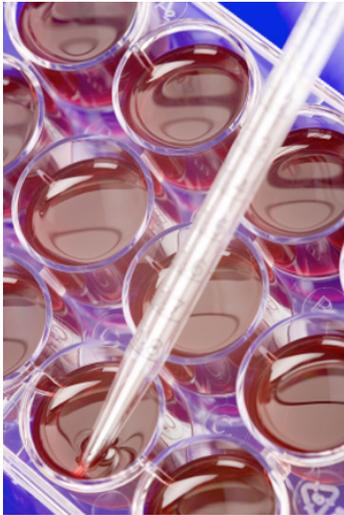


Do Parents of Embryonic Stem Cell Lines Need Ethical Protection?

By Coco Ballantyne

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Now that some of the gates blocking embryonic stem cell research in the U.S. may be opening thanks to the Obama administration, the ethical guidelines for such research may be getting a closer look. A key question: Should research on embryonic stem cells be subject to the same stringent rules that govern human subjects research?

That was one of the questions that came up last night at a meeting of the New York Stem Cell Foundation. Harold Varmus -- an Obama supporter who now co-chairs the President's Council of Advisers on Science and Technology -- told a crowd gathered at the Harvard Club in midtown Manhattan that there is "reason to believe that there will be some executive order in the near future to reverse the Bush doctrine," a.k.a the ban on federal funding for research on embryonic stem-cell lines produced after August 9, 2001.

Such a reversal would presumably mean more federal funding for embryonic stem cell research, and Lawrence Tabak, acting deputy director of the National Institutes of Health (NIH), said last night that the NIH is already preparing for the expected policy shift. As soon as the ban is lifted, the agency will move to develop a new set of guidelines that will, among other issues, detail which types of embryonic stem cell studies constitute human subjects research.

That's an important distinction. To work with typical cell lines that cannot be linked to a living person, scientists needn't obtain special clearance from the federal government. Human research is, understandably, subject to stricter ethical standards than other types of biomedical research. Scientists doing human subjects research are required to obtain pre-approval from institutional review boards (IRB's)—ethics committees that monitor research conduct and protect the rights and welfare of study participants. Any university or private research institution that receives funding from the feds is required to have an IRB.

Everyone would agree that if stem cells are being used in humans -- say in the Geron trial of stem cells in spinal cord injuries approved last week -- the trials need a closer look. But does it make sense to put those stringent standards in place for what some would say is just a collection of cells, if a scientist is working in the lab?

We checked in with Josephine Johnston, a bioethicist at the Hastings Center, in Garrison, New York, for her thoughts. She says that certain types of studies involving human embryonic stem cells would already be considered human subjects research under current federal regulations, and thus protected by IRBs. "Human embryos in a dish are not considered human subjects, but the embryo

donors might be,” Johnston says. If the embryo donors (mom and dad) identify themselves to scientists, providing personal data and perhaps even biological samples, then says Johnson, “they are pretty clearly human subjects.”

Imagine this scenario: You’re a member of a couple that has had a baby using in vitro fertilization. You give your extra embryos away, but you don’t want to participate in any research. (While it’s tough to estimate how many embryos are discarded every year, Johnston says there are some 400,000 frozen embryos stored in fertility clinics around the U.S., and some of these might eventually be donated to science.) Theoretically, there would be no link between you and those embryos, but remember that your DNA is in that cell line. “If you have the genetic material from an individual [contained within those embryos], might you be able to get identifying, private information about that person?” asks Johnston. “We don’t currently have the technology but it could be developed in the future.”

That squares with what Tabak told ScientificAmerican.com last night in response to a question prompted by vicka, one of our Twitter followers. (Oh yeah: We live-tweeted the meeting.) “The issue of identity becomes a key element in the decision,” Tabak said.