

6250) of Chapter 3.5 of Division 7 of Title 1 of the Government Code, shall apply to all records of the Institute, except as otherwise provided in this section.

(2) Nothing in this section shall be construed to require disclosure of any records that are any of the following:

(A) Personnel, medical or similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy.

(B) Records containing or reflecting confidential intellectual property or work product, whether patentable or not, including, but not limited to, any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information, which is not patented, which is known only to certain individuals who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives its user an opportunity to obtain a business advantage over competitors who do not know it or use it.

(C) Pre-publication scientific working papers or research data.

(f) **Competitive Bidding**

(1) The Institute shall, except as otherwise provided in this section, be governed by the competitive bidding requirements applicable to the University of California, as set forth in Article 1 (commencing with section 10500), Chapter 2.1, Part 2, Division 2 of the Public Contract Code.

(2) For all Institute contracts, the ICOC shall follow the procedures required of the Regents by Article 1 (commencing with section 10500), Chapter 2.1, Part 2, Division 2 of the Public Contract Code with respect to contracts let by the University of California.

(3) The requirements of this section shall not be applicable to grants or loans approved by the ICOC.

(4) Except as provided in this section, the Public Contract Code shall not apply to contracts let by the Institute.

(g) **Conflicts of Interest**

(1) The Political Reform Act, Title 9 (commencing with section 81000) of the Government Code, shall apply to the Institute and to the ICOC, except as provided in this section and in section 125281.09(e).

(A) No member of the ICOC shall make, participate in making, or in any way attempt to use his or her official position to influence a decision to approve or award a grant, loan or contract to his or her employer, but a member may participate in a decision to approve or award a grant, loan or contract to a non-profit entity in the same field as his or her employer.

(B) A member of the ICOC may participate in a decision to approve or award a grant, loan or contract to an entity for the purpose of research involving a disease from which a member or his or her immediate family suffers or in which the member has an interest as a representative of a disease advocacy organization.

(C) The adoption of standards is not a decision subject to this section.

(2) Service as a member of the ICOC by a member of the faculty or

administration of any system of the University of California shall not, by itself, be deemed to be inconsistent, incompatible, in conflict with, or inimical to the duties of the ICOC member as a member of the faculty or administration of any system of the University of California and shall not result in the automatic vacation of either such office. Service as a member of the ICOC by a representative or employee of a disease advocacy organization, a non-profit academic and research institution, or a life science commercial entity shall not be deemed to be inconsistent, incompatible, in conflict with, or inimical to the duties of the ICOC member as a representative or employee of that organization, institution or entity.

(3) Government Code section 1090 shall not apply to any grant, loan or contract made by the ICOC except where both of the following conditions are met:

(A) The grant, loan or contract directly relates to services to be provided by any member of the ICOC or the entity the member represents or financially benefits the member or the entity he or she represents.

(B) The member fails to recuse himself or herself from making, participating in making, or in any way attempting to use his or her official position to influence a decision on the grant loan or contract.

(h) **Patent Royalties and License Revenues Paid To The State of California**  
The ICOC shall establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the state of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements.

(i) **Preference for California Suppliers**  
The ICOC shall establish standards to ensure that grantees purchase goods and services from California suppliers to the extent reasonably possible, in a good faith effort to achieve a goal of more than 50 per cent of such purchases from California suppliers.

#### **125281.06 Medical and Scientific Accountability Standards**

##### **(a) Medical Standards**

In order to avoid duplication or conflicts in technical standards for scientific and medical research, with alternative state programs, the Institute will develop its own scientific and medical standards to carry out the specific controls and intent of the Act, notwithstanding Health and Safety Code sections 125300 (b), 125320, 125118, 125118.5, 125119, 125119.3 and 125119.5, or any other current or future state laws or regulations dealing with the study and research of pluripotent stem cells and/or progenitor cells, or other Vital Research Opportunities, except Health and Safety Code section 125315. The ICOC, its working committees and its grantees shall be governed solely by the provisions of this Act in the establishment of standards, the award of grants and the conduct of grants awarded pursuant to this Act.

The ICOC shall establish standards as follows:

##### **(1) Informed Consent**

Standards for obtaining the informed consent of research donors, patients, or participants, which initially shall be generally based on the standards in place on January 1, 2003, for all research funded by the National Institutes of Health, with modifications to adapt to the mission and objectives of the Institute.

**(2) Controls on Research Involving Humans**

Standards for the review of research involving human subjects which initially shall be generally based on the Institutional Review Board standards promulgated by the National Institutes of Health and in effect on January 1, 2003, with modifications to adapt to the mission and objectives of the Institute.

**(3) Prohibition on Compensation**

Standards prohibiting compensation to research donors or participants, while permitting reimbursement of expenses.

**(4) Patient Privacy Laws**

Standards to assure compliance with state and federal patient privacy laws.

**(5) Limitations on Payments for Cells**

Standards limiting payments for the purchase of stem cells or stem cell lines to reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation or legal transaction or other administrative costs associated with these medical procedures and specifically including any required payments for medical or scientific technologies, products, or processes for royalties, patent or licensing fees or other costs for intellectual property.

**(6) Time Limits for Obtaining Cells**

Standards setting a limit on the time during which cells may be extracted from blastocysts, which shall initially be 8 to 12 days after cell division begins, not counting any time during which the blastocysts and/or cells have been stored frozen.

**125281.07 ICOC Functions**

The ICOC shall perform the following functions:

- (a) Oversee the operations of the Institute.**
- (b) Develop annual and long-term strategic research and financial plans for the Institute.**
- (c) Make final decisions on research standards and grant awards in California.**
- (d) Ensure the completion of an annual financial audit of the Institute's operations.**
- (e) Issue public reports on the activities of the Institute.**
- (f) Establish policies regarding intellectual property rights arising from research funded by the Institute.**
- (g) Establish rules and guidelines for the operation of the ICOC and its working groups.**
- (h) Perform all other acts necessary or appropriate in the exercise of its power, authority, and jurisdiction over the Institute.**
- (i) Select members of the working groups.**