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STEM CELL CENTER SET AT HARVARD

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Harvard University will soon launch a multimillion-dollar center to grow and study human embryonic stem cells, in what could be the largest American effort yet to circumvent the Bush administration's tight restrictions on the controversial research.

Set to be announced in April, the stem cell plan will bring together researchers from Harvard and all of the Harvard-affiliated hospitals to unlock the mysteries of a type of cell that has the potential to develop into any healthy tissue in the body, but has triggered ethical controversy over the way it is created. Though not housed in a central building, the initiative will be large, even by Harvard standards, with a fund-raising goal of about \$100 million, according to the scientists involved. The move by Harvard, one of the nation's top centers for biomedical research, marks a declaration of independence from the rules surrounding federal science funding and signals increasing frustration among American stem cell scientists. Embryonic stem cells, they say, hold tremendous promise to cure diseases such as Parkinson's and diabetes. Yet President Bush, citing concerns about the use of fertilized human egg cells in research, sharply curtailed government support for the research in 2001.

"Harvard has the resources, Harvard has the breadth, and, frankly, Harvard has the responsibility to be taking up the slack that the government is leaving," said Dr. George Q. Daley, who is involved in planning the initiative and is an associate professor at Harvard Medical School and Children's Hospital in Boston.

The Harvard center is part of a growing challenge to the Bush rules, which block federal money to any scientists working with human embryonic stem cell lines created after August 2001. The initiative, tentatively named the **Harvard Stem Cell Institute**, will fund research into all kinds of stem cells, including the creation of a bank of human embryonic stem cell lines that will be made available to the Boston research community and beyond. The work on embryonic cells will be carefully sequestered, so it does not run afoul of US policy.

Though it did not outlaw the research, the Bush policy has been profoundly influential on science, since this kind of cutting-edge laboratory work is largely paid for with federal grants. This month, members of a South Korean team

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announced that they had created the world's first line of stem cells derived from a cloned human embryo - a sign, scientists say, that the research momentum in this field has shifted overseas.

Increasingly, American research centers have been seeking ways to work around the restriction. In December 2002, Stanford University announced a \$12 million donation to study cancer by creating human embryonic stem cell lines. Privately funded efforts to study embryonic stem cells are underway at the University of Wisconsin-Madison, the University of Minnesota, and the University of California, San Francisco.

Activists in California are pushing a \$3 billion ballot initiative to finance the work. Last week, Governor James E. McGreevey of New Jersey said the state would give \$6.5 million to create and study new cell lines with Rutgers University, making it the first state to fund the research.

If this movement begins to yield the kinds of scientific advances that researchers hope, it could provoke a political showdown between scientists who want the license to push ahead, and an administration with deep ethical reservations about experiments on very early-stage human embryos.

"Every success will change the argument," said Dr. Leonard Zon, a researcher at Children's Hospital and president of the International Society for Stem Cell Research. "The American people will not stand for scientists not being able to work on their diseases."

When Bush first announced the federal restriction, he said that more than 60 cell lines would be available to researchers, but today scientists have access to 15 of the lines on the list, and those lines have numerous problems that make them difficult to work with, said Zon.

Under the current rules, though, scientists interested in working with newer human embryonic stem cells have to keep that work separate from any research done with federal money. Most university research scientists survive on research grants from the federal government, and a portion of these grants typically goes to support the basic infrastructure behind any investigation, including the lab and its equipment. If that equipment was then used in embryonic stem cell work, the government could in theory shut off its funding to that laboratory. If government officials objected to an initiative like Harvard's, they could investigate its use of such equipment - one reason, the scientists said, they were being so careful in building the facilities.

Harvard biologist Douglas Melton, who will codirect the initiative, already has been creating new lines of human embryonic stem cells, using private money and eggs donated from Boston IVF, a fertility clinic, with the consent of the patients. But before Melton could begin, he had a new lab built in the renovated basement of another building, far from the Petri dishes and microscopes that had been a part of his federally funded work in the past.

Part of the Harvard plan will be a new, privately funded Massachusetts General Hospital laboratory with its own doors and a separate storage area, said Dr. David T. Scadden, an MGH researcher who will direct the Harvard initiative with Melton.

Melton and Scadden said that the Harvard initiative will not focus solely on human embryonic stem cells, but will include research on adult stem cells as well as basic research on animals. Indeed, embryonic stem cells offer great promise in basic biology because scientists can use them to learn how the entire body develops from a single cell.

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In the medical world, the Harvard initiative also represents a vote of confidence in a futuristic approach to medicine known as cell therapy. Since the earliest days of the healing arts, patients have been treated with drugs, whether gathered from plants or manufactured in a pharmaceutical lab. But for a range of degenerative diseases, doctors envision a day when patients are given powerful cells that can build a healthy brain, heart, or other tissues.

"This is a new way of approaching medicine," said Scadden. "The current arrows in the quiver just aren't going to solve the problem."

Scadden said that turning the research into medical treatments is a guiding priority of the initiative. MGH is constructing a massive building near the Charles River that will include a center for regenerative medicine, directed by Scadden. That center will have an area set aside for creating large numbers of therapeutic cells once the scientific problems can be solved, Scadden said.

But Scadden and other scientists are working under a cloud of potentially difficult ethical issues. To isolate a line of the cells, biologists typically start with a fertilized human egg cell, which is allowed to grow for about a week. When it has reached about 100 cells, the embryonic stem cells are extracted.

Critics, including a number of politicians, religious groups, and antiabortion activists, charge that this process means destroying lives, or potential lives, and that no end, however worthy, justify this means. If the dividing egg cell were placed into a woman's uterus, it could develop into a baby.

Defenders of the work say that fertility clinics have in their freezers thousands of these fertilized eggs that will otherwise be destroyed. They say it's wrong to think of the cells, in this early stage of development, as human lives.

The Harvard initiative will not be purely a research enterprise. The business school, the school of government, the law school, and the divinity school will be invited to participate, as part of an effort to understand the ethical, social, and business dimensions of the new technology, according to Steven E. Hyman, Harvard's provost.

The work on embryonic stem cells will be overseen by a panel that already reviews such work for Harvard, in addition to the review boards at individual institutions.

Hyman cautioned that the university has not decided on a fund-raising goal, but said that the effort will be substantial.

In March, the university is planning a program to introduce alumni to the research, hoping to attract donors. On April 23, scientists and university officials are organizing a scientific conference that will serve as the public launch of the institute.

Regardless of how much private money is raised, the scientists said they are determined to continue the research.

"If I turned my back on this," said Scadden, "I just wouldn't forgive myself."

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