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News

Consent issues restrict stem-cell use

Some human embryonic cell lines may not be eligible for research.

Monya Baker

Stanford University is to tell its researchers that around one-quarter of the human embryonic stem-cell lines eligible for US government funding are now off-limits because of ethics concerns.

The institute, in Palo Alto, California, is concerned that some of the women who donated the embryos for these stem-cell lines did not give informed consent for the lines to be used in research. Johns Hopkins University in Baltimore, Maryland, has decided to reconsider lines individually as researchers express an interest in using them.

The concerns follow an analysis by bioethicist Robert Streiffer of the University of Wisconsin, Madison, who obtained copies of the informed consent forms given to donors of the 21 lines that have been approved for federal research funding by the US National Institutes of Health (NIH). Streiffer compared these forms with guidelines set by the US National Academy of Sciences (NAS). None of the forms met the guidelines exactly, he concluded, and some deviated egregiously (R. Streiffer *Hastings Cent. Rep.* **38**, 40–47; 2008).

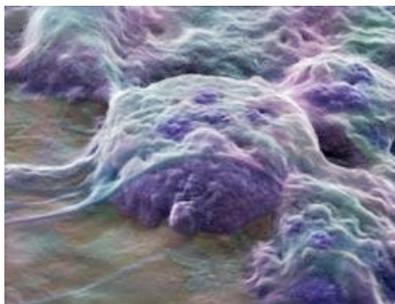
Now, ethics oversight committees at universities across the United States are questioning which lines should be permissible for research — and hoping that another agency, such as the NIH or a state government, will make the decision for them.

On the basis of Streiffer's analysis, Stanford has decided that as many as five of the lines should not be used, it has emerged. The lines were derived by two biotechnology companies — BresaGen, based in Athens, Georgia, and Cellartis in Göteborg, Sweden — both of which say they obtained adequate consent according to standards in place at the time. But rather than signing a separate form authorizing research, the form signed by donors for lines derived by BresaGen (now owned by Novacell) was for fertility treatment and noted that multiply fertilized eggs or embryos that were not developing could be used for scientific study. The consent form used by Cellartis stated that cells would be destroyed after a few days in culture. Neither consent form stated explicitly that the research would potentially destroy viable embryos.

All the NIH-approved lines were derived before August 2001, when President George W. Bush declared that only lines already in existence could receive federal support. In 2005, responding to calls from the scientific community, an advisory committee of the NAS issued guidelines that covered what kinds of experiments should be conducted on human embryonic stem cells and how donors of gametes and embryos should be treated. Later, the committee declared that the lines on the NIH registry had been derived under conditions “substantially similar” to its guidelines and instructed research oversight committees to consider the lines as acceptably derived.

But members of the committee relied on the NIH's 2001 assessment that the lines were appropriate for research use. “It didn't occur to us that we should get the consent forms to look at them,” says committee study director Frances Sharples, who says that the NAS will revisit the issue of which lines are acceptable at a meeting later this year.

“We understood that the lines were in substantial compliance with NAS guidelines,” says NAS committee co-chair



Some human embryonic stem cells may have been obtained without adequate consent for research.

A. Cavanagh/Wellcome Images

“It didn't occur to us that we should get the consent forms to look at them.”

Jonathan Moreno, who is a senior fellow at the Center for American Progress, a think tank based in Washington DC. "It shows the lengths to which the administration pushed the NIH to get as many lines on record as it could. It shows that it's time to move on."

The NIH will not be taking any lines off its registry, says Story Landis, head of the agency's Stem Cell Task Force. "Streiffer's paper deals with application of 2008 standards to cell lines that were put on the registry in 2001," she says, adding that NIH staff determined that the registry lines met the criteria put forth by the president in 2001.

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It's unclear the extent to which reassessment will affect research on human embryonic stem cells. Many scientists with private or state funding are already using newer non-NIH lines derived under better conditions. Of the lines on the NIH registry, the ones from BresaGen and Cellartis are the least used. Nonetheless, they have been shipped to dozens of researchers.

For more, see [The Niche stem-cell blog \(http://tinyurl.com/6ae7ne\)](http://tinyurl.com/6ae7ne).

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Story Landis is mistaken in asserting that the analysis in "Informed Consent and Federal Funding for Stem Cell Research" applies 2008 standards to lines that were established in 2001. As the article explicitly notes, the standards for informed consent in the context of embryo donation had been discussed by the Human Embryo Research Panel in 1994, the American Society for Reproductive Medicine in 1997, and the National Bioethics Advisory Commission in 1999, among other places. Moreover, these standards themselves derive from principles about informed consent that, as the article points out, "have been internationally recognized in both ethical discussions and legal regulations for decades." Dr. Landis also says that the NIH registry lines met the criteria put forth by President Bush. But one of those criteria was that the embryos had to have been donated with informed consent, and the analysis goes into some detail as to the ways in which that criterion was not met. Here are two examples. First, the BresaGen consent form provided by the NIH to me does not provide any information to the donors about the research except the information that their surplus embryos may be used for research. On no plausible account of informed consent does that count as sufficiently informed. Second, the Cellartis form provided by the NIH to me states that all cells used in the study will be destroyed after the study is completed. Thus, researchers do not have informed consent to use those cells in subsequent studies. Please see the article itself for more substantiating details. Sincerely, Robert Streiffer

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Posted by: **Robert Streiffer** | 28 Jul, 2008

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