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May 22, 2009

The Honorable Raynard Kington
Acting Director
The National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Kington:

We are writing on behalf of the American Society for Cell Biology (ASCB) to share our thoughts regarding the draft U.S. National Institutes of Health Guidelines for Human Stem Cell Research, which appeared in the Federal Register on April 23, 2009. The guidelines were drafted in response to Executive Order 13505, *Removing Barriers to responsible Scientific Research Involving Human Stem Cells*.

The ASCB is generally supportive of the draft guidelines. We believe they are an excellent first step and outline a responsible path forward for responsible, ethical, and productive research that could drastically change medical science in the decades to come.

Two critical changes need to be made to the current draft guidelines. First, we believe that a major flaw exists in section II. B, *Eligibility of Human Embryonic Stem Cells for Use in Research*. While this section provides a reasonable standard for the eligibility of human embryonic stem cell lines derived in the future, it does not recognize the existence of hundreds of stem cell lines currently in use in research labs across the United States. While these existing lines were derived according to the most ethical standards recognized at the time of derivation, they may not meet the new, more rigorous standards set forth in the NIH draft guidelines. To prohibit their eligibility for federal funds under this new policy would do great harm to the field of stem cell research. Federally funded researchers would be forced to stop their work and wait for a yet unknown number of new embryonic stem cells that comply with the new NIH guidelines to be derived. Such a halt to research would be detrimental to the scientific community and would also be devastating to patients around the world who might benefit from this important research.

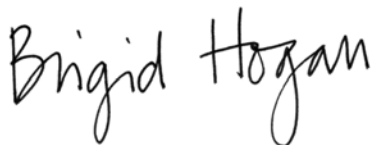
Therefore, we urge the NIH to include a provision within Section II to allow human embryonic stem cell lines previously and ethically derived to be eligible for use in federally funded research under these guidelines. Instead of requiring previously derived cell lines to comply with either the National Academy of Sciences (NAS) guidelines or the guidelines by the International Society of Stem Cell Research (ISSCR), we propose a different standard. We recommend that the final guidelines allow NIH funding for any lines derived prior to the implementation of the new policy that had been derived: a) with informed consent, b) without undue inducement, and c) with oversight by an ethics advisory committee, such as an Institutional Review Board.

Second, we would also urge the replacement of section *II C, Prior to the Use of NIH Funds*. We are concerned that the requirement that each recipient of federal funds ensure the compliance of the cell lines to be used would be administratively burdensome and serve as an unnecessary restriction on research. Under the draft guidelines, each investigator who wishes to use a cell line in his or her research must provide assurances that the cell line complies with the NIH Guidelines. This repeated reauthorization of the same cell lines seems, to us, to be unnecessary. It is also possible that different institutions might judge the eligibility of the same cell line differently. This lack of uniformity threatens the free flow of scientific investigation.

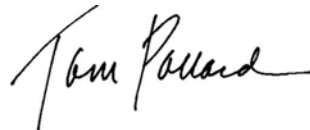
In place of bureaucratic and legal confusion, we call on the NIH to establish an NIH registry of human embryonic stem cell lines available for federally funded research. We propose that when a cell line is first used in federally funded research, assurance documentation be submitted to an NIH-run registry. The registry would allow researchers to review the cell lines that meet the NIH guidelines and then apply to use those stem cells lines.

In closing, we urge the NIH to ensure that the final guidelines retain the flexibility necessary to keep pace with the advances in science. A scientifically flexible policy that nurtures progress in ethically sound pioneering research will benefit science, the public, and the NIH.

Sincerely,



Brigid Hogan
President
The American Society for Cell Biology



Tom Pollard
Chair, Public Policy Committee
The American Society for Cell Biology