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**THE INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH RELEASES NEW
GUIDELINES TO SHAPE FUTURE OF STEM CELL THERAPY**

Regulation needed as new study reveals clinics exaggerate claims and omit risks

Deerfield, IL, December 3, 2008 – Today, the International Society for Stem Cell Research (ISSCR), the world’s leading professional organization of stem cell researchers, released new guidelines for the responsible development of safe and effective stem cell therapies for patients. A Commentary article that summarizes the *Guidelines for the Clinical Translation of Stem Cells* will be published by Cell Press in the December issue of *Cell Stem Cell*, the official affiliated journal of the ISSCR.

These guidelines define a roadmap for medical researchers and doctors, outlining what needs to be accomplished to move stem cells from promising research to proven treatments for patients. The new guidelines will accelerate the translation of stem cell research into practice while addressing associated scientific, clinical, regulatory, ethical and social issues. Founded on core principles of scientific rigor and ethical conduct, the recommendations offered in the guidelines include an insistence on expert evaluation and independent oversight, a thorough informed consent process to provide patients with essential information on the unique aspects of stem cell-based treatments, and transparency in reporting of clinical trial results.

“Our guidelines will arm patients and their doctors with the information they need to make decisions about whether to seek stem cell treatments,” said Dr. Olle Lindvall, co-chair of the ISSCR task force that developed the guidelines and professor in clinical neurology at the University of Lund. “Stem cell research holds tremendous promise for the development of novel therapies for many serious diseases. However, as clinicians and scientists, we recognize an urgent need to address the problem of unproven stem cell treatments being marketed directly to patients.”

Too often rogue clinics around the world exploit patients’ hopes by offering unproven stem cell therapies, typically for large sums of money and without credible scientific rationale, oversight or patient protections.

This concern is further emphasized in a Correspondence article from Dr. Timothy Caulfield and colleagues of the University of Alberta, Canada, which also appears in the December issue of *Cell Stem Cell*. A content analysis of claims made on 19 Web sites offering so-called “stem cell therapies” was performed to assess the portrayal of the services offered by each

organization. In addition, the authors assessed whether these claims are substantiated by research reported in the professional medical literature. The authors provide clear evidence that the vast majority of the clinics examined over-promise results and gravely underestimate the potential risks of their offered treatments.

The ISSCR's new guidelines establish standards that can be used to judge the claims made by stem cell clinics and whether the treatments they offer are being developed responsibly. The ISSCR also offers a handbook for patients and their doctors evaluating a stem cell therapy.

The ISSCR urges governments and regulatory bodies to enact the recommendations outlined in these guidelines. The guidelines call for countries without an official regulatory body to develop a way to monitor new stem cell-based treatments, and the ISSCR has offered to advise agencies that want to build these regulatory capacities.

“Regulators have a responsibility to prevent exploitation of patients in their jurisdictions, and where necessary, to close fraudulent clinics and take disciplinary action against the doctors involved,” said Dr. George Q. Daley, immediate past-president of the ISSCR and associate director of the Stem Cell Program at Children's Hospital Boston.

To develop these new guidelines, the ISSCR convened an international task force of experts in stem cell science, clinical research and bioethics from 13 countries. The task force was led by Dr. Lindvall and Dr. Insoo Hyun, ISSCR member and associate professor of bioethics at the Case Western Reserve University School of Medicine.

“Our task force has captured the most current, comprehensive thinking on translational stem cell research. The result – these new guidelines – will be valuable for all members of the stem cell community,” said Dr. Fiona Watt, president of the ISSCR.

Patients, medical researchers, regulators and those interested should visit the ISSCR's Web site at www.ISSCR.org to see the Guidelines, a handbook for patients and more information on stem cell research. In addition, the content of the Guidelines is digested in the Commentary article authored by the task force, which is available online at www.cellstemcell.com/.

The International Society for Stem Cell Research (ISSCR) is an independent, nonprofit membership organization established to promote and foster the exchange and dissemination of information and ideas relating to stem cells, to encourage the general field of research involving stem cells and to promote professional and public education in all areas of stem cell research and application.

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