 years, recruitment of women to provide gametes for stem cell research has been discouraged through several sets of guidelines and policies.

In the United Kingdom (UK), the Human Fertilisation and Embryology Authority (HFEA) has permitted so-called 'egg-sharing', in which women undergoing their own IVF treatment can donate extra eggs (for purposes of reproduction or research, albeit only in a licensed research project), and receive their treatment for free or at reduced rates. Yet the HFEA has prohibited payment to any other egg donors (Ramsey, 2007). Suggestions have also been made to allow women in poorer countries to provide eggs to women in wealthier countries through egg sharing in return for free or less expensive IVF treatment (Heng, 2005). Such eggs from poorer countries could presumably also be used for research. Yet such international marketing of embryos may pose particular ethical concerns, given cultural and economic differences between countries. Moreover, importantly, the use of embryos acquired through egg sharing usually does not advance research goals for SCNT, which aims to produce disease-specific and patient-specific stem cells. Embryos remaining from preimplantation genetic diagnosis (PGD) could produce disease-specific stem cell lines, but have also been frozen, which probably impairs their usefulness; and unused embryos may have been initially unselected because they appeared in fact less viable in morphology or development. Hence, they may be less efficacious for research purposes, too.

In the USA, the National Academy of Sciences (NAS) stated that donors providing gametes specifically for stem cell research should not receive compensation beyond reimbursement for time and travel expenses (NAS, 2005, 2007, 2008). The California Institute for Regenerative Medicine (CIRM, 2007) subsequently adopted this policy to govern payments for potential egg donors, and will not accept eggs supernumerary for reproductive egg donation cycles where donors received traditional compensation. CIRM's decision may be in response to arguments from two groups, religious conservatives urging that payment fails to adequately respect human dignity, and certain feminists averring that payment represents commodification of the body. Indeed, given that the risks and benefits of egg donation for research purposes are not wholly clear, some critics have argued that a moratorium should be placed on all egg donation for this purpose (Beeson and Lippman, 2006). Massachusetts, which has similarly set aside funds for stem cell research, has also adopted the NAS policy, which outlaws payment *per se* to donors.

In both Europe and the USA, several issues concerning payment for the procurement of eggs for HESC have received some discussion (Hyun, 2006; Thompson, 2007), and arguments for and against have been laid out (Okie, 2005; Robertson, 2006; Steinbrook, 2006; Ramsey, 2007; Spar, 2007), but unfortunately, most of these discussions took place before researchers, funded by States and private philanthropy, began actual recruitment.

In the USA, recent state efforts, and initiation of actual recruitment and research are raising and highlighting critical new challenges. In 2007, for example, New York pledged \$600 million over 6 years, for stem cell research. President Obama's reversal of President Bush's ban on federal funding makes reconsiderations of these issues even more urgent.

Despite arguments in favour of compensation (Hyun, 2006; Thompson, 2007), opposition continues, making it important to examine new relevant data, and reflect on why these obstacles exist, and how to address them.

In 2007, the American College of Obstetrics and Gynecology (2006) and the American Society for Reproductive Medicine (ASRM) (2007) guidelines endorsed reasonable payment of donors for SCNT. The International Society for Stem Cell Researchers (ISSCR) also opened the door to possible compensation, saying, "Reimbursement for direct expenses incurred by donors as a consequence of the consent process may be determined during the SCRO (Stem Cell Research Oversight) process (Ethics Committee, ASRM 2000; Daley *et al.*, 2007)". Nevertheless, NAS, CIRM and Massachusetts policies remain unchanged.

Moreover, although New York has adopted ISSCR guidelines, final decisions are still left up to local Embryonic Stem Cell Research Oversight (ESCRO) Committees. Questions then arise as to how ESCRO Committees will in fact make these decisions. Institutional Review Boards (IRB), for example, are known to vary widely (Klitzman, 2008).

Opponents argue that additional compensation may result in undue inducement and exploitation (Beeson and Lippman, 2006; CIRM, 2007; Ramsey, 2007). Women may decide to provide eggs primarily because of financial need, undervaluing the physical and psychological risks of donation. Critics argue, too, that eggs should not be bought and sold in the marketplace like other commodities, and that to do so represents a lack of dignity and respect. Commentators have also argued (ASRM, 2000) that payment might decrease altruistic donations; that poorer women might differentially donate; that blood and organ donors are not likewise compensated; and as was mentioned above, that embryos could alternatively be donated by women already undergoing IVF therapy.

Yet, on the other hand, compensation does not necessarily violate key underlying ethical principles. Although egg donation appears to be a relatively safe procedure, women do face some physical and psychological risks in donating oocytes, undergoing ovarian hyperstimulation and egg retrieval, and are inconvenienced by weeks of required therapy. Concerns remain as to whether exposures to gonadotrophins increase the incidence of ovarian neoplasms and cancers (Mertes and Pennings, 2007), although well designed retrospective studies have failed to document a relationship (Brinton *et al.*, 2005; Kanakas and Mantzavinos, 2006). Thus, payment may well be appropriate. Moreover, in the clinical setting, donors are paid. Hence, for research subjects to receive a smaller payment than individuals undergoing the same activities in the commercial sector is inequitable.

Restrictions based on fears of undue influence may themselves be paternalistic. US Federal regulations prohibit, but do not define 'undue inducement' and 'coercion' (US Department of Health and Human Services, 2005); and precise definitions of these terms remain unclear (Ripley, 2006). Furthermore, critics have argued that IRB interpret these terms too broadly and are overly concerned about coercion in research, which, these commentators maintain, occurs rarely, if at all (Emmanuel, 2004). Indeed, no research has been published on whether coercion actually occurs in current research, and if so, how often. Moreover, for women to provide informed consent, respect of their autonomy in making their own informed choices is itself very important. Although high payments, beyond a certain point, could potentially become ethically problematic, that should not preclude other, lesser and more reasonable amounts. Compensation for a woman's expenses, 'time, inconvenience and discomfort associated with oocyte retrieval can also be distinguished from payment for the oocytes themselves' (ASRM, 2007).

Although blood and living organ donors are uncompensated, blood donation is minimally risky, and living individuals who donate organs generally do so to close family members and

loved ones. Thus, these examples do not wholly apply to the case of HESC research. Importantly, despite arguments that payments may decrease altruistic donation, almost no such donation has in fact yet occurred. In fact, researchers have experienced difficulties in recruiting women to donate eggs for free. In larger centres, egg donors are available to participate in stem cell research efforts without denying infertile couples interested in accessing eggs an opportunity to receive these. To date, at Harvard, for example, years of significant recruitment efforts and costly advertisements have generated interest from hundreds of women, but when told they would not be compensated more than for direct expenses, all but one potential donor declined to participate (Eggan, personal communication). Yet one privately funded researcher who has paid donors (an average of US\$3673 per egg) has indeed been able to recruit donors (Vogel, 2006).

This lack of donors in the absence of compensation in and of itself indicates a need to revisit this debate. Although critics have heretofore argued that donations could be obtained without payment, researchers' recent experiences reveal that prohibition of payment in fact impedes scientific progress, raising more forcefully issues that need to be entered into the debate concerning social benefit and social justice. Patients who might benefit from treatments arguably may soon be delayed from receiving them because of prohibitions on payment of donors. Providing fair compensation could thus offer important social benefits by facilitating donation that could greatly advance the pace and success of research, leading to treatments that can aid innumerable patients.

Further questions arise regarding how much egg donors do, or should get paid if payment indeed becomes permissible. Of note, across all areas of medical research, uncertainties persist about how much subjects do or should get paid, and few data are available on how often participants in fact get compensated, how much, and how researchers, participants and IRB view and approach these decisions. Varying models have been proposed to determine appropriate amounts: a 'market model' (based on supply and demand, and potentially providing more payment for subjects undertaking more risk), a 'wage payment model' (based primarily on providing a low, standardized wage that could be increased for particularly uncomfortable or onerous tasks), and a 'reimbursement model' (covering expenses, including opportunity costs from missed work) (Dickert and Gradey, 1999). In practice, these models may not always be distinct, and whether and how often they are in fact followed remains unknown. Only a handful of studies have been conducted on how often study participants are actually paid. Recently, it was found that most published articles fail to mention whether participants have in fact been paid, and if so, how much (Klitzman *et al.*, 2007). In at least two areas (diabetes and depression), most on-line recruitment sites for research do compensate participants (Klitzman *et al.*, 2008). Thus, in medical research overall, major questions persist of not only whether, but how much participants are or should be paid.

ASRM's guidelines for compensation of egg donors endorsed the concept of fair payment, initially with ceilings of US\$5000, revised as the marketplace has altered rates of payment, recommending most recently US\$10,000 (ASRM, 2007). Indeed, a market model supports paying the same as for egg donation for clinical purposes: typically US\$2000–8000 (Kliff, 2007). Alternatively, a wage model could suggest that egg donors receive approximately the same per hour as do sperm donors. Thus, a 1993 analysis suggested that if sperm donors receive approximately US\$25 for approximately 1 h, then oocyte donors, spending approximately 56 h in procedures and counselling, should receive equivalent compensation per hour, or US\$1400 for egg donors (Siebel and Kiessling, 1993). By the year 2000, sperm donors received approximately US\$60–75, which would translate to up to approximately US\$4200. Today, sperm donors receive even more. Such a wage model, providing what many

would see as a reasonable, but not excessive amount of compensation, would also offset the possibility of recruiting only the poorest women.

Yet astonishingly, the views of women who may consider donation have been absent from these debates. In fact, several feminist scholars have argued that these women's voices are important in these discussions (Dickenson, 2006). Surprisingly, no datum has been found on how women either might donate eggs for reproductive purposes or, more broadly, view these issues.

Hence, we decided to explore how women already enrolled as egg donors for reproductive purposes perceive these questions: whether they would be willing to provide eggs for research, and if so, whether they would do so without payment, and, if not, how much they think would be appropriate.

## Materials and methods

### Definitions

ASRM = American Society for Reproductive Medicine; CIRM = California Institute of Regenerative Medicine; ESCRO Committees = Embryonic Stem Cell Research Oversight Committees; HESC = human embryonic stem cell; HFEA = Human Fertilization and Embryology Authority; IRB = Institutional Review Board; ISSCR = International Society for Stem Cell Researchers; NAS = National Academy of Science; PGD = preimplantation genetic diagnosis; SCNT = somatic cell nuclear transfer; SCRO = Stem Cell Research Oversight.

### Survey procedure

In the past 5 years, over 1000 women have been screened, and over 250 have been enrolled into the egg donor programme at Columbia University. Typically, Columbia University performs around 100 egg donation attempts annually. Hence, many more potential donors are screened than are actually employed. Usually, couples select egg donors of similar race, religion or educational backgrounds to themselves. This study surveyed 230 consecutive women enrolled or presently participating as egg donors in the Columbia University programme for assisted reproduction, who now receive an US\$8000 payment for this service. Questions were administered by one of the authors, and no women refused to respond to the questions.

These donors undergo a rigorous medical and psychosocial evaluation, with biological and genetic tests. Once enrolled, they are prescribed 1 month of ovarian stimulation followed by transvaginal ultrasound guided needle aspiration of their eggs for harvest, a procedure that requires approximately 10–15 min of anaesthetic sedation. Women are free to drop out of the programme at any time, and receive partial payment for the time dedicated. Full payment follows the aspiration of eggs, regardless of the number harvested or the egg quality.

At the time of their presentation for either the initial screening interview or during a follow-up visit, donors' attitudes were surveyed with respect to stem cell research, and compensation for participating in SCNT research. Donors ( $n = 230$ ) were  $26.2 \pm 0.8$  years old; 100% were college educated; and 62% were Caucasian, 11% Hispanic, 10% Asian, 6% African American and 11% mixed ethnicity. None had ever been enrolled in research as a subject, and 36% had previously participated in at least one attempt at egg donation.

## Results

Table 1 displays the results of the surveyed questions. Table 2 displays respondents' answers concerning the minimum amount of compensation they felt necessary to undergo a cycle of egg donation for purposes of stem cell research.

In brief, only 2% would provide services without payment. Approximately one-third would participate for a smaller fee (US\$8000) than that usually given to commercial donors as compensation, while another third requested full payment. Although about half would prefer to donate to reproductive rather than research purposes, the other half would not.

## Discussion

This paper describes how efforts to recruit donors for HESC research without compensation have not been successful, and how women donating oocytes for clinical purposes would appear to be willing to do so for SCNT research as well, but feel that equivalent compensation would be appropriate. Thus, failures to recruit women appear to result from economics, not a lack of interest among potential donors, and can thus be addressed through equity in payment.

Critics may argue that researchers have not spent enough time and effort trying to obtain donations, and should first attempt to improve upon such efforts. That is not altogether unreasonable. Additional time and effort, prior to implementation of additional compensation, should be expended relatively swiftly and for a fixed and limited period. These efforts and their results should be carefully documented, and information about them made accessible such that they can be evaluated in a timely manner, so as not to unduly delay beneficial stem cell research that might otherwise occur. Moreover, such efforts should not in the meantime delay necessary consideration of the issues presented here. To allow participants to decide whether they wish to have their eggs used for research and/or reproductive purposes in fact maximizes their autonomy. Women's preferences can be respected, and they can be given options of whether to donate for research or not. Justice dictates that payment of egg providers for stem cell research represents a non-discriminating policy of allowing women of all backgrounds to freely participate in research that serves the common good. Particularly as more states are considering and starting stem cell funding, it is vital at least to consider these possibilities now, proactively.

Importantly, egg donors, undergoing the complex procedures involved, need assurance that follow-up care will be provided, as necessary. Free medical care needs to be offered if problems arise in the short, medium or long term. Currently, in many locales, egg donors for reproductive purposes are often sought and paid if they have traits that couples seeking eggs view as desirable (e.g. indicators of success, such as an Ivy League education). Hence, in certain areas, poorer women may currently be excluded from such egg donation (although empirical data on this possible phenomenon have not been published). For research purposes, donation that offers compensation may lead to poorer women donating proportionately more than at present. Thus, provisions for egg donation for research must give special attention to ensuring that these women receive follow-up health care as needed.

In addition, if donation for research with compensation and appropriate free medical follow-up occurs, healthcare providers will then increasingly face complex ethical questions. For example, providers will have to decide what groups of women to target for recruitment, and how. For example, physicians could focus on recruiting healthy paid donors versus perhaps less healthy unpaid individuals who have, or are at risk for, diseases for which HESC treatments may be developed, and who may thus be potential beneficiaries of the research. Some critics may argue that because of the medical risks involved in donation, the latter

group should be targeted more, since they may ultimately benefit more from the eventual research. Similarly, certain critics may assert that these at-risk individuals should donate without compensation, since these women and/or their family members may ultimately benefit, and consequently other donors would not need to be paid. Yet, the potential benefits of HESC research are not yet wholly clear, i.e., whether effective treatments will in fact be developed, and if so, for what diseases. Unpaid donors face risks; and they and their families may never in fact receive any benefit.

These data raise larger questions, too, of when, if ever, social benefits resulting from scientific research should begin to be considered and possibly outweigh fears of potential individual risks (e.g., of commodification or exploitation). In states, such as NY, where local laws do not forbid payment, fairness dictates that such efforts should be made to permit donations to move the science ahead. Thus, social benefits of research may need to be weighed more heavily against countervailing concerns. Indeed, in countries that have banned the compensation of egg donors, the number of achieved IVF cycles have greatly diminished (Craft and Thornhill, 2005; Sauer, 2005). Hence, women have sought care outside national borders (Spar, 2005).

Nevertheless, challenges may arise when cell lines that result from paid donors are then exported and used in other states or countries that still prohibit payment. However, if in fact voluntary donation is relatively unsuccessful in other states and countries, these other political entities will presumably need to re-evaluate their current policies. Yet, governments may arrive at somewhat differing policies that could still perhaps hamper inter-institutional collaborations. Questions then emerge, too, of whether researchers will be forced to consider moving to other states or countries in order to do their work.

The overseeing of egg providing must be vigilant, with an IRB, working with an ESCRO Committee. Nevertheless, further guidelines need to be developed and refined to help ESCRO Committees in addressing these issues. NAS guidelines are non-binding, and the degree to which states and research institutions follow them is unknown. No research has yet been published on whether ESCRO Committees vary, and if so, how. Anecdotally, some ESCRO Committees do or will follow these guidelines 'generally', though deviating in certain unclear ways. Further study of these differences could be enormously beneficial. Some ESCRO Committees may opt to accept such cell lines under current policies, while other ESCRO Committees may face pressures at their local institutions (e.g. if an institutional hospital Chief Executive Officer personally opposes payments). Thus, bans such as that of President Bush's on national funding of HESC may have unintended adverse consequences in creating 'patchworks' of differing policies, instead of centralized guidelines and standards, impeding collaborations across political boundaries.

Regardless of the level of payment, IRB and ESCRO Committees, in adhering to the highest possible standards, should carefully review and monitor recruitment processes and materials (e.g. flyers and advertisements). Previous work indicates that in general, IRB do not screen recruitment information adequately, and that despite federal guidelines, on-line recruitment information, for example, is usually biased, presenting benefits with compensation, but not risks or burdens (Klitzman *et al.*, 2008).

To optimize policy, urgent needs also exist for research on payment practices. Thus, researchers should investigate the impact of recruitment approaches on enrollment, e.g. assessing the socioeconomic status of women who decide to provide eggs or not, the medical and psychological impacts that providing oocytes has on donors, and the ways ESCRO Committees approach and make decisions about these issues. Finally, if women

receive compensation, they should then best be termed egg ‘providers’ rather than egg ‘donors’ *per se*.

In sum, the data presented here support the notion that oocyte donors should be fairly compensated; and highlight critical needs for research and attention to examine the many issues emerging in this new and rapidly evolving field.

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## Biography



Dr Robert Klitzman

Robert Klitzman, MD, is an Associate Professor of Clinical Psychiatry in the College of Physicians and Surgeons and the Mailman School of Public Health at Columbia University. He is the Director of the Ethics and Policy Core of the HIV Center, and a member of the Division of Psychiatry, Law and Ethics, and co-founded and for 5 years co-directed the Center for Bioethics there. He has written numerous articles, and books (including most recently, *When Doctors Become Patients*), exploring ethical and policy issues concerning

genetics, stigma and discrimination of genetic disease and HIV, professional socialization and training, and other areas.

**Table 1**

Responses of donors ( $n = 230$ ) to inquiries regarding stem cells and participation in providing gametes for research.

In addition to using donor eggs for reproduction, eggs can also be used for medical research such as seeking cures for cancer. Are you aware of this?	Yes	No	
	52%	48%	
Do you believe people should be able to donate their eggs for medical research, such as stem cell research?	Yes	No	Unsure
	93%	5%	2%
Knowing that the process for donating eggs for research and for reproduction is the same, would you be willing to donate your eggs for medical research?	Yes	No	Unsure
	82%	13%	5%
In several States and various countries in the world, it is illegal to compensate donors who want to donate eggs for medical research. Are you aware of this?	Yes	No	Unsure
	38%	61%	1%
Do you think you should be compensated the same financially whether you are donating eggs for reproduction or for research?	Yes	No	Unsure
	74%	18%	8%
Financial compensation for egg donors may be limited when they are donating for research purposes. If payment was limited to travel reimbursement only, would you still consider donating your eggs?	Yes	No	Unsure
	43%	51%	6%
Would you prefer to donate for research or to a reproductive couple?	Research	Reproductive couple	No preference
	9%	51%	40%

**Table 2**

Survey questionnaire responses to question: knowing that the process when donating eggs for research and for reproduction is the same, what minimum amount of money would be acceptable for you to agree to participate? Response rate is percentage of total number 230.

<i>Response rate (%)</i>	<i>n</i>	<i>Minimum amount of money (US\$)</i>
2.2	5	Free
8.7	20	1000–2000
8.7	20	2000–4000
10.0	23	4000–6000
1.7	4	6000–8000
32.6	75	8000
3.9	9	9000–10,000
0.9	2	>10,000
31.3	72	Uncertain