

## **SUE AND BILL GROSS CENTER FOR STEM CELL RESEARCH**

### **RESPONSIBLE CONDUCT OF STEM CELL RESEARCH AT UCI**

Scientists at the Sue and Bill Gross Center for Stem Cell Research join the mainstream medical community in believing that research using human embryonic stem cells should be explored - within strict ethical limits - to develop new treatments and cures for devastating diseases and injuries.

Like any medical research conducted on the frontier of science, embryonic stem cell (ESC) research must be conducted in accordance with long-standing principles of medical ethics that protect research donors, research participants (called “subjects”) and society. ESC researchers must also make the public aware of the ethical standards governing these studies, as we are all stakeholders in their responsible exploration.

The Gross Center for Stem Cell Research developed this fact sheet to help explain the ethical safeguards governing ESC research at UCI to our neighbors in the Orange County community.

#### **What ethical principles are applied to ESC research?**

Research using human embryonic stem cells is undertaken in accordance with widely accepted ethical standards (as is all research conducted at the University of California, Irvine) as well as ESC-specific standards adopted in recent years.

Three ethical conventions - the Nuremberg Code, the Declaration of Helsinki and the Belmont Report - are the underpinnings of human subjects protection in this country.

#### **Ethical Safeguards Governing Embryonic Stem Cell Research at UCI**

##### Established Ethical Principles

- ◆ *Nuremberg Code*
- ◆ *Declaration of Helsinki*
- ◆ *Belmont Report*
- ◆ *45 CFR 46 - the “Common Rule”*

##### Specific ESC Guidelines & Standards

- ◆ *National Academy of Science Guidelines for Research on Human ESCs*
- ◆ *Proposition 71, as enforced by the California Institute for Regenerative Medicine*

The Nuremberg Code stressed a number of fundamental ethical principles, including that research involving human subjects be premised on relevant data from animal models; that scientific investigators be appropriately qualified; that research subjects must give their informed, voluntary consent prior to participation in clinical research; that research subjects may discontinue participation at any time; and that clinical research must serve important scientific aims that are not outweighed by the potential risks to research subjects.

The Declaration of Helsinki required that scientists and clinicians first consider the health of research participants, emphasizing the difference between procedures that directly benefit participants (like an experimental therapy) and those that do not (like donating biological

materials for research).

The Belmont Report set forth three principles underlying the ethical conduct of research: beneficence, justice and respect for the individual. It explains how these principles apply to research practices and is most notably apparent in Federal protections such as *45 CFR Part 46* (the “Common Rule”), which establishes minimum Federal protections for human subjects research.

In addition, state and Federal bodies have established guidelines that specifically address the ethical questions raised by embryonic stem cells. In 2005, the National Academy of Science recommended guidelines for ESC research, and urged all institutions pursuing this science to establish Embryonic Stem Cell Research Oversight Committees to ensure that the new guidelines will be followed. UCI was among the first California institutions to implement the National Academy’s guidelines.

Finally, California’s passage of Proposition 71 in November 2004 not only ushered in a \$3 billion stem cell research program in our state but also the legal framework for the implementation of a state-based code of ethics. The state agency now overseeing the Proposition 71 program (called the California Institute for Regenerative Medicine) adopted the National Academy’s guidelines as well as standards governing embryo donation that exceed Federal requirements.

### **How does UCI enforce these ethical safeguards?**

ESC research projects at UCI require the review and approval of *at least* two ethical oversight committees: an Institutional Review Board (IRB), and the Embryonic Stem Cell Research Oversight (ESCRO) Committee. Additional reviews may be required if the research involves animal use, radiation or biohazard safety issues, or potential financial conflicts of interest.

Federal law requires that any proposed research study involving human subjects or identifiable human tissue undergoes review by an ethics panel called an Institutional Review Board. IRBs are themselves constituted in accordance with Federal regulations that have been in force for more than 30 years. In general, the IRB is primarily responsible for reviewing all human subjects research and ensuring compliance with Federal protections of human rights, safety and privacy. It also reviews consent forms to ensure that research participants gave their consent in an informed, voluntary, understandable and uncoerced manner.

UCI’s ESCRO Committee assures that human embryonic stem cells are used in accordance with the National Academy of Science guidelines and established ethical principles; and in compliance with applicable state and campus policies regarding the use of these cells. When considering a proposed ESC research project, the members of the ESCRO Committee consider the ethical and social issues presented by the scientific protocol as well as its scholarly merit. ESCRO also ensures that the origin and derivation of ESC cultures has been rigorously documented in order to establish that these cell cultures were derived with the informed consent of the embryo donors and without coercion (including direct compensation).

#### **UCI ESCRO Committee**

*UCI has established an Embryonic Stem Cell Research Oversight (ESCRO) Committee to ensure that research involving embryonic stem cells serves important research aims and is conducted according to the highest ethical standards.*

*For more information, visit:*

<http://www.rgs.uci.edu/ora/rp/escro/>

## **Who sits on the IRB and ESCRO Committees?**

There are three IRB committees at UCI: two review biomedical research and a third reviews social or behavioral research. Each committee is composed of scientists, non-scientists and community members with varying backgrounds. Members are appointed by the Vice Chancellor for Research, Dr. Susan Bryant, who is responsible for human subjects protections at UCI. (Dr. Bryant is also a member of the governing board of the California Institute for Regenerative Medicine.)

The UCI ESCRO committee is comprised of ten individuals. Seven are UCI faculty members, one of whom is also an expert in ethics, who bring basic and clinical research experience to the group. The remaining three individuals are community representatives, including two patient advocates and an accomplished theologian who each resides in Orange County. Its chairperson, Dr. Sidney Golub, is a Professor Emeritus of Microbiology and Molecular Genetics at UCI and has held several leadership positions in science administration, ethics and policy.

## **How does UCI keep the public informed of its ESC research activities?**

The Gross Center for Stem Cell Research has actively engaged the surrounding community in order to educate the public about the science and ethics of stem cells. It provides several lay-accessible materials on its web-site ([stemcell.uci.edu](http://stemcell.uci.edu)) and frequently dispatches speakers to local community groups.

The Center has also formed a Patient Advisory Committee that involves Orange County patient leaders in the stewardship of its stem cell program, a unique and essential element of conducting its stem cell explorations in the interest of public transparency and the spirit of Proposition 71.

In addition, the Gross Center has teamed with the UCI Department of Humanities on an on-going lecture series called the “Stem Cell Dialogues,” which presents the ethical, legal and social issues surrounding human embryonic stem cell research.