

NIH stem cell guidelines should be modified, UCSF team reports

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A UCSF team, led by bioethicist Bernard Lo, MD, recommends that the National Institutes of Health ethics guidelines for embryonic stem cell research be modified to better protect the rights of individuals donating egg or sperm to patients undergoing in vitro fertilization.

The recommendation is reported in the February 19, 2010 issue of *Science*.

Third parties frequently donate sperm and egg, or "gametes," for patients attempting to create embryos in the [in vitro fertilization](#) clinic.

Under current practice in the United States, gamete donors sign a form giving the IVF patient unrestricted legal authority to determine how to dispose of any embryos that may be leftover following fertility treatments. Donor banks and IVF clinics are not required to brief gamete donors about the various options for disposition, which include donating the embryos for stem cell research, thereby enabling scientists to derive new human embryonic stem cell lines; discarding the embryos, or donating them to other IVF patients.

While many state, national, and international scientific committees and agencies have recommended that third-party gamete donors give formal "informed consent" for stem cell research with embryos remaining after infertility treatment, the NIH did not stipulate this requirement in its guidelines issued in March 2009. As these guidelines determine which human embryonic stem cell (hESC) lines may be studied under NIH

research grants - which are expected to play a growing role in funding stem cell research - the ethical implications are significant, says Lo, chair of the UCSF Gamete, Embryonic Stem Cell Research Committee, members of which published the *Science* paper.

"We urge the NIH to revise its guidelines to require that gamete donors be advised that embryos containing their sperm or egg could be used for embryonic stem cell research, before they grant dispositional authority over embryos to the IVF patient," he says. "Because some gamete donors may not approve of embryonic stem cell research, we consider this the ethically appropriate position."

In their paper, the team recommends a process that is less complex than the detailed "informed consent" process carried out when IVF patients donate embryos for research. They suggest the disclosure to gamete donors may be made through oral discussion or brochures before donors sign a form authorizing the IVF patient to determine the disposition of embryos.

Importantly, says Lo, the gamete donors' instructions would not disrupt the IVF process. IVF patients would learn of a gamete donor's restrictions in advance of selecting embryos for IVF treatment, and could select other gamete donors if not satisfied with the donors' disposition restrictions.

The recommendation is consistent with that of the National Academy of Sciences and the International Society for Stem Cell Research says Lo, a member of the ethics committee of the ISSCR, and the co-chair of the Standards Working Group of the California Institute for Regenerative Medicine.

"It would be highly desirable to have consistency among standards and regulations," he says. "If such harmonization were achieved, many

university Institutional Review Boards and other research oversight bodies would likely allow NIH-eligible human embryonic stem cell lines to be used for any otherwise acceptable hESC research."

"It's critical that we consider all parties involved in the creation of embryos and honor their wishes," says co-author Arnold Kriegstein, MD, PhD, director of the Eli and Edythe Broad Center of Regeneration Medicine and Stem Cell Research at UCSF.

"The field of human embryonic [stem cell research](#) offers enormous promise for patients suffering from devastating diseases. We want to build this field on an ethical foundation of which we can be proud."

Exceptions to the guideline could be justified for hESC lines already in existence if there were strong scientific reasons to use the cell lines and the third-party gamete donor had granted rights to the IVF patient to determine disposition of the [embryos](#).

Provided by University of California - San Francisco

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