September 20, 2006

COLUMBIA UNIVERSITY POLICY ON THE CONDUCT OF RESEARCH WITH HUMAN EMBRYOS AND HUMAN EMBRYONIC STEM CELLS*

A. INTRODUCTION

Columbia University believes that human embryonic and human stem cell research is essential to advancing the development of treatments for many human diseases. The University strongly supports the use of human embryos and stem cells – embryonic, fetal and adult – for legitimate research and therapeutic purposes.

Columbia University also believes that the use of somatic cell nuclear transfer (also known as "therapeutic cloning" or "research cloning") offers promise in understanding the pathogenesis of disease and in developing therapeutic solutions to combat disease.

The University opposes the use of either embryonic or stem cell technology or somatic cell nuclear transfer for human reproductive cloning.

Columbia University recognizes that the prohibition on the use of federal funds to support most research using human embryos or human embryonic stem cell lines requires it to provide safeguards to prevent federal funds from being used for such research.

This Policy only applies to human embryos and human embryonic stem cells and does not apply to research involving fetal tissue or stem cells derived from human adults, umbilical cord blood, placentas or fetuses, or research involving any other type of human cells.

B. DEFINITIONS

"hESC": human pluripotent stem cells derived from the blastocyst stage of human embryos.

"Human Embryo": any organism, prior to implantation, that is derived by fertilization, parthenogenesis, cloning or any other means from one or more human gametes or human diploid cells.

"Human Subject": a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual or (b) identifiable private information.

"Human Subjects Research": Research involving Human Subjects.

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* This Policy was originally issued as the Columbia University Institutional Policy on the Conduct of Research with Human Embryonic Stem Cells on February 8, 2005 and amended as of December 21, 2005 and May 24, 2006.

"Registry": the NIH Human Embryonic Stem Cell Registry.

"Research": a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge.

"2001 Notice": the NIH Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cell Registry (November 7, 2001). http://grants.nih.gov/grants/guide/notice-files/no7-00-02-005.html

C. COMPLIANCE WITH LAWS, REGULATIONS AND POLICIES

The University will comply with all applicable federal and state laws, regulations and policies with respect to research involving Human Embryos and hESC.

1. Federal Policy With Respect To Support For Human Embryo Research

The following is a summary of current federal policy with respect to support for Human Embryo research:

a. Except in very limited circumstances, federal funds may not be used for:

(i) the creation of a Human Embryo for research purposes or

(ii) research in which a Human Embryo is destroyed, discarded or knowingly subjected to greater than minimal risk.

b. Research involving Human Embryos may be conducted with private funding.

2. Federal Policy With Respect To Support For hESC Research

The following is a summary of current federal policy with respect to support for hESC research:

a. Research involving hESC may be conducted with federal support if such cells are derived from cell lines meeting the criteria of the 2001 Notice and are listed on the Registry (see http://escr.nih.gov) ("Registry hESC").

b. Research involving the derivation of new hESC (including hESC derived using somatic cell nuclear transfer) or the use of hESC lines that are not listed on the Registry ("Non-Registry hESC") may not be conducted with federal support, but research using Non-Registry hESC may be conducted with private funding.

3. Financial Guidelines For Research Involving Human Embryos and hESC

The current financial guidelines applicable to all University Human Embryo and hESC research may be found in the Columbia University Human Embryo and Human Embryonic Stem Cell Research Special Operating Procedures, dated May 24, 2006 (the "Special Procedures").

D. UNIVERSITY EMBRYONIC RESEARCH COMMITTEE

1. Each research project involving Human Embryos, Registry hESC or Non-Registry hESC must be approved by the University Embryonic Research Committee (the "Embryonic Research Committee") prior to the commencement of such project.

2. The Embryonic Research Committee will be chaired by the Executive Vice President for Research (the "EVPR"), who will select its members. The Embryonic Research Committee shall include at least one ethicist, one representative of the Office of the General Counsel, one representative of the University Institutional Review Board ("IRB") and one person not affiliated with the University.

3. The following information should be provided by the principal investigator to the Embryonic Research Committee in connection with a request for approval of a proposed research project:

- A copy of the protocol for such proposed research project;
- A discussion of the source and derivation of each Human Embryo or line of hESC to be used in such research project, together with any written agreement relating to the receipt of such Human Embryo or hESC;
- The sources of all funding for such research project; and
- The steps that have been taken to ensure compliance with the Special Procedures, including specific training of all personnel with respect to its requirements.

4. As part of its review of a proposed research project, the Embryonic Research Committee will determine whether such research is exempt from the requirements of IRB review in accordance with Section E of this Policy.

5. In addition to reviewing requests for approval of research projects, the EVPR may convene the Embryonic Research Committee to consider any audit findings of research projects, the interpretation of applicable laws and regulations, amendments to this Policy or other related purposes.

6. Human Embryos and hESC lines may not be distributed by any investigator to any other investigator at the University without the prior written approval of the Embryonic Research Committee.

7. Any University investigator who distributes Human Embryos or hESC outside the University should receive, prior to such distribution, a written acknowledgement from

the recipient that any research involving such Human Embryos and hESC shall be conducted in accordance with applicable federal laws and regulations.

E. IRB REVIEW OF HUMAN EMBRYO AND hESC RESEARCH

1. Research involving Human Embryos or hESC lines where the source (donor) cannot be identified by the relevant Columbia University investigator does not constitute Human Subjects Research and does not require IRB review.

2. Research involving Human Embryos or hESC lines where the source (donor) may be identified by the applicable Columbia University investigator, including cell lines that retain links (such as a code) to identifiable information, is considered to be Human Subjects Research that requires IRB review. Furthermore, research involving Human Embryos or hESC lines where there is interaction or intervention with a living individual and information about such individual, or tissue from such individual, is obtained, is likewise considered to be Human Subjects Research that requires IRB review.