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**HEADLINE:** NIH Opens Website for Human Embryonic Stem Cell Lines for Approval and Announces Members of Working Group

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**DATELINE:** WASHINGTON

**BODY:**

The U.S. Department of Health & Human Services' National Institutes of Health issued the following news release:

National Institutes of Health (NIH) Director Francis S. Collins, M.D., Ph.D., announces that NIH is now accepting requests for human embryonic stem cell (hESC) lines to be approved for use in NIH-funded research. The NIH Director is also pleased to announce the members of a new working group of the Advisory Committee to the Director (ACD): the Working Group for Human Embryonic Stem Cell Eligibility Review.

NIH will today begin accepting requests for hESCs to be approved for use in NIH-funded research. Information may be submitted through NIH Form 2890, which is available at <http://stemcells.nih.gov/>. Today it becomes an interactive Web form allowing the submission of information online.

In announcing the members of the Working Group, Dr. Collins said, "I appreciate the willingness of these individuals to assist NIH in supporting responsible, scientifically worthy human stem cell research, as encouraged by the President's Executive Order. Their expertise and sound judgment will help NIH move forward in this important effort."

Jeffrey R. Botkin, M.D., M.P.H., will serve as the working group's chairman. Dr. Botkin is a professor of pediatrics, Department of Pediatrics, and adjunct professor of medicine, Department of Internal Medicine-Division of Medical Ethics, at University of Utah's School of Medicine. He is also the associate vice president for research integrity at the University of Utah. Dr. Botkin has recently served on the Secretary's Advisory Committee on Human Research Protection.

The other members of the Working Group are:

\* Dena S. Davis, J.D., Ph.D., professor of law, Cleveland-Marshall College of Law, Cleveland State University, Ohio

\* Pamela B. Davis, M.D., Ph.D., dean of the School of Medicine, Case Western Reserve University, Ohio

\* David A. Grainger, M.D., M.P.H., director, Center for Reproductive Medicine; associate dean for research; professor, Department of Obstetrics and Gynecology; director, director, Division of Reproductive Endocrinology; University of Kansas School of Medicine-Wichita

\* Richard P. Lifton, M.D., Ph.D., chair, Department of Genetics; professor of genetics, medicine and molecular biophysics and biochemistry; investigator, Howard Hughes Medical Institute, Yale School of Medicine, Conn.

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\* Bernard Lo, M.D., professor of medicine; director, Program in Medical Ethics; Department of Medicine, University of California, San Francisco

\* Terry Magnuson, Ph.D., professor and chair of the Department of Genetics of the School of Medicine, University of North Carolina at Chapel Hill

\* Jeffrey C. Murray, M.D., professor of neonatology and genetics; professor of biological sciences, dentistry, and epidemiology in the College of Public Health; Department of Pediatrics, University of Iowa Children's Hospital;

\* Carlos Pavao, M.P.A., training and technical specialist, Education Development Center, Inc., Atlanta, Ga.; member, NIH Director's Council of Public Representatives

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. In addition, on July 30, 2009, the President directed all Federal departments and agencies that support and conduct stem cell research to adopt the Guidelines. For hESCs derived from embryos donated in the United States on or after the effective date of the Guidelines (July 7, 2009), specific provisions regarding the embryo donation and informed consent process apply and are detailed in Section II (A) of the Guidelines.

As described in the Guidelines, the Working Group will consider two other categories of hESCs and make recommendations to the ACD regarding their eligibility for use in NIH-funded research.

After considering the analysis done by the Working Group, the ACD will make recommendations to the NIH Director regarding the eligibility of particular hESCs for use in NIH-funded research. The NIH Director will make the final decisions regarding the eligibility of the hESCs and list those deemed eligible on the NIH Human Embryonic Stem Cell Registry. Once an hESC line is listed on the Registry, there is no need for further submissions requesting review of that particular line.

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/>.

Contact: Jenny Haliski, Office of Communications and Public Liaison, 301/496-5787, [haliskij@od.nih.gov](mailto:haliskij@od.nih.gov)

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