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Kim Kozlowski

Gestation slow on embryo science

Nine months after voters approved a constitutional amendment that eased restrictions on embryonic stem cell research in Michigan, little has changed.

Scientists remain in a holding pattern and residents still are unable to donate embryos, while two review boards work to approve the required donor consent forms.

The committees have a backlog of issues to approve and it is unclear when they will approve the consent forms.

"We would love to start doing the research, because we've gone through years of trying to get the law in Michigan changed," said Ed Goldman, an attorney and member of one of the oversight committees. "But we want to do it properly."

Judy Johnston, 42, is contemplating donating four embryos left over from the in-vitro fertilization process that led to the birth of her daughter, Susanne.

Johnston later learned that the woman who donated her eggs to her carries a gene that can lead to a genetic disorder. Susanne, 3, is healthy but one of the other embryos may have the gene -- making them desirable to researchers.

"They might be able to look into ways to treat it in utero or treat it after the babies are born," Johnston said. "There are so many people who could benefit from the work that is coming out of that field."

Oversight is stringent

The delay, some in the research community say, is a testament to the stringent oversight that proponents assured voters would take place when they sought to pass the constitutional amendment in November.

"We not only have state and federal laws to follow, but our internal oversight boards, too," said Martin Fischhoff, managing director of the A. Alfred Taubman Medical Research Institute, which has been a major force in pushing the research forward. "This just shows how regulated the science is."

Scientists, mainly at the University of Michigan, will derive embryonic stem cell lines from donated frozen embryos created in fertility clinics.

In-vitro patients who don't give to science or use the embryos to have other children can choose to discard leftover embryos, donate them to other couples with fertility issues or store them indefinitely -- at a cost of hundreds of dollars annually, depending on the number of embryos. Researchers also plan to recruit adults at U-M disease clinics to donate skin cells, which can be coaxed into acting like embryonic stem cells.

The Human Pluripotent Stem Cell Research Committee and the U-M Institutional Review Boards at the medical school have been reviewing the forms for months. The committees include scientists, ethicists, physicians, attorneys and community members who meet regularly to examine the ethics, privacy and relevance of proposed research.

The forms were altered following feedback from the committee and guidelines from the National Institutes of Health that were announced July 6.

"Now the revised consent documents are in re-review," said Sean Morrison, director of the U-M Center for Stem Cell Biology. "These committees do not approve things in a matter of days."

Michigan lags behind

Part of the delay is Michigan hasn't been doing the research, unlike other states, so they have had to create consent forms that many states have been using for years, said Sue O'Shea, co-director of the Consortium for Stem Cell Therapies.

"Michigan is behind because we haven't been able to do a lot of this work," O'Shea said**.**

But once the work launches, U-M plans to study neurodevelopment diseases because they are present early in life and develop over time. Work could be done on Down syndrome, muscular dystrophy and Rett Syndrome, a common form of autism in girls. Researchers are optimistic, after scientists in Scotland and the United States recently discovered how to reverse some Rett Syndrome symptoms in mice.

"Understanding how to do that in humans offers a lot of hope for kids," O'Shea said.

U-M has received numerous calls from people wanting to donate their frozen embryos to science, but they can't accept them until the procedure is in place.

Robyn Kovacs of White Lake Township, who conceived a child through in-vitro fertilization, hopes it happens quickly so she can donate her 10 leftover frozen embryos. "They don't need to be sitting in a freezer," she said. "They should be doing something."

No easy task

Creating a climate for Michigan researchers to create embryonic stem cell lines did not come easily.

A 1978 law essentially banned the research and was regarded as the most restrictive in the nation.

Lawmakers tried to change that law by introducing a bill in the Michigan Legislature during the 2005-06 and 2007-08 sessions, but the bills went nowhere.

Following the legislative failure, advocates collected signatures and placed a constitutional amendment, Proposal 2, on the ballot. Voters approved it in November.

After the election, President Obama lifted restrictions that limited research to a handful of federally approved lines.

"We have spent months going through the regulatory processes put in place by university and federal regulations," Morrison said, "but hope the research contemplated under Prop 2 will soon begin at the University of Michigan."

Those who want to donate their embryos hope so, too, and even those without anything to offer researchers.

"Life would be better served if leftover embryos were donated to science, so questions could be answered to help others out," said Troy resident Nancy Becker, 41, who considered donating to science but used all of her embryos to help conceive her daughter.