July 7, 2014

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.

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

Dickey Amendment: Section 509, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 3/11/09, as extended from time to time.

Eligible Research: research involving (a) Human Embryos not prohibited by the Dickey Amendment or (b) hESC permitted by the Executive Order and the Guidelines.

Executive Order: Executive Order 13505 issued on March 9, 2009.

Guidelines: the NIH Guidelines for Human Stem Cell Research, effective July 7, 2009.

hESC: cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers.

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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, May 24, 2006, September 20, 2006, August 26, 2009, July 15, 2013 and August 5, 2013.

Human Embryo: any organism not protected as a human subject under 45 C.F.R. Part 46, that is derived by fertilization, parthenogenesis, cloning or any other means from one or more human gametes or human diploid cells.

Human Subjects Research: Research involving 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.

Ineligible Research: research involving Human Embryos or hESC other than Eligible Research.

Registry: the NIH Human Embryonic Stem Cell Registry established under the Guidelines.

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

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 non-federal 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 that are listed on the Registry or approved by the NIH pursuant to the Guidelines.

b. The following research may not be conducted with federal support, but may be conducted with non-federal funding:

(i) Research in which hESCs (even if derived from embryos donated in accordance with the Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts;

(ii) Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with the Guidelines) or human induced pluripotent stem cells may contribute to the germ line;

(iii) Research involving the derivation of hESC from human embryos; and

(iv) Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis and/or IVF embryos created for research purposes.

3. Financial Guidelines For Research Involving Human Embryos and hESC

The Columbia University Human Embryo and Human Embryonic Stem Cell Research Special Operating Procedures, dated May 24, 2006, are no longer in effect and no special procedures are required when an investigator conducts both Eligible Research and Ineligible Research except as provided in OMB Circular A-21. Circular A-21 provides that, with respect to the direct costs of research, only "reasonable", "allocable" and "allowable" costs may be charged to the government. Although the direct costs of "unallowable" activities may not be charged to the federal government, the government will pay its share of resources that are used for both federal and non-federal purposes. Circular A-21 states that "a cost is allocable to a particular cost objective…if the goods and services involved are chargeable or assignable to such cost objective in accordance with relative benefits received or other equitable relationship". See Circular A-21 at C.4.A http://www.whitehouse.gov/omb/rewrite/circulars/a021/a21_2004.html#c. For example, if personnel time or general-purpose laboratory materials are being used for both allowable and unallowable research, the federal government will pay the costs of that proportion of the resource being used for federally sponsored research. The allocation of costs between Eligible Research and Ineligible Research should be determined accordingly.

With respect to indirect costs, Circular A-21 assumes that there is an established relationship between the direct costs of a research project and the F&A costs – represented by the institutional F&A rate – and F&A costs can be calculated by applying the F&A rate to certain direct costs associated with the research project. As the direct costs of Ineligible Research are not allowable under federal cost principles, it follows that the F&A costs allocable to such direct costs are also not chargeable to the federal government.

Any general restrictions on the use of federally funded equipment for non-federally funded research should be followed.

D. UNIVERSITY HUMAN EMBRYONIC AND HUMAN EMBRYONIC STEM CELL RESEARCH COMMITTEE

1. Each research project involving Human Embryos or hESC must be approved by the University Human Embryonic and Human Embryonic Stem Cell Research Committee (the "Committee") prior to the commencement of such project.

To the extent that the sponsor of any research project has additional requirements with respect to approval by the Committee of such project, such requirements will be described in Annex A to this Policy.

2. The Executive Vice President for Research ("**EVPR**") will select the members of the Committee, one of whom shall be named the Chair. The 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 scientist and one non-scientist not affiliated with the University.

3. The Committee will be administered by the Vice President for Research Operations ("**VPRO**").

4. The following information should be provided by the principal investigator to the 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; and
- The sources of all funding for such research project.

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

6. Each member of the Committee will execute a Conflict of Interest Statement in form approved by the Committee that provides that a member must excuse him/herself from any meeting or voting of the Committee where his/her presence might pose a real or perceived conflict of interest.

7. All decisions of the Committee will be made by the affirmative vote of a majority of the members of the Committee. The Committee may approve a proposed research project by email as well as at a meeting of the members.

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

9. 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 Committee.

10. Any University investigator who distributes Human Embryos or hESC outside of the University should receive, prior to such distribution, a written acknowledgement from the recipient that any research involving such Human Embryos and hESC will be conducted in accordance with applicable federal laws and regulations.

11. All records pertaining to the activities and reviews and the subject research conducted will be maintained by the VPRO and will be retained for at least six years after the completion of the research.

E. IRB REVIEW OF HUMAN EMBRYO AND hESC RESEARCH

1. With certain limited exceptions relating to medical devices, 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.

Annex A

Additional Sponsor Requirements with respect to Committee Approval

This Annex sets forth additional sponsor requirements with respect to Committee approval.

NYSTEM (New York State Stem Cell Science)

Any research project funded by NYSTEM that involves the following types of cells or tissues must be approved by the Committee prior to the commencement of such project:

- human embryonic stem cells;
- human totipotent or pluripotent cells;
- human pluripotent stem cell lines;
- human neural and gonadal progenitor stem cells; or
- other human somatic tissues for stem cell research (excluding cells that remain restricted in tissue potential and are not known to possess totipotent or pluripotent potential).