

New ISSCR guidelines for stem cell research and translation outline best practices

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The International Society for Stem Cell Research (ISSCR), the world's largest professional organization of stem cell scientists, today released newly updated guidelines for stem cell research and the development of new clinical therapies. The new guidance comes at a time when rapidly evolving technologies like gene editing in human embryos and emerging areas of stem cell discovery and its applications are providing unprecedented opportunities to understand human biology and disease, but also raising questions that have social and ethical implications. The guidelines build on widely shared principles in science that call for rigor, oversight, and transparency in all areas of practice. Adherence to these principles provides assurance that stem cell research is conducted with scientific and ethical integrity and that new therapies are evidence-based.

"The field of stem cell research is growing at a rapid pace, with scientists and physicians developing new therapies that can help patients around the world who suffer from a wide variety of conditions," said Sean J. Morrison, Ph.D., ISSCR president and director of the Children's Medical Center Research Institute at UT Southwestern. "These [guidelines](#) are essential to protect the integrity of the research and to assure that stem cell treatments are safe and effective," he said.

The ISSCR developed earlier sets of guidelines that are widely followed by researchers and institutions around the world ([Guidelines for the Conduct of Human Embryonic Stem Cell Research, 2006](#); [Guidelines for the Clinical Translation of Stem Cells, 2008](#)). The [2016 guidelines](#) update and expand those topic areas and bring all guidance together

under common principles of research integrity, patient welfare, respect for research subjects, transparency, and social justice. At their core, the new guidelines preserve the imperative for a specialized oversight process for research involving human embryos, in recognition of the unique sensitivities surrounding such research. Responding to advances in science, the guidelines encompass a broader and more expansive scope of research and clinical endeavor than before, imposing rigor on all stages of the research, addressing the cost of regenerative medicine products, and highlighting the need for accurate and effective public communication.

"By addressing ethical uncertainties, articulating standards, and protecting patients and the public interest, these guidelines provide a path for rapid advances in [stem cell biology](#) and medicine," said Jonathan Kimmelman, Ph.D., ISSCR Guidelines Update Task Force chair, and associate professor of Biomedical Ethics at McGill University. "Science moves quickly, and we recognize the guidelines are a living document that will undergo ongoing review, interpretation, and revision in order to support the community," he said.

The new guidelines address several issues not included in previous versions; they:

- Define an Embryo Research Oversight (EMRO) process to encompass both human embryonic stem cell research and human embryo research that may not explicitly pertain to stem cells or generating new stem cell lines;
- Exclude the generation of induced pluripotent [stem cells](#) (iPS cells) from specific stem cell research oversight, and instead call on the existing human subjects review processes to oversee donor cell recruitment (iPS cells behave like [embryonic stem cells](#) but are derived by reprogramming more differentiated tissue cells);
- Support laboratory-based research that entails gene editing of the

nuclear genomes of human sperm, egg, or embryos, when performed under rigorous review, but hold that any attempt to apply this clinically would be premature and should be prohibited at this time;

- Define principles for evaluating both basic and clinically applied research on mitochondrial replacement therapy, in concordance with recent deliberations in the U.K., U.S., and elsewhere;
- Determine that, with careful review to ensure there is no undue financial inducement to participate, it may be acceptable to compensate women who donate eggs for research;
- Recognize that the development of increasingly complex in vitro models of early stages of human development should undergo specialized review;
- Highlight opportunities to strengthen preclinical studies in stem cell research, including reproducibility and stringent standards for experimental design;
- Call for robust standards for preclinical and clinical research evidence as clinical trials progress and rigorous evaluation for safety and efficacy before marketing approval;
- Address the valuable contributions made by patients or patient groups to support clinical research and a framework to ensure this is achieved without compromising the integrity of the research;
- Highlight the responsibility of all groups communicating stem cell science and medicine—scientists, clinicians, industry, science communicators, and media—to present accurate, balanced reports of progress and setbacks.

"The public recognizes that [stem cell research](#) holds promise for treating diseases and disorders affecting millions of people around the world," said George Q. Daley, M.D., Ph.D., member of the ISSCR Guidelines Update Steering Committee and professor of Biological Chemistry and Molecular Pharmacology at Harvard Medical School. "We remain

steadfast in our commitment that only safe and effective treatments based on proven science should be marketed to patients," he said.

The new guidelines were developed by an international task force of 25 experts in stem cell science, clinical research, and bioethics, from 9 countries, with review and feedback from 85 external individuals and organizations. A list of task force members may be found along with the guidelines on ISSCR's website: [2016 Guidelines for Stem Cell Research and Clinical Translation](#).

Several articles published today provide additional information about aspects of the new ISSCR guidance and the task force discussions:

- "Setting Global Standards for Stem Cell Research and Clinical Translation: The 2016 Guidelines" (Available at noon ET, May 12, *Stem Cell Reports*; [StemCellReports.cell.com](#)) by Daley and colleagues
- "[Global Standards for Stem Cell Research](#)" (*Nature*) by Kimmelman and colleagues.
- "[Translating Stem Cell-Based Interventions Ethically: The ISSCR Guidelines](#)" (*Lancet*) by Kimmelman and colleagues
- "[Confronting Stem Cell Hype](#)" (*Science*) by Caulfield and colleagues

Provided by International Society for Stem Cell Research

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