Egg Donation for Stem Cell Research: How New York State Developed Its Oversight and Compensation Policies

By Beth E. Roxland, J.D., M.Bioethics

In 2009, New York became the first state to permit its funded researchers to reimburse women who donate oocytes directly and solely to stem cell research, not only for the woman's out-of-pocket expenses, but also for the time, burden and discomfort associated with the donation process. This article explores the extensive deliberations leading up to the decision on donor compensation, which included analysis of the scientific need for oocytes, the procedures and risks involved in the egg retrieval process, and methods for ensuring fully informed, voluntary consent from donors. It also examines the ethical and policy rationales behind the decision to permit compensation for oocyte donations to stem cell research in amounts allowed by the State for oocyte donations to *in vitro* fertilization.

I. Introduction

Several state-funded stem cell research programs allow women who donate their oocytes (eggs) directly and solely to research to be reimbursed for the actual expenses – such as the costs of travel and medical care – incurred as a result of the donation process. On June 11, 2009, New York became the first state to permit compensation beyond out-of-pocket expenses, in recognition of the significant time, burden, and discomfort associated with oocyte donation. Specifically, New York's Empire State Stem Cell Board (the "ESSCB" or the "Board") voted to allow its funded researchers to compensate oocyte donors, in amounts equal to that allowed by the State for donation of oocytes to in vitro fertilization ("IVF"), as long as: (1) the remuneration is truly for the donor's time and burden rather than for the oocytes themselves; (2) fully-informed, voluntary consent is obtained; and (3) other procedural mechanisms designed to safeguard donors are followed.[1]

The Board's controversial decision[2,3,4,5] was the result of more than two years of deliberations that centered not only on the ethics of compensation, but also on the scientific necessity of obtaining fresh oocytes, the potential risks posed by the oocyte donation process, and methods for maximizing donor comprehension during the informed consent process. It also reflects the Board's notion of the need for equity between women donating to IVF and those donating to science, as well as the observation that promising research has been impeded due to a dearth of donations in jurisdictions that prohibit compensation beyond direct reimbursements.[6]

This article will provide an overview and analysis of how the Board arrived at two key determinations – its decision to permit women to donate their oocytes directly to stem cell research, and its decision to allow compensation for those donations – in order to illustrate the comprehensiveness of New York's egg donor policies.[7]

II. Background

A. State-Funded Stem Cell Research

In the United States, federal government grants fund the majority of publically-sponsored research. Federal funding of stem cell research has been curtailed, however, by two articulated policies. First, the Dickey-Wicker Amendment prohibits federal funding for research in which a human embryo or fetus is created or destroyed for research purposes.[8] This precludes funding for the derivation of new embryonic stem cell lines, although it allows funding for research on embryonic stem cell lines once they have been derived.

Second, in 2001, the Bush Administration further restricted federal funding to the embryonic stem cell lines that were in existence and approved by the National Institutes of Health ("NIH") as of that time.[9,10] Although the latter restriction was lifted by President Obama in 2009,[11] federal funding currently is available only for research on cell lines derived from embryos that were in excess of those needed for clinical reproductive treatments,[12] and the Dickey-Wicker Amendment continues to prohibit funding for the derivation of new human embryonic stem cell lines.

Due in part to these funding restrictions, several states instituted stem cell research funding programs within the last decade. State-funded programs have become the mainstay of cutting-edge research and continue to play an essential role in advancing research that is currently ineligible for funding by the federal government.

B. The Empire State Stem Cell Board

1. Statutory Creation

In 2007, New York State committed $600 million over eleven years to stem cell research,[13] making it the second largest state-funded stem cell research program (referred to as "NYSTEM") in the United States. For further information on NYSTEM and its successes, please refer to the NYSTEM article in this Report (Anders, et al).

The NYSTEM program is administered by the Empire State Stem Cell Board, which is comprised of a Funding Committee and an Ethics Committee. The Funding Committee is tasked with, among other things, setting criteria for an independent scientific peer review of grant applications and recommending standards for the scientific and medical oversight of awards.[14] The Ethics Committee, which is composed of experts in the fields of biomedical ethics, health law, policy, and philosophy, is charged with making recommendations to the Funding Committee regarding medical and ethical standards for funded research.[15]

The Ethics Committee has the difficult task of reconciling closely-held but divergent views on science and ethics in order to formulate policy that advances this promising area of research in an ethically-acceptable manner. The Committee's charge is particularly complex because it requires not only conceptual determinations of appropriate ethical conduct, but practical application of these principles in implementing a research funding program.

2. Legal Framework and Consensus Guidelines

It is important to note at the outset that neither the Ethics Committee nor the Board as a whole was provided with authority to enact law or regulation. Instead, the Board obligates its grantees to adhere to its standards by contract, the terms to which grantees must assent prior to receiving NYSTEM funds. Accordingly, one must look to the terms of the NYSTEM contract – and in particular, Appendix A-2 – to ascertain NYSTEM's ethics and research oversight rules.

While the Ethics Committee has fairly wide latitude in its policy deliberations, many of the issues relating to oocyte donation for stem cell research, such as informed consent, are also controlled by law because these acts of donating are considered human subjects research. Human subjects research laws, in conjunction with the additional Board requirements discussed below, provide rules for the conduct and oversight of research donation of oocytes, which do not apply in the context of donations for IVF purposes.

Specifically, the federal Common Rule[16] and New York State's analogous human subjects research statutes,[17] provide for oversight of research at an institutional level by an Institutional Review Board ("IRB"), or the State's equivalent, called a Human Research Review Committee. In addition, the Board chose to follow the recommendations of the two most prominent stem cell consensus bodies – the National Academies of Science ("NAS")[18] and the International Society of Stem Cell Research ("ISSCR")[19] – and instituted a second oversight committee to review ethical matters, called an Embryonic Stem Cell Review Oversight ("ESCRO") committee.[20]

III. Should Women Be Permitted to Donate Their Oocytes Directly and Solely to Stem Cell Research?

The ethical framework for research demands that the individual and societal benefits of the research are not outweighed by the risks posed to research participants. For research – and, in particular, protocols that have no prospect of direct benefit, but present some degree of risk to the participant – to be considered ethical, it must also have proper scientific justification.

A. Scientific Need for Fresh Oocytes

The Ethics Committee did not presuppose a valid scientific need for fresh oocytes, but instead explored the issue of whether research requiring oocytes is sufficiently justified. If it is not, then the risk to oocyte donors would not be outweighed by the benefit to society, and oocyte donation arguably should be precluded.

The Committee heard expert presentations and reviewed medical and scientific literature on various forms of research requiring fresh oocytes, the most prevalent of which is somatic cell nuclear transfer ("SCNT"). In SCNT, the nucleus of an oocyte is removed and replaced with the nucleus of a somatic, or "adult," cell, resulting in cells that contain the genetic information from the somatic cell. It is hoped that SCNT will lead to disease models and patient-specific therapies.

Some Committee members and commentators asserted that the value of SCNT has been over-sold, and that it was unclear whether SCNT will successfully fulfill its promise.[21] However, the Committee agreed generally that research need not meet such a high burden of proof, *i.e.*, certainty of success. The Committee found sufficient evidence of scientific merit in protocols requiring fresh egg donation, such that these protocols could (and should) be presented to IRBs and ESCROs for case-by-case determinations.[22] The Committee also discussed alternative forms of research that do not require oocytes, including induced pluripotent stem cell research (commonly referred to as "iPSC research"), in which adult somatic cells are reprogrammed to a pluripotent state. While the field of iPSC research is promising, the Committee asserted that the existence of alternative forms of research does not require foreclosing funding for other potentially valuable forms of stem cell research. It also noted that iPSC research was in a relatively nascent stage and that iPS cells have shown limitations in certain studies.[23,24,25,26]

B. Risk/ Benefit Calculation

1. Egg Retrieval

After addressing the scientific need for research requiring oocyte donation, the Committee proceeded to examine the process by which eggs are obtained.

Procedures for stimulating development of multiple ovarian follicles – which apply in both the IVF and research donation contexts – typically involve daily hormone injections over 7 to 10 days.[27] Mature oocytes are retrieved by an ultrasound-guided needle inserted through the vagina, under local anesthesia. The time commitment for one cycle has been estimated at 56 hours,[28] and

includes medical screening and monitoring, interviews and counseling, blood tests, and other medical procedures.

Although serious complications are rare, medical literature reflects uncertainty in the frequency and severity of such occurrences. There is a small risk of complications resulting from the egg retrieval procedure, which can include infection, complications from anesthesia, and ovarian puncture.[29,30] Egg donors may also experience psychological effects from donation, including stress about the medical procedures involved, anxiety about future fertility, or distress related to learning of an unanticipated medical or genetic condition through the donor screening process.[31]

One potentially significant side-effect from the fertility drugs is ovarian hyper-stimulation syndrome ("OHSS"), symptoms of which range from abdominal pain and nausea to kidney damage.[32] In cases of severe OHSS, hospitalization is required. Estimations of the occurrence of severe OHSS vary (from 0.1 to 5.0%),[34,35] but the literature generally holds that the frequency of OHSS is lower for women who only donate eggs rather those who undergo full IVF and achieve pregnancy.[36]

Some literature asserts the possibility of increased incidence of ovarian, cervical and breast cancers, as well as a potential impact on future fertility, but few studies have supported those claims.[37,38,39,40,41] One study, however, showed a 1.8% increase in the likelihood of developing uterine cancer.[42] Rare and isolated cases of colon cancer have also been reported, but a definitive link has not been established.[43,44] There is general agreement that further large-scale longitudinal studies should be conducted to further determine the nature and extent of the risks presented by the fertility drugs used to stimulate ovarian production.[45,46]

2. Ethics Committee Deliberations

In analyzing the benefits and risks of research requiring fresh oocyte donations, the Ethics Committee noted that the donation process holds out no prospect of direct physical benefit to the donor, but that a donor might benefit psychologically from contributing to the advancement of science. Stem cell research also holds out a substantial societal benefit in its potential to provide cures and treatments to illness and conditions, particularly in the areas of regenerative medicine and cell-based therapies.

The Committee asserted that, while the risks of donation are not insignificant, society finds it ethically-acceptable for women to undergo the exact same procedures to donate for IVF purposes.[47] Similarly, the Committee noted that society permits individuals to participate in research, such as early phase drug trials, that holds out no prospect of direct benefit but poses some risk to the subject.

While the Committee found the risk-benefit ratio sufficiently favorable to allow oocyte donation for stem cell research, it mandated that risks to donors be minimized, which can be accomplished by screening donors for factors pre-disposing them to complications,[48] individually tailoring the medical regimen, and carefully monitoring donors during and after the donation.[49,50,51] The Committee also required that oocyte procurement be performed only by a medically-qualified, experienced physician, and that nonaggressive hormone stimulation cycles and frequent monitoring be used to reduce the risk of OHSS.[52]

Importantly, the Committee provided two additional protections for oocyte donors. First, it mandated that grantees assume responsibility for donors' medical costs, including the costs of any treating injuries that arise from the donation.[53] Second, grantees must provide counseling services to potential donors, preferably free of charge to the donor.[54] These two requirements are relatively unique in their strength of protection of oocyte donors.

C. Informed Consent

The linchpin of the Board's finding that compensation for oocyte donation is ethically-appropriate lies in its extensive policies intended to ensure donors' fully informed, voluntary consent to the donation.

Federal and state informed consent laws list numerous categories of information that must be disclosed to potential donors, including (1) the goals of the research protocol, (2) any foreseeable risks and benefits of participation, and (3) alternatives to participation[55,56,57] In addition to these legal requirements, the Board incorporated in its contracts provisions from the NAS and ISSCR Guidelines, such as requirements for ethics reviews by an ESCRO committee,[58] disclosure of risks by a neutral party not affiliated with the research,[59] and discussion of any commercial potential of the research.[60]

To compensate for noted deficiencies in the informed consent process in other contexts, the Board chose to impose supplemental, and in some instances, unique, informed consent standards.[61] First, literature reflects that the consent process is often focused on the informed consent form rather than on a conversation that allows donors to comprehend and digest the information provided. To address this issue, the Board requires that informed consent be obtained through a "dynamic process – *i.e.*, a dialogue that encourages the potential donor to ask questions, and prompts the potential donor to confirm his or her understanding of the information being disclosed."[62] It also requires that "language barriers and the education level of subjects" be taken into account, in order to maximize comprehension.[63]

Second, in line with the Board's focus on potential risks associated with oocyte donation, it mandated that grantees exercise "special care" in disclosing "both the short- and long-term health risks arising out of the oocyte donation process in a manner that reflects the most current scientific knowledge of such risks."[64]

Finally, Board members acknowledged that some donors may be morally opposed to certain types of research, such as SCNT. To further respect donor autonomy, the Board obligates grantees to provide donors with the opportunity to restrict the types of research that can be done initially with their oocytes (which pertains mostly to the process of cell line derivation). Donors also must be informed that their materials may be disseminated to other institutions or to a tissue bank, and that any restrictions placed beyond initial-use restrictions cannot be guaranteed.[65]

Accordingly, the Board decided that women should be allowed to donate oocytes to stem cell research, so long as: (1) there is thorough review of the research protocol by relevant oversight bodies, (2) the investigator provides sufficient scientific justification for the research and the need for oocytes, (3) risks to donors are minimized

as much as possible, and (4) donors' rights are protected by a comprehensive informed consent process.

IV. Compensation for Women Who Donate Their Oocytes Directly and Solely to Stem Cell Research

Taking into account the societal interest in furthering stem cell research requiring fresh oocytes, and that experiences in other jurisdictions indicate that a lack of reasonable compensation has created a significant impediment to oocyte donation, the Ethics Committee undertook the issue of whether or how to compensate women for oocyte donation.[66] The Committee examined the compensation issue for more than one year, reviewing relevant laws, policy guidelines, and literature representing different perspectives.

A. Relevant Guidelines and Law

The NAS Guidelines allow for reimbursement of direct expenses incurred in the oocyte donation process, such as travel and lost wages, but clearly state that, "[n]o payments beyond reimbursements, cash or in-kind, should be provided for donating oocytes for research purposes."[67] In contrast, the ISSCR Guidelines allow compensation beyond direct reimbursements as long as the jurisdiction allows for such compensation, and "a detailed and rigorous review" is conducted by an ESCRO "to ensure that reimbursement of direct expenses or financial considerations of any kind do not constitute an undue inducement."[68] ISSCR makes clear, though, that no financial considerations should be given for the number or quality of eggs themselves, such that any compensation is truly for the time and burden that is involved with the donation process, and not for the purchase of the eggs.[69]

There is no federal or New York State law that directly controls compensation for oocyte donors in the context of research. However, human subjects research laws require that informed consent be obtained in circumstances that minimize coercion and undue influence – concerns that are implicated when compensation is provided.

B. Ethics

After reviewing relevant laws and policy statements, the Committee analyzed prevailing ethical theories concerning the appropriateness of compensation for oocyte donors. For context, a brief summary of these principles follows.

1. Undue Inducement/ Autonomy

An argument frequently made against offering financial inducements to research participants is that it can compromise an individual's ability to provide free and voluntary informed consent, possibly hindering the their ability to act in his or her best interests.[70] Not every offer of compensation is an undue inducement, however: "if the risks and benefits of the research to the patient or others are positive, payment alone to an otherwise competent and informed subject will not be 'undue' nor is compensation 'coercive' merely because it provides an incentive to persons to donate."[71] An incentive may become an undue inducement if it is a person's sole motivation for participating,[72] if it blinds a person to the risks involved in the research, or if it leads a person to conceal or misrepresent information that would disqualify her from being eligible to participate. Notably, one must examine the donor's social, cultural, and economic background, rather than just the amount of compensation offered, to determine whether an inducement is undue.[73]

Some have countered that the few studies conducted in this area have not supported the theory that increased amounts of money affect a person's perception of risk presented by a protocol.[74,75] Others assert that a decision can still be "voluntary" even if it is motivated in part by financial gain, and that it is not appropriate to second-guess the validity of that motivation. Some data support the theory that women are not unduly influenced by compensation, but are simply making cost-benefit decisions regarding the worth of their time and burden.[76]

2. Justice/Equity

One common notion of justice is that persons similarly situated should be treated in the same manner. Compensation for participation in other forms of human subject research has been prevalent for over 100 years,[77,78] and compensation for oocyte donations in the IVF context has been commonplace since 1984.[79] With respect to the latter, the New York State Department of Health allows payments for reproductive donations in line with American Society for Reproductive Medicine (ASRM),[80] which states that:

> [A]t this time sums of $5,000 or more require justification and sums above $10,000 are not appropriate…. Payment…should reflect the amount of time expended and the burdens of the procedures performed…. In no circumstances should payment be conditioned on successful retrieval of oocytes or number of oocytes retrieved.[81]

The oocyte retrieval process is the same, regardless of whether the ultimate destination is a clinic or research facility. In addition, the underlying motivation to donate – whether it is to help an infertile couple or advance science for the treatment of diseases – is similar. Therefore, it is arguable that justice requires the terms and conditions surrounding the donations be the same.

3. Exploitation

Theories of "exploitation" can both support and undercut the argument for compensation.

Some have argued that offering compensation to donors will disproportionately encourage socio-economically disadvantaged individuals to participate in potentially risky research protocols in which they, and their economically stable peers, would not otherwise participate. In addition, historical cases of exploitation of subjects – and in particular, women – by the scientific community have resulted in significant distrust of the institution of research.[82] Providing compensation as an incentive to engage in risky behavior may exacerbate that distrust.

Proponents of compensation counter that providing compensation for research participation is the only opportunity for the donor – rather than the researcher or the institution – to reap any financial benefit from research that may be commercially valuable.[83] Others note that it is arguably exploitative to ask women to undergo

the time, inconvenience, burden, and pain of donation without providing fair compensation.[84,85] Indeed, failing to remunerate women for these sacrifices reinforces the stereotype that women should be natural caregivers and reproductive entities, and does not account for the significant contribution they are providing to society by donating.

4. Commodification

It has been suggested that allowing compensation for donation of oocytes leads to commoditization of the body, akin to selling body parts.[86] Reducing individuals to spare parts or tissues undermines fundamental social and cultural attitudes towards human life,[87] and may have a deleterious effect on what it means to be human.[88]

Some justify payment for body parts with the social value of alleviating the shortage of such parts.[89] However, it is not necessary to go that far to defend compensation for oocyte donation. Proponents of compensation argue that there is an ethical and moral distinction between paying for a donor's time, burden, and assumption of risk, and paying for the biological product itself.[90] Others analogize compensation for egg donation to compensation for other "renewable" biological materials, like blood or sperm,[91] which is permissible in most jurisdictions.[92,93]

Lastly, while some commentators assert that compensating women for their reproductive tissues may result in a diminution of dignity, there is scant evidence that decades of compensation for IVF donations have resulted in any notable diminution in dignity.[94]

5. Practical Considerations

States that have explicitly addressed the issue of oocyte donor compensation generally have followed the NAS model and allow only for reimbursement of direct expenses.[95,96,97] It is well-documented, however, that these jurisdictions suffer from a dearth of donations: even large, well-funded programs, such as those in Massachusetts (one egg donor, to date)[98] and California (no egg donors, to date).[99] Studies similarly show that women who are interested in donating to research are nevertheless unwilling to undertake the substantial burden and risk associated with donation without reasonable compensation.[100]

A policy of oocyte donor compensation may also lead to greater genetic diversity in biological materials available to stem cell researchers. Historically the IVF system has heavily favored Caucasian women with certain qualities deemed favorable, and, as such, most frozen embryos in excess of the IVF process are of limited genetic variability and not representative of many diseases found outside of these populations.[101] This lack of genetic diversity impedes research into potential treatments and cures for conditions afflicting non-IVF donor populations, and some have argued that providing compensation for non-traditional IVF donors might increase the pool of genetic diversity for research.

C. New York's Policy on Compensation of Women Who Donate Oocytes Directly and Solely to Stem Cell Research

After extensive review and deliberation, the Ethics Committee concluded that some level of compensation beyond reimbursement for out-of-pocket expenses is necessary to encourage oocyte donations and promote stem cell science. Therefore, the Ethics Committee recommended, and the Funding Committee agreed, that women who donate their oocytes directly and solely to stem cell research also could be compensated – within specified limits – for the time, burden and discomfort associated with the donation process.[102]

The Board noted that it is legally and ethically permissible to provide compensation for participation in other forms of human subjects research, including research that presents no prospect of direct benefit to the participant, and asserted that it should not engage in "stem cell exceptionalism" by setting different rules for the stem cell research context. It similarly found no principled basis for distinguishing between oocyte donations to IVF, for which compensation is permitted, and donations to stem cell research. Further, the Board asserted that there is arguably greater social utility in donating for stem cell research than donating for a private reproductive purpose, and that additional procedural safeguards, which are not available in the reproductive context, are in place to protect women who donate eggs to research.

Although the Board agreed that there are valid concerns about physical risks associated with the donation process, it decided that the appropriate policy response is to require thorough disclosure of these risks and to allow women to decide for themselves whether to undertake them.[103] The Board believed that it is unnecessarily paternalistic to promulgate a policy on the premise that women cannot fully weigh the risks and benefits of participation when offered reasonable compensation, particularly in light of the Board's rigorous informed consent requirements intended to maximize donor comprehension of risks.

After reviewing numerous models for compensation,[104] the Board reasoned that equity required a policy permitting women who donate oocytes to stem cell research to be compensated in amounts parallel to those who donate oocytes to IVF. Therefore, it concluded that amounts up to $5,000 are reasonable, but sums above $5,000 require justification, and sums above $10,000 are prohibited. In so finding, the Board sought to strike a balance between providing reasonable and fair compensation for a woman's time and burden, in an amount sufficient to overcome disincentives to donation, and avoiding undue inducements to donate.

In addition, the Board prohibited remuneration based on the number or quality of eggs produced, in order to prevent commodification of oocytes. Instead, the Board stressed that compensation must be based on the time and burden involved in the donation process.[105] The Board also instituted rules and procedural safeguards to protect against compensation amounting to an undue inducement to donate,[106] and against possible exploitation of socio-economically disadvantaged women.[107]

Lastly, the Board considered the option of permitting grantees to compensate oocyte donors, but precluding grantees from using state funds for that purpose. While such a policy might be less controversial, the Board noted that it would impose complicated recordkeeping and other compliance requirements on researchers and enforcement obligations on regulators. More fundamentally, however, the Board believed that if it is ethical to provide public funds for research on cell lines derived from an oocyte from which the donor was compensated,

it is also ethical to permit public funds to be used for that compensation. Accordingly, the Board decided to allow grantees to use public funds acquired from NYSTEM to compensate oocyte donors, in line with NYSTEM's strict ethics and oversight standards.

V. Conclusion

The Empire State Stem Cell Board's decision to compensate oocyte donors was linked inextricably to its policies on research oversight and informed consent. This article attempts to illustrate the complex process by which the Board arrived at this decision, and to provide an example of how other stem cell research governing bodies can use this experience to develop oocyte donation policies.

Acknowledgements

The author wishes to express her gratitude to Carrie S. Zoubul, J.D., M.A., and Susie A. Han, M.A., M.A., whose dedication and editorial assistance was integral in drafting this article. In addition, thank you to Dr. Geoffrey Lomax, Robert N. Swidler, J.D., Nancy Neveloff Dubler, LL.B., and Thomas G. Conway, J.D., for their review and insightful analysis.

The views expressed in this article are solely those of the Author. The Author has no conflicts of interest.

Beth E. Roxland, J.D., M.Bioethics

Ms. Roxland is the Executive Director of the New York State Task Force on Life and the Law, a governor-appointed commission charged with making recommendations for law and policy on bioethical issues. While at the Task Force, Ms. Roxland has been actively involved in its ongoing creation of guidelines for conducting research on adults who lack full decisional capacity, and for the allocation of scarce ventilators in the event of a pandemic influenza outbreak.

Ms. Roxland is also the Special Advisor to the Commissioner of Health on Stem Cell Research Ethics. In this role, she has led consensus-building meetings of, and provided ethical and legal staff support to, the Empire State Stem Cell Board on a range of issues, including informed consent, respect for the embryo, chimeric research, and compensation of women who donate their oocytes to stem cell research.

Prior to joining the Task Force, Ms. Roxland was a Senior Associate in the litigation department of Simpson Thacher and Bartlett LLP, where she worked on cases ranging from multi-billion dollar insurance disputes to pro bono *matters involving surreptitious genetic testing of potential criminals. Ms. Roxland also served as a law clerk to the Honorable Barbara S. Jones in the U.S. District Court for the Southern District of New York.*

Ms. Roxland graduated from Columbia University with a Bachelor's degree in biology, and received a joint Master's in Bioethics-Juris Doctor magna cum laude *from the University of Pennsylvania. She drafted her Master's thesis on federal funding for stem cell research, and served as a Senior Editor of the* University of Pennsylvania Law Review.

References

1. The Board's vote on this policy was nearly unanimous, with a 19-1 overall vote. Father Thomas Berg of the Board's Ethics Committee dissented.
2. Editorial. Reasonable Compensation. *NY Times*, July 11, 2009, at A18.
3. Steinbock, B. Paying Egg Donors for Research: In Defense of New York's Landmark Decision. Bioethics Forum, July 1, 2009, http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=3638.
4. Ochs, R. New York's Decision to Pay Egg Donors Sparks Debate. *Newsday*, July 12, 2009, at A6.
5. Ertelt, S. New York Stem Cell Research Board Agrees to Pay for Women's Eggs for Science. LifeNews.com, June 12, 2009, http://www.lifenews.com/bio2872.html.
6. Empire State Stem Cell Board. Statement on the Compensation of Oocyte Donors (June 11, 2009), http://stemcell.ny.gov/docs/ESSCB_Statement_on_Compensation_of_Oocyte_Donors.pdf.
7. This article seeks to address the Board's deliberations, but it also provides literature post-dating the decision, as well as general commentary on relevant issues. For a precise record of the Board's discussions and policies, including contract language and minutes of meetings, please see: www.stemcell.ny.gov.
8. 123 Stat. 524 (2009). The Dickey-Wicker Amendment has been attached every year since 1996 to the act appropriating money to the Department of Health and Human Services (the umbrella agency under which the National Institutes of Health and the Food and Drug Administration are housed).
9. National Institutes of Health. Human Embryonic Stem Cell Policy Under Former President Bush (Aug. 9, 2001-Mar. 9, 2009), http://stemcells.nih.gov/policy/2001policy.htm.
10. National Institutes of Health. Update on Existing Human Embryonic Stem Cells (Aug. 27, 2001), http://stemcells.nih.gov/policy/statements/082701list.asp.
11. Exec. Order No. 13505, 74 Fed. Reg. 10667 (Mar. 11, 2009).
12. National Institutes of Health. Guidelines on Human Stem Cell Research (2009), available at http://stemcells.nih.gov/policy/2009guidelines.
13. N.Y. St. Fin. Law § 99-p.
14. N.Y. Pub. Health Law § 265-b(2).
15. *Id.* § 265-c(2)(b).
16. 45 C.F.R. § 46.101 *et. seq.*
17. N.Y. Pub. Health Law § 2440 *et. seq.*

References (continued)

18. National Academy of Sciences. Amendments to the Guidelines for Embryonic Stem Cell Research § 2.0 (2010) [hereinafter NAS Guidelines].
19. International Society for Stem Cell Research. Guidelines for the Conduct of Human Embryonic Stem Cell Research § 8 (2006) [hereinafter ISSCR Guidelines].
20. All major institutions in New York State that are engaged in stem cell research have convened an ESCRO to work with investigators.
21. McLeod, C. & Baylis, F. Donating Fresh Versus Frozen Embryos to Stem Cell Research: In Whose Interests? *J. Med. Ethics* 21, 465-477 (2007).
22. In addition, scientific merit is scrutinized during the ESSCB's peer review and funding processes. See Sturman, L. *et al.* NYSTEM: Catalyzing New York State's World Class Stem Cell Research Community (included in this report).
23. Statement of Kevin Eggan, Minutes of ESSCB Ethics Committee Meeting (Oct. 16, 2008), http://stemcell.ny.gov/ethics/minutes_ethicscomm_10_16_2008.pdf.
24. Urbach, A. et al. Differential Modeling of Fragile X Syndrome by Human Embryonic Stem Cells and Induced Pluripotent Stem Cells. *Cell Stem Cell* 6, 407-411 (2010).
25. Tulpule, A. et al. Knockdown of Fanconi Anemia Genes in Human Embryonic Stem Cells Reveals Early Developmental Defects in the Hematopoetic Lineage. *Blood* 115, 3453-3462 (2010).
26. Lensch, W. Cellular Reprogramming and Pluripotency Induction. *Brit. Med. Bul.* 90. 19-35 (2009).
27. Steinbrook, R. Egg Donation and Human Embryonic Stem-Cell Research. *New Engl. J. Med.* 354, 324-326 (2006).
28. American Society of Reproductive Medicine (ASRM), Ethics Committee. Financial Compensation of Oocyte Donors. *Fertil. & Steril.* 88, 305-309 (2006).
29. Sauer, M. Defining the Incidence of Serious Complications Experienced by Oocyte Donors: A Review of 1000 Cases. *Am. J. Obstet. Gynecol.* 184, 277-278 (2001).
30. Institute of Medicine. Assessing the Medical Risks of Human Oocyte Donation for Research: Workshop Report. Washington, D.C.: The National Academies Press (2007).
31. *Id.*
32. *Id.*
33. *Id.*; Steinbrook, *supra* note 27.
34. Delvigne, A. & Rozenberg S. Epidemiology and Prevention of Ovarian Hyper-stimulation Syndrome (OHSS): A Review. *Hum. Reprod. Update* 8, 559-577 (2002).
35. Hyun, I. Fair Payment or Undue Inducement? *Nature* 442, 629-630 (2006).
36. Institute of Medicine, *supra* note 30.
37. *Id.*
38. Brinton, L. Long-term Effects of Ovulation-stimulating Drugs on Cancer Risk. *Repro. Bio. Med. Online* 15, 38-44 (2007) [hereinafter Long-term Effects].
39. Brinton L. et al. Breast Cancer Risk Associated with Ovulation-stimulating Drugs. *Hum. Repro.* 19, 2005-2013 (2004).
40. Ness R. et al. Infertility, Fertility Drugs, and Ovarian Cancer: A Pooled Analysis of Case-control Studies. *Am. J. Epid.* 155, 217-224 (2002).
41. Brinton, L. et al. Ovarian Cancer Risk After the Use of Ovulation-stimulating Drugs, *Obstet. and Gynecol.* 103, 1194-1203 (2004).
42. Althuis, M. et al. Uterine Cancer After Use of Clomiphene Citrate to Induce Ovulation. *Am. J. Epid.* 161, 607-615 (2005).
43. Ahuja, K. & Simons, E. Cancer of the Colon in an Egg Donor: Ethical and Policy Repercussions for Donor Recruitment. *Hum. Repro.* 13, 227-31 (1998).
44. Statement of Dr. Jennifer Schneider, Minutes of ESSCB Ethics Committee Meeting (Oct. 16, 2008), http://stemcell.ny.gov/ethics/minutes_ethicscomm_10_16_2008.pdf
45. Brinton, L., Long-term Effects, *supra* note 38.
46. Pearson, H. Health Effects of Egg Donation May Take Decades to Emerge. *Nature* 442, 607-608 (2006).
47. Foohey, P. Paying Women for Their Eggs for Use in Stem Cell Research. *Pace L. Rev.* 30, 903-906 (2010). Numerous commentators have pointed out the lack of parity between rather strong negative reactions to donating eggs for research and donating to reproduction, despite the health risks being identical. Some have attributed this to traditional societal views of maternally-related sacrifices as more appropriate.
48. Donor exclusion criteria should include, for example, patients with a history of pelvic inflammatory disease, polycystic ovarian syndrome, or ovarian tumors. Carson, M. et al. Proposed Oocyte Donation Guidelines for Stem Cell Research. *Fert. & Steril.* (2010).
49. Institute of Medicine, *supra* note 30.
50. Statements of Dr. Catherine Rackowsky, Minutes of ESSCB Ethics Committee Meeting (June 27, 2008), http://stemcell.ny.gov/ethics/minutes_ethicscomm_6_27_2008.pdf.
51. N.Y. Pub. Health Law § 4362; N.Y. Comp. Code R. & Regs. § 52-8.4.
52. Appendix A-2, Empire State Stem Cell Board, Contract Policy Statements and Conditions, § E.4 (l) & n.12 (quoting ISSCR Guidelines §11.5(b)) (2010), http://stemcell.ny.gov/docs/esscb-appendix-a-2-rev-01-10.pdf.
53. *Id.* § E.4 (i).
54. *Id.* § E.4 (k).
55. 45 C.F.R. § 46.111(4); 45 C.F.R. §§ 46.116(a)(1)-(8) & (b)(1)-(6).
56. N.Y. Pub. Health Law § 2444.
57. In addition to human subjects research statutes, New York's tissue banking laws provide additional informed consent requirements. N.Y. Pub. Health Law § 4360, *et. seq.*; 10 N.Y. Comp. Code R. & Regs. § 52-1.1, *et. seq.*, specifically § 52-8 (governing reproductive tissue) and § 52-11 (governing non-transplant anatomic banks).
58. NAS Guidelines, *supra* note 18, § 4.2; ISSCR Guidelines, *supra* note 19, § 12.1(b). See also Taylor, P. Comprehensive Institutional Review of Legal, Ethical and Scientific Issues in Human Embryonic Stem Cell Research, ESCROs and Beyond. *NYSBA Health L. J.* 10, 43-55 (2005).
59. App. A-2, *supra* note 52, § E.4 (a) & n.5 (quoting ISSCR Guidelines § 11.6 (i)).
60. *Id.* § E.4 (h) & n.9.
61. The Ethics Committee is also engaged in drafting model informed consent forms for use by its grantees, to help facilitate comprehensive, understandable disclosures.
62. App. A-2, supra note 52, § E.4 (a).
63. *Id.* § E.4 (a) & n.4 (quoting ISSCR Guidelines § 11.3).
64. *Id.* § E.4 (l) & n.12 (quoting ISSCR Guidelines § 11.5(b)).
65. *Id.* § E.4 (f).

References (continued)

66. A semantic issue arises when a woman is compensated for providing her oocytes: arguably the woman who is compensated is no longer a "donor," but rather a "seller" or "vendor." See Isasi, R. & Knoppers, B. Monetary Payments for the Procurement of Oocytes for Stem Cell Research: In Search of Ethical and Political Consistency. *Stem Cell Research* 1, 37-44 (2007). However, when the compensation is limited to a capped reimbursement for time and burden, as the Board provided, and not on the market value of the eggs, Board members asserted that it remains fair to continue to use the term "donor."
67. NAS Guidelines, *supra* note 18, § 3.4(b).
68. ISSCR Guidelines, *supra* note 19, § 11.5(b)(2).
69. *Id.* § 11.5(b)(3).
70. Isasi, R. & Knoppers, B., *supra* note 66.
71. Robertson, J. Compensation and Egg Donation for Research. *Fertil. & Steril.* 86, 1573-1575 (2006).
72. Bentley, J. & Thacker, P. The Influence of Risk and Monetary Payment on the Research Participation Decision Making Process. *J. Med. Ethics* 30, 293-298 (2004).
73. Isasi, R. & Knoppers, B., *supra* note 66.
74. Halpern S., Karlawish J., Casarett D., Berlin J., & Asch D. Empirical Assessment of Whether Moderate Payments are Undue or Unjust Inducement for Participation in Clinical Trials. *Arch. Int. Med.* 164, 801-803 (2004).
75. Bentley, J. & Thacker, P., *supra* note 72.
76. Klitzman, R. & Sauer, M. Payment of Egg Donors in the USA. *Repro. Biomed.* Online 18, 603-608 (2009).
77. Grady, C. The Payment of Clinical Research Subjects. *J. Clin. Invest.* 115, 1681-1687 (2005).
78. Steinbrook, R., *supra* note 27.
79. New York State Task Force on Life and the Law. Assisted Reproductive Technologies: Analysis and Recommendations for Public Policy (1998), http://www.health.state.ny.us/nysdoh/taskfce/execsum.htm.
80. Minutes of the ESSCB Ethics Committee Meeting (May 12, 2009), http://stemcell.ny.gov/ethics/ecm_5_12_2009.html.
81. ASRM, *supra* note 28.
82. Grady, D. A Lasting Gift to Medicine That Wasn't Really a Gift. *NY Times*, Feb. 1, 2010.
83. Steinbrook, R., *supra* note 27.
84. Hyun, I., *supra* note 35.
85. Levens, E. & DeCherney, A. Human Oocyte Research: The Ethics of Donation and Donor Protection. *JAMA* 300, 2174-2176 (2008).
86. Andrews, L. & Nelkin, D. Whose Body is It Anyway? Disputes Over Body Tissue in a Biotechnology Age. *Lancet* 351, 53-57 (1998).
87. Isasi, R. & Knoppers, B., *supra* note 66.
88. Sharp, L. The Commodification of the Body and Its Parts. *Ann. Rev. Anthro.* 29, 287-328 (2000).
89. Robertson, J., *supra* note 71.
90. AS RM, *supra* note 28.
91. Crockin, S. A Legal Defense for Compensating Research Egg Donors, *Cell Stem Cell*, 6, 99-102 (2010).
92. Baum, K. Golden Eggs: Towards the Rational Regulation of Oocyte Donation. *BYU L. Rev.* 2001, 107-166 (2001).
93. See also N.Y. Pub. Health Law § 4307 (distinguishing between organs and blood).
94. Foohey, P., *supra* note 47.
95. Cal. Code of Regs. tit. 17 § 100020(h) (allowing use of state funds for reimbursement for "permissible expenses").
96. Advisory Ruling of the Commonwealth of Massachusetts Re: Meaning of Valuable Consideration in Chapter 111L as it pertains to the Donation of Gametes by Women for Research (May 18, 2006) (allowing use of state funds for reimbursement of associated costs and lost wages), http://www.iascr.org/docs/MA-ValuableConsideration2006.pdf
97. Connecticut Attorney General's Opinion Re: Public Act No. 05-149: An Act Permitting Stem Cell Research and Banning the Cloning of Human Beings (Nov. 13, 2008), http://www.ct.gov/ag/cwp/view.asp?A=1770&Q=328050.
98. Statement of Kevin Eggan, *supra* note 23.
99. McLeod, C. & Baylis, F., *supra* note 21.
100. Klitzman, R. & Sauer, M., *supra* note 76.
101. Mosher, J. et al. Lack of Population Diversity in Commonly Used hESC Lines. *New Eng. J. Med.* 362, 183-185 (2010).
102. Minutes of ESSCB Full Board Meeting (June 11, 2009), http://stemcell.ny.gov/full/minutes_fullcomm_6_11_2009.pdf.
103. *Cf. Int'l Union v. Johnson Controls,* 499 U.S. 187 (1991) (striking down as discriminatory an employer policy banning women of reproductive age from working in positions where exposure to dangerous levels of lead was unavoidable, and noting women are free to make choices that may imperil their health or reproductive future).
104. An in-depth review of payment models is beyond the scope of this article. For a comprehensive examination of these models, see Grady, C., supra note 77, and Dickert N. & Grady C. What's the Price of a Research Subject? Approaches to Payment for Research Participation. *New Eng. J. Med.* 341, 198-203 (1999).
105. App. A-2, *supra* note 52, § E.5.
106. *Id.* § E.4 (b).
107. *Id.* § E, n.12 (quoting ISSCR Guidelines § 11.5(b)(i)).