

Statement of the Empire State Stem Cell Board on the Compensation of Oocyte Donors

On June 11, 2009, the Empire State Stem Cell Board (the “Board”) voted to allow funding of research on stem cell lines derived using eggs (called “oocytes”) donated solely for research purposes where the donor was, or will be, compensated for the expense, time, burden and discomfort associated with the donation process -- within specified limits -- as is currently permitted when women donate oocytes for reproductive purposes in New York State. The Board’s decision followed extensive deliberation that included consideration of the great potential of stem cell research, national and international ethical standards, and mechanisms to safeguard the rights and welfare of oocyte donors. The Board agreed that it is ethical and appropriate for women donating oocytes for research purposes to be compensated in the same manner as women who donate oocytes for reproductive purposes and for such payments to be reimbursable as an allowable expense under NYSTEM contracts.

This measure affects *only* donations of oocytes specifically and solely to stem cell research. NYSTEM does not permit payment for donation to stem cell research of oocytes or embryos that are in excess of clinical need from *in vitro* fertilization processes.

The Board offers the following brief statement on its oocyte donor payment decision:¹

Sources of recently-harvested oocytes are necessary for certain stem cell research pursuing medical advances to alleviate pain and suffering by people afflicted with debilitating and life-threatening diseases. Experiences in other jurisdictions indicate that lack of reasonable compensation to women who donate their oocytes to stem cell research has created a significant impediment to such donation, limiting the progress of stem cell research. Accordingly, over the past year, the ESSCB has intensively examined and discussed the issue of whether it is ethically appropriate to provide women who donate their oocytes to stem cell research with any form of reimbursement, in recognition of the considerable financial and physical burdens associated with the donation process.

When women donate their oocytes for reproductive purposes (*i.e.*, for *in vitro* fertilization), New York State permits reasonable reimbursements for out-of-pocket expenses, time, burden and discomfort associated with the donation, in amounts consistent with the guidelines developed by the American Society for Reproductive Medicine (ASRM).² Such reimbursements are widely accepted as ethical, so long as

¹ Greater detail of the Ethics and Funding Committee’s deliberations on this issue, including the minutes and archived webcasts of meetings, can be found at: www.stemcell.ny.gov.

² See ASRM, *Financial Compensation of Oocyte Donors*, 88 Fertility & Sterility 305 (2007). While we encourage review of the entire article for ASRM’s reasoned analysis supporting defined payments to oocytes donors, we note

they are not made contingent upon the quality or number of oocytes retrieved, the amount does not act as an undue inducement to donate, and the short- and long-term risks and benefits of donation are fully disclosed to the donor.

There is no principled reason to distinguish between donation of oocytes for reproductive purposes and research purposes when determining the ethicality of reimbursement. The risks associated with donating oocytes to stem cell research are no greater than those associated with reproductive donations. Moreover, donating oocytes to stem cell research arguably confers a greater benefit to society than does oocyte donation for private reproductive use.

Similarly, there is no ethical basis for promulgating different payment policies for women who donate oocytes to stem cell research and for participants in other types of human subjects research. National and international consensus bodies, as well as ethics scholars, generally have found it acceptable to provide reasonable compensation to subjects who participate in human subjects research to remunerate for the time and discomfort associated with participation in such research. To treat differently women who donate oocytes to stem cell research would be unjust, and would demean the significant contribution that oocyte donors make to society by participating in stem cell research.

The Board acknowledges that excessively high payments to oocyte donors could act as an undue influence to donate, or cause a woman to discount the risks associated with donation. However, the Board believes that reasonable reimbursement coupled with other safeguards protects against this possibility, and that a policy prohibiting reasonable payments because they may interfere with a woman's ability to weigh the risks and benefits of donation is unnecessarily paternalistic. In addition to the safeguards specified in NYSTEM's new donor payment contract provisions (*e.g.*, rigorous review by an institutional oversight committee, prohibition against payment of valuable consideration, and adherence to ASRM's guidelines), the Board has previously instituted by contract a number of important safeguards, including requiring full disclosure of all physical and psychological risks associated with oocyte donation, directing that informed consent be obtained through a dynamic process focused on the donor's comprehension of the information provided, and mandating availability of psychological counseling prior to donation. We are confident that procedures implemented by institutional oversight committees (IRBs and ESCROs), as mandated by law and by NYSTEM contract requirements, will protect against potential exploitation of donors and will ensure equitable access to opportunities.

On these bases, the Ethics Committee recommended, and the Funding Committee adopted,³ a measure to allow NYSTEM-funded research to proceed on cell lines created from oocytes donated solely to research, where the oocyte donor was

that the article specifically states that, "at this time sums of \$5,000 or more require justification and sums above \$10,000 are not appropriate." *Id.* at 308.

³ The vote of the Ethics Committee to make the recommendation on May 12, 2009 was 10-1, with Fr. Thomas Berg being the dissenting vote. The Funding Committee unanimously adopted the recommendation.

provided with reimbursement for: (1) out-of-pocket expenses, which may include the costs associated with travel, housing, child care, and medical care, incurred as a result of the donation process; and (2) the time, burden and inconvenience associated with oocyte donation, in an amount consistent with New York State standards applicable to donations of oocytes for reproductive purposes and not to exceed the range permitted by ASRM. The measure requires that all payments be reviewed rigorously by an institutional oversight body to ensure that the amount would not constitute an undue inducement to donate, and that no consideration of any kind may be given for the number or quality of the oocytes themselves.

With respect to the source of funds for these payments, the Board believes that since it is ethical to provide NYSTEM funds for research on cell lines derived from an oocyte from which the donor was paid in accordance with the strict standards of the NYSTEM contract, it is also ethical to permit NYSTEM funds to be used for the payment of the donor. Therefore, the measure also includes a provision allowing use of NYSTEM funds for oocyte donor payment where that payment complies with all of the NYSTEM contract requirements.