

## Consensus Statement

February 24, 2006

*Stem cell and related research holds out immense promise for good. This research has the potential to dramatically increase our understanding of human biology from which may come new treatments for many serious diseases and injuries. The moral reason to conduct stem cell and nuclear reprogramming research thus comes from both the possibility of advancing knowledge and the values of relieving suffering and promoting human welfare. Furthermore, intra- and international scientific collaboration are vital to the success and advancement of science.*

*While we strive for consensus on a fundamental ethical framework for stem cell research, we acknowledge the reality of cultural diversity and moral disagreement about some elements of stem cell research. Inconsistent and conflicting laws prevent some scientists from engaging in this research and hinder global collaboration. Societies have the authority to regulate science, and scientists have a responsibility to obey the law. However, policy makers should refrain from interfering with the freedom of citizens unless good and sufficient justification can be produced for so doing. As scientists, philosophers, bioethicists, lawyers, clinicians, journal editors and regulators involved in this field, we have reached consensus that if humankind is to have the very best chance of realizing the benefits of stem cell research in an ethically acceptable manner, the following principles should govern the ethical and legal regulation and oversight of stem cell and related research and its clinical applications. This is by no means a comprehensive list of principles, but rather a declaration of those discussed and agreed upon by our group:*

1. Stem cell research should seek to minimize harm, and any risk of harm should be commensurate with expected overall benefit. Scientists and clinicians should conduct research according to ethically acceptable norms. For example, research should be conducted so as to protect the well-being, liberty and rights of cell and tissue donors as well as research participants. Research participants and donors of human materials must provide valid informed consent, and conflicts of interest should be appropriately addressed.
2. The law carries great power to facilitate or restrict scientific exploration in the area of stem cell research. Law makers should be circumspect when regulating science. When enacted, laws or regulations governing science nationally and internationally ought to be flexible, so as to accommodate rapid scientific advance.
3. Scientists and clinicians have a responsibility to obey the law. However, they also have the right to know through clear and explicit laws, what is and is not permitted with respect to their research, the jurisdiction of any prohibitions, and related penalties, so that they can regulate their behavior accordingly.
4. In countries with laws that restrict elements of human embryonic stem cell (hESC) research but that do not expressly prohibit international collaborations, research institutions should neither discriminate against nor restrict the freedom of their investigators who want to travel to do work that is undertaken with scientific and ethical integrity.

5. Law makers should be similarly circumspect in restricting citizens' conduct extraterritorially with regard to stem cell research. So long as scientifically and ethically defensible hESC research is undertaken in a country in which it is legally permissible, scientists should be free to participate in that research without fear of being liable to prosecution, restriction, or discrimination in another jurisdiction.

6. It is essential that scientists and policy makers consult each other and the public in the attempt to develop regulatory regimes for stem cell research that strike the best possible balance between free scientific inquiry and social values.

7. Journal editors should encourage authors to include in manuscripts explicit descriptions of their roles in the published research so as to clarify the appropriateness of their participation, in particular for researchers residing in countries with more restrictive laws and collaborating with researchers residing in countries with more permissive laws.

*In addition, we reached consensus on the following forward-looking strategies to foster the scientific and ethical integrity of research in a global context:*

8. Insofar as ESC lines are a precious resource and replication and scientific collaboration are vital to scientific advancement, we encourage scientists conducting stem cell research to submit any stem cell lines they derive to national or international depositories that subscribe to internationally accepted standards of quality and make cell lines and data (e.g. DNA fingerprinting and micro satellite data) publicly available.

9. Journal editors should support and promote high standards for scientific peer review. For studies generating new ESC lines described in manuscripts submitted for publication, we encourage journal editors to require that authors submit data verifying the authenticity of the ESC line(s), and an explanation of how the authors have complied with accepted standards of good cell culture practice<sup>1</sup>. We further urge journal editors to require that the source of the cells used in the research be clearly specified.

10. Journal editors should also support and promote high standards for ethical integrity in stem cell science. Journal editors should require a statement from scientists that their research conforms to local laws and policies, and that, where applicable, it has been approved by all appropriate oversight committees. Authors should provide statements of all conflicts of interest that affect their research. On request from editors, authors should provide protocols approved by ethics review committees, consent forms, information provided to potential human subjects and tissue donors, and other related documents or information that may bear on the ethics of the research.

11. For the purposes of oversight, regulations and applications to ethics review boards and funding agencies, etc., human materials donors in the context of human ESC research ought to be treated as human research subjects.

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<sup>1</sup> Coecke S, et al. Guidance on good cell culture practice: A report of the second ECVAM task force on good cell culture practice. ATLA: 2005; 33: 261-287.

12. We encourage the creation of a public database for the deposition of statements of ethical conduct and guidance, research protocols, consent forms, information provided to potential human subjects and tissue donors and other related documents that bear on the ethics of stem cell research.

13. As the science evolves, academies of science and relevant professional organizations, in consultation with the public, should continue to develop guidelines for the ethical conduct of stem cell research and clinical trials. Insofar as possible, these guidelines should be applicable to stem cell research internationally and should continue to address the challenges of international collaboration.

14. Funding bodies must take adequate steps to satisfy themselves that those they fund intend to carry out their research ethically and in accordance with relevant national regulations and appropriate international guidance as it emerges.

15. Research institutions and laboratories are encouraged to provide opportunity for researchers to engage in ethical discussion, review, and education.

*While we believe we have accomplished much, we believe there is much work to be done. For example:*

16. Insofar as donors of human materials are treated as human subjects, many of the ethical issues raised by hESC research can be adequately addressed through existing international codes of ethics and policy documents governing research involving human subjects. However, new ethical challenges in the conduct of stem cell research that are on the horizon cannot be adequately addressed by existing international ethical codes or practices. Examples are gametes derived from hESC, and human-non human chimeras. At least one national effort is currently underway to anticipate such challenges<sup>2</sup>. However, it is imperative that international efforts to address these new issues be initiated as soon as possible in order to ensure that science proceeds in an ethically acceptable fashion and to reduce the likelihood that diversity in international response will result in obstacles to ethical conduct similar to those raised by existing differences in national policies governing hESC research and nuclear transfer.

17. Steps should be taken to develop consensus in ethical standards and practices in hESC research for international collaboration to proceed with confidence and for research from anywhere in the world that adheres to these standards and practices to be accepted as valid and valuable by the scientific community and academic journals.

18. To achieve this goal, it will be necessary to specify what these standards and practices should be through the international efforts of scientists, philosophers, bioethicists, lawyers, clinicians, journal editors and regulators involved in this field, in collaboration and consultation with the public. It is imperative that scientists in particular actively and honestly engage with the public about the promises and limitations of this research.

19. This process of identification of international ethical standards and practices should include concerted efforts to engage people throughout the world in honest and realistic conversations about the science and ethics of stem cell research and its emerging applications.

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<sup>2</sup> The Human Fertilization and Embryology Authority (HFEA) is conducting at least one national effort to anticipate to these challenges.

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