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MEMORANDUM

Roberto Peccei
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TO: Deans, Directors, Department Chairs, and Faculty

FROM: Roberto Peccei, Vice Chancellor for Research *RDP*

RE: Change in Institutional Review Board (IRB) Requirements for Human Embryonic Stem Cell (hESC) Research

DATE: January 4, 2007

This memorandum announces a change in the Institutional Review Board (IRB) requirements for the review and oversight of human embryonic stem cell (hESC) research. **Beginning January 1, 2007, California law and campus policy no longer require IRB review of purely *in vitro* hESC research that does not meet the federal threshold of human subject research.** Regardless of IRB review requirements, **all** hESC research must still be reviewed and overseen by the UCLA Embryonic Stem Cell Research Oversight (ESCRO) committee^{1,2} as well as any other applicable compliance committee such as the Chancellor's Animal Research Committee (ARC).

BACKGROUND

California law required IRB review of stem cell research, including hESC research, regardless of whether the project met the federal regulatory threshold of human subjects research. The Governor signed a Bill³ that changes the responsibility for review and oversight of hESC research that does not include human subjects as defined by the federal regulations.

PLEASE NOTE: Research with hESCs or related lines⁴ that include the following procedures must still have IRB as well as ESCRO review and oversight:

¹ California Health & Safety Code 125119(a)(1). "All research projects involving the derivation or use of [hESCs] shall be reviewed and approved by a stem cell research oversight committee prior to being undertaken."

² Vice Chancellor Roberto Peccei. Memorandum: Creation of UCLA Embryonic Stem Cell Research Oversight (ESCRO) Committee, April 12, 2006, <http://www.research.ucla.edu/researchpol/StemcellDocs/VCR%20cover%20letter%20060413.pdf>

³ California Senate Bill No. 1260, Chapter 483.

⁴ California law defines a covered stem cell line as "a culture-derived, human pluripotent stem cell population that is capable of: 1) sustained propagation in culture; and (2) self-renewal to produce daughter cells with equivalent developmental potential. This definition includes both embryonic and non-embryonic human stem cell lines regardless of the tissue of origin. "Pluripotent" means capable of differentiation into mesoderm, ectoderm, and endoderm." http://www.cirm.ca.gov/laws/pdf/AdoptedRegs_100010.pdf

1. Clinical research in which human subjects are given hESCs or related products,
2. When the UCLA research team will have a research related direct interaction or intervention with the cell donors, including the donation of blastocysts or gametes for the purpose of creating hESCs, or
3. Cells provided to the UCLA research team that are:
 - a. **Identified cells/lines:** These cells/lines are supplied with a personal identifier (such as a name or patient number) that links the cells/lines directly to the donor, or
 - b. **Coded cells/lines:** Sometimes termed “linked” or “identifiable,” these cell/lines are supplied from identified cells/lines to the UCLA investigator with a direct or an indirect code that could be used to identify the donor.

If you are contemplating the conduct of hESC research and have specific questions regarding IRB review and ESCRO review, please contact:

- **IRB Review:** Farida Lada, Assistant Director, Office for Protection of Research Subjects at x55344 or flada@oprs.ucla.edu,
- **ESCRO Review:** Steven Peckman, Associate Director, UCLA Institute for Stem Cell Biology and Medicine at x54958 or speckman@mednet.ucla.edu.

In order to submit applications to the ESCRO committee, please contact Ms. Courtney Carrell at x55268 or ccarrell@mednet.ucla.edu.