STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

Wendy E. Saunders
Executive Deputy Commissioner

May 26, 2009

Dr. Raynard Kington
NIH Acting Director
NIH Stem Cell Guidelines, MSC 7997
9000 Rockville Pike
Bethesda, Maryland 20892-7997

Dear Acting Director Kington:

On behalf of the Empire State Stem Cell Board (the "ESSCB" or the "Board"),[1] we thank you for the opportunity to comment on the National Institutes of Health's (NIH) Draft Guidelines for Human Stem Cell Research (74 Fed. Reg. 18,578-80 (Apr. 23, 2009)) ("Draft Guidelines").

The ESSCB was created in 2007 for the purpose of awarding grants for basic, applied, translational and other research and development activities that will advance scientific discoveries in fields related to stem cell biology. New York State has committed $600 million over eleven years to be spent on stem cell research, making it the second largest state funded program in the country. To date, $118.7 million in research funding has been recommended for award.

The ESSCB has spent considerable time analyzing pivotal ethical issues surrounding the conduct of stem cell research, including usage of embryos in research and informed consent. The ESSCB's deliberations have been guided in part by the federal Common Rule (45 C.F.R. § 46), as well as ethics guidelines promulgated by prominent consensus bodies, such as the National Academies of Science (NAS) and the International Society for Stem Cell Research (ISSCR). Consideration of these standards has had the two-pronged effect of ensuring that the ESSCB's policies adhere to the highest of ethical principles and of fostering essential public-private collaborations with institutions that have based their policies on these widely-recognized standards.

The ESSCB commends the Obama Administration for creating policies that promote the very important science of stem cell research. Stem cell research represents one of the most revolutionary areas of medical research today, holding out the possibility of creating treatments – and even cures – for countless diseases.

[1] The ESSCB voted 19-1 in support of this letter. Fr. Thomas Berg, who dissented from this vote, will submit a separate letter containing his comments.

While the NIH's Draft Guidelines represent a significant improvement on previous federal policy, the ESSCB respectfully requests that the NIH reexamine its proposed policies as discussed below prior to issuing final guidelines.

First, the ESSCB urges the NIH to reconsider its limitation of NIH funding of human embryonic stem cell research only to cell lines derived from embryos that were created for reproductive purposes and were in excess of clinical need. (Draft Guidelines § II.B). The Dickey-Wicker Amendment, which the ESSCB will not comment on in this letter, does not prevent the NIH from funding research on stem cell lines derived from embryos that were created for research purposes with non-NIH funds. Further, the ESSCB believes that, given the proper constraints, research using embryos that were specifically created for research can be ethical and that a blanket restriction is unwarranted. The proposed restriction will impede significantly the progress of science by disqualifying from federal funding eligibility disease- or individual- specific cell lines that were otherwise ethically derived. Accordingly, we advocate that the NIH allow funding for research using cell lines that were derived from embryos that were created for research purposes.

Second, the Board strongly encourages the NIH to align its provisions, particularly in the area of informed consent, with the widely-accepted principles embodied in the Common Rule (voluntary informed consent, independent oversight of the informed consent process and the avoidance of undue inducements) rather than create novel requirements. In addition, we respectfully suggest that the NIH harmonize their policies with the NAS and/or ISSCR Guidelines.[2] This harmonization should include endorsement of the value of the special expertise and scope of ethical review provided by stem cell review oversight committees (commonly called SCROs, or ESCROs where the scope of review involves embryonic stem cells). It should also include adoption of the ISSCR's policy of allowing usage of biological products where obtaining re-consent to donation is prohibitively difficult and the initial consent is reviewed by an oversight body for compliance with prevailing ethical standards. (*See* ISSCR Guideline 11.2).

Third, the Board is concerned that certain stem cell lines that were created in compliance with widely-accepted ethical standards may not be eligible for federal funding where they do not meet the new, unique standards currently proposed by the NIH. This would disqualify from funding many lines that have served as the basis for a significant amount of valuable research. Accordingly, the Board respectfully requests that the NIH's guidelines provide a mechanism pursuant to which a cell line imported from another jurisdiction or institution, or created prior to the effective date of the guidelines, may be used in research so long as it was "acceptably derived." (*Cf.* NAS Guideline 1.6(b)).[3]

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[2] We note that the ESSCB has found the ISSCR Guidelines particularly insightful and instructive in several ways, including their emphasis on the dynamic process that should occur when obtaining informed consent.

[3] According to the NAS Guidelines,

> "Acceptably derived" means that the cell lines were derived from gametes or embryos for which (i) the donation protocol was reviewed and approved by an IRB or, in the case of donations taking place outside the United States, a substantially equivalent oversight body;

Similarly, the Board believes that the NIH should continue to fund research on the stem cell lines that were approved for use in federally-funded research following the Bush Administration's policy announced on August 9, 2001. (*Cf.* NAS Guideline 1.5(a) (allowing use of the lines)). While the Board acknowledges the serious ethical questions regarding the derivation of some of these lines,[4] it nevertheless believes that, in light of the substantial research that has been conducted on these lines to date, they should be eligible for federal funding.

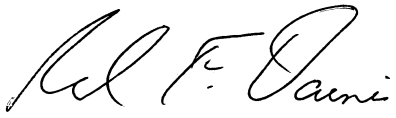
Finally, the ESSCB believes that some of the provisions in the draft guidelines are ambiguous and should be clarified in the following manner:

- Section II.B.4 requires "a clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate human embryos for research purposes. (Draft Guidelines § II.B.4). We believe that the term "separation" is ambiguous and could be subject to a range of interpretations. Therefore, we request that the NIH clarify that this provision does not preclude the initial consent for creation of an embryo for reproductive purposes from containing an authorization to allow embryos in excess of clinical need to be used in research.

- Section II.B.2 mandates that "no inducements were offered for these donations." (Draft Guidelines § II.B.2). While the Board believes that this phrase is intended to prohibit payments or other inducements to donors for the donation of their embryo to research, it may be read expansively to prohibit usage of embryos that were created with gametes whose donors were provided with inducements in the course of reproductive processes. We recommend that this requirement be amended to read "no inducements were offered for the embryos to be donated for research purposes."

We thank you again for the opportunity to comment on this very important matter, and welcome further occasion for discussion or consultation.

Sincerely,



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Chair, Empire State Stem Cell Board

(ii) consent to donate was voluntary and informed;
(iii) donation was made with reimbursement policies consistent with these Guidelines; and
(iv) donation and derivation complied with the extant legal requirements of the relevant jurisdiction. (NAS Guideline 1.6(b)).

[4] *See, e.g.*, Robert Streiffer, *Informed Consent and Federal Funding for Stem Cell Research*, 38 Hastings Ctr. Rep. 40-47 (2008).