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## First Human Embryonic Stem Cell Lines Approved for Use Under New NIH Guidelines

NIH Director Francis S. Collins, M.D., Ph.D., today announced the approval of the first 13 human embryonic stem cell (hESC) lines for use in NIH-funded research under the NIH Guidelines for Human Stem Cell Research adopted in July 2009.

"I am happy to say that we now have human embryonic stem cell lines eligible for use by our research community under our new stem cell policy," Dr. Collins said. "In accordance with the guidelines, these stem cell lines were derived from embryos that were donated under ethically sound informed consent processes. More lines are under review now, and we anticipate continuing to expand this list of responsibly derived lines eligible for NIH funding."

Children's Hospital Boston developed 11 of the approved lines and Rockefeller University in New York City developed two of the approved lines. An additional 96 lines have been submitted to NIH for either internal administrative review or consideration by the external Working Group for Human Embryonic Stem Cell Eligibility Review and the NIH Advisory Committee to the Director (ACD), including more than 20 that will be considered by the ACD on December 4, 2009. The working group provides findings to the ACD, which makes recommendations to the NIH Director, who decides whether the hESCs may be used in NIH-funded research and lists those deemed eligible on the NIH Human Embryonic Stem Cell Registry.

Research using hESCs is already yielding information about the complex events that occur during human development. Researchers hope that eventually cells differentiated from hESCs may be used to treat a myriad of diseases, conditions, and disabilities and to test the safety of new drugs in the laboratory.

On March 9, 2009, President Obama issued Executive Order 13505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells. The executive order states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

The NIH Guidelines for Human Stem Cell Research were published on July 7, 2009, and are available at <http://stemcells.nih.gov/policy/2009guidelines.htm>. The guidelines implement the executive order, as it

pertains to extramural NIH-funded stem cell research, establish policy and procedures under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

Children's Hospital Boston and Rockefeller University submitted information about the informed consent process for embryo donation to the NIH administrative review process, which confirms that the submissions met specific requirements regarding informed consent for embryo donation as detailed in the guidelines.

More than 30 NIH grants funded in the 2009 fiscal year totaling more than \$20 million proposed to use hESCs; these grants have been restricted until approved lines became available on the NIH registry. With today's announcement and following NIH approval, these principal investigators may obtain registry-listed hESCs, if they are appropriate for their project, from the owners of the lines and proceed with their research. This group of grants includes research using hESCs for the therapeutic regeneration of diseased or damaged heart muscle cells, developing systems for the production of neural stem cells and different types of neurons from hESCs in culture, and developing a cell culture system for the large scale production and self-renewal of hESCs.

In addition, a number of Challenge Grant applications, which could be funded through the American Recovery and Reinvestment Act in the 2010 fiscal year, proposed to use hESCs. Researchers examining other topics that could benefit from the use of hESCs are encouraged to apply for funding using these approved lines.

The NIH Human Embryonic Stem Cell Registry of approved hESCs is found at [http://grants.nih.gov/stem\\_cells/registry/current.htm](http://grants.nih.gov/stem_cells/registry/current.htm). For additional information on stem cells and NIH research, go to <http://stemcells.nih.gov/>.

The Office of the Director, the central office at NIH, is responsible for setting policy for NIH, which includes 27 Institutes and Centers. This involves planning, managing, and coordinating the programs and activities of all NIH components. The Office of the Director also includes program offices which are responsible for stimulating specific areas of research throughout NIH. Additional information is available at <http://www.nih.gov/icd/od/>.

The National Institutes of Health (NIH) — *The Nation's Medical Research Agency* — includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit [www.nih.gov](http://www.nih.gov).



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