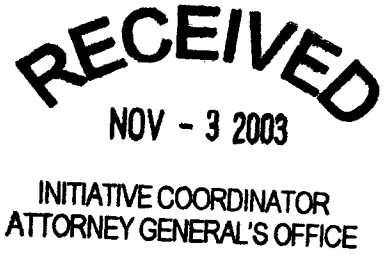
SA2003RF0055

October 31, 2003



VIA MESSENGER

Office of the Attorney General
1300 "I" Street
Sacramento, CA 95814

Attention: Tricia Knight

Re: California Stem Cell Research and Cures Act

Dear Ms. Knight:

Pursuant to Elections Code section 9002, we request that the Attorney General prepare a title and summary of a measure entitled the "California Stem Cell Research and Cures Act." The text of the measure, a check for $200.00, the address at which we are registered to vote and the signed statement certifying that we will not willfully allow initiative signatures to be used for purposes other than qualification of the measure are enclosed.

Please direct all correspondence and inquiries regarding this measure to:

Roberta B. Johansen
James C. Harrison
Remcho, Johansen & Purcell
P.O. Box 189
San Leandro, CA 94577
Phone: (510) 401-0140

Sincerely,

Roberta B. Johansen James C. Harrison

SA2003RF0055

Signed Statement Required by Elections Code Section 9608

I, Roberta B. Johansen, acknowledge that it is a misdemeanor under state law (Section 18650 of the Elections Code) to knowingly or willfully allow the signatures on an initiative petition to be used for any purpose other than qualification of the proposed measure for the ballot. I certify that I will not knowingly or willfully allow the signatures for this initiative to be used for any purpose other than qualification of the measure for the ballot.

Roberta B. Johansen

Dated this 28th day of October, 2003

RECEIVED
NOV - 3 2003
INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

SA2003RF0055

Signed Statement Required by Elections Code Section 9608

I, James C. Harrison, acknowledge that it is a misdemeanor under state law (Section 18650 of the Elections Code) to knowingly or willfully allow the signatures on an initiative petition to be used for any purpose other than qualification of the proposed measure for the ballot. I certify that I will not knowingly or willfully allow the signatures for this initiative to be used for any purpose other than qualification of the measure for the ballot.

James C. Harrison

Dated this 28th day of October, 2003

RECEIVED
NOV - 3 2003
INITIATIVE COORDINATOR
ATTORNEY GENERAL'S OFFICE

SA 2003R F0055

CALIFORNIA STEM CELL RESEARCH AND CURES INITIATIVE

SEC. 1. TITLE

This measure shall be known as the "California Stem Cell Research and Cures Act."

SEC. 2. FINDINGS AND DECLARATIONS

The people of California find and declare the following:

Millions of children and adults suffer from devastating diseases or injury that are currently incurable, including Cancer, Diabetes, Heart Disease, Alzheimer's, Parkinson's, Spinal Cord injuries, Blindness, Lou Gehrig's Disease, HIV/AIDS, Mental Health disorders, Multiple Sclerosis, Huntington's Disease and more than 70 other diseases and injuries.

Recently medical science has discovered a new way to attack chronic diseases and injuries. The cure and treatment of these diseases can potentially be accomplished through the use of new regenerative medical therapies including a special type of human cells, called stem cells. These life-saving medical breakthroughs can only happen if adequate funding is made available to advance stem cell research, develop therapies, and conduct clinical trials.

About half of California's families have a child or adult who has suffered or will suffer from a serious, often critical or terminal medical condition that could potentially be treated or cured with stem cell therapies. In these cases of chronic illness or when patients face a medical crisis, the healthcare system may simply not be able to meet the needs of patients or control spiraling costs unless therapy focus switches away from maintenance and toward prevention and cures.

Unfortunately, the federal government is not providing adequate funding necessary for the urgent research and facilities needed to develop stem cell therapies to treat and cure diseases and serious injuries. This critical funding gap currently prevents the rapid advancement of research that could benefit millions of Californians.

The California Stem Cell Research and Cures Act will close this funding gap by establishing an Institute which will issue bonds to support stem cell research, emphasizing pluripotent stem cell and progenitor cell research and other vital medical technologies, for the development of life-saving regenerative medical treatments and cures.

SEC. 3. PURPOSE AND INTENT

It is the intent of the people of California in enacting this measure to:

- Authorize an average of $295 million per year in bonds over a 10-year period to fund stem cell research and dedicated facilities for scientists at California's universities and other advanced medical research facilities throughout the state.

- Maximize the use of research funds by giving priority to stem cell research that has the greatest potential for therapies and cures, specifically focused on pluripotent stem cell and progenitor cell research among other vital research opportunities that cannot, or are unlikely to receive timely or sufficient federal funding, unencumbered by limitations that would impede the research. Research shall be subject to accepted patient disclosure and patient consent standards.

- Assure that the research is conducted safely and ethically by including provisions to require compliance with standards based on national models that protect patient safety, patient rights and patient privacy.

- Prohibit the use of bond proceeds of this initiative for funding for human reproductive cloning.

- Improve the California healthcare system and reduce the long-term healthcare cost burden on California through the development of therapies that treat diseases and injuries with the ultimate goal to cure them.

- Require strict fiscal and public accountability through mandatory independent audits, open meetings, public hearings and annual reports to the public. Create an Independent Citizen's Oversight Committee composed of representatives of the University of California campuses with medical schools; other California universities and California medical research institutions; California disease advocacy groups; and California experts in the development of medical therapies.

- Protect and benefit the California budget: by postponing general fund payments on the bonds for the first five years; by funding scientific and medical research that will significantly reduce state health care costs in the future; and by providing an opportunity for the state to benefit from royalties, patents, and licensing fees that result from the research.

- Benefit the California economy by creating projects, jobs, and therapies that will generate millions of dollars in new tax revenues in our state.

- Advance the biotech industry in California to world leadership, as an economic engine for California's future.

SEC. 4. Article XXXV is added to the California Constitution to read:

Section 1 There is hereby established the California Institute for Regenerative Medicine ("Institute").

Section 2 The Institute shall have the following purposes:

(a) To make grants and loans for stem cell research, for research facilities and for other vital research opportunities to realize therapies, protocols, and/or medical procedures that will result in, as speedily as possible, the cure for, and/or substantial mitigation of, major diseases, injuries and orphan diseases.

(b) To support all stages of the process of developing cures, from laboratory research through successful clinical trials.

(c) To establish the appropriate regulatory standards and oversight bodies for research and facilities development.

Section 3 No funds authorized for, or made available to, the Institute shall be used for research involving human reproductive cloning.

Section 4 Funds authorized for, or made available to, the Institute shall be continuously appropriated without regard to fiscal year, be

available and used only for the purposes provided herein, and shall not be subject to appropriation or transfer by the Legislature or the Governor for any other purpose.

Section 5 There is hereby established a right to conduct stem cell research which includes research involving adult stem cells, cord blood stem cells, pluripotent stem cells and/or progenitor cells. Pluripotent stem cells are cells that are capable of self-renewal, and have broad potential to differentiate into multiple adult cell types. Pluripotent stem cells may be derived from somatic cell nuclear transfer or from surplus products of in vitro fertilization treatments when such products are donated under appropriate informed consent procedures. Progenitor cells are multipotent or precursor cells that are partially differentiated but retain the ability to divide and give rise to differentiated cells.

Section 6 Notwithstanding any other provision of this Constitution or any law, the Institute, which is established in state government, may utilize state issued tax-exempt and taxable bonds to fund its operations, medical and scientific research, including therapy development through clinical trials, and facilities.

Section 7 Notwithstanding any other provision of this Constitution, including Article VII, or any law, the Institute and its employees are exempt from Civil Service.

SEC. 5. Chapter 3 commencing with Section 125281.01 is added to Part 5 of Division 106 of the Health and Safety Code to read:

Chapter 3

California Stem Cell Research and Cures/Bond Act

ARTICLE 1.

California Stem Cell Research and Cures Act

125281.01 General – Independent Citizen's Oversight Committee ("ICOC")
This Chapter implements California Constitution article XXXV which established

the California Institute for Regenerative Medicine ("Institute").

125281.02 Creation of the ICOC

There is hereby created the Independent Citizen's Oversight Committee, hereinafter, the ICOC, which shall govern the Institute and is hereby vested with full power, authority and jurisdiction over the Institute.

125281.03 ICOC Membership; Appointments; Terms of Office

(a) ICOC Membership

The ICOC shall have 29 members, appointed as follows:

(1) The Chancellors of the University of California at San Francisco, Davis, San Diego, Los Angeles and Irvine, shall each appoint an executive officer from his or her campus.

(2) The Governor, the Lieutenant Governor, the Treasurer and the Controller shall each appoint an executive officer from the following three categories:

(A) a California university, excluding the five campuses of the University of California described in paragraph (1), that has demonstrated success and leadership in stem cell research, and that has:

(i) a nationally-ranked research hospital and medical school; this criteria will apply to only two of the four appointments.

(ii) a recent proven history of administering scientific and/or medical research grants and contracts in an average annual range exceeding $100 million.

(iii) a ranking within the past five years in the top 10 United States universities with the highest number of life-science patents or that has research or clinical faculty who are members of the National Academy of Sciences.

(B) a California non-profit academic and research institution that is not a part of the University of California, that has demonstrated success and leadership in stem cell research, and that has:

(i) a nationally-ranked research hospital or that has research or clinical faculty who are members of the National Academy of Sciences.

(ii) a proven history in the last five years of managing a research budget in the lifesciences exceeding $20 million.

(C) a California life-science commercial entity that is not actively engaged in researching or developing therapies with pluripotent or progenitor stem cells, that has a background in implementing successful experimental medical therapies, and that has not been awarded, or applied for, funding by the Institute at the time of appointment. A board member of such entity with a successful history of developing innovative medical therapies may be appointed in lieu of an executive officer.

(D) only one member shall be appointed from a single university, institution, or entity. The executive officer of a California university, a non-profit research institution or life-science commercial entity who is appointed as a member, may from time to time delegate those duties to an executive officer of the entity or to the dean of the medical school, if applicable.

(3) The Governor, the Lieutenant Governor, the Treasurer, and the Controller shall appoint members from among California representatives of California regional, state, or national disease advocacy groups, as follows:

(A) The Governor shall appoint two members, one from each of the following disease advocacy groups: spinal cord injury, and Alzheimer's disease.

(B) The Lieutenant Governor shall appoint two members, one from each of the following disease advocacy groups: type II diabetes; and multiple sclerosis or amyotrophic lateral sclerosis.

(C) The Treasurer shall appoint two members, one from each of the following disease groups: type I diabetes and heart disease.

(D) The Controller shall appoint two members, one from each of the following disease groups: cancer and Parkinson's disease.

(4) The Speaker of the Assembly shall appoint a member from among California representatives of a California regional, state, or national Mental Health disease advocacy group.

(5) The President Pro Tem of the Senate shall appoint a member from among California representatives of a California regional, state, or national HIV/AIDS disease advocacy group.

(6) A Chairperson and Vice Chairperson who shall be elected by the ICOC members. Within 40 days of the effective date of this Act, each Constitutional Officer shall nominate a candidate for Chairperson and another candidate for Vice Chairperson. The Chairperson and Vice Chairperson shall each be elected for a term of six years. The Chairperson and Vice Chairperson of ICOC shall be full or part-time employees of the Institute and shall meet the following criteria:

(A) **Mandatory Chairperson Criteria**

(i) Documented history in successful stem cell research advocacy.

(ii) Experience with state and federal legislative processes that must include some experience with medical legislative approvals of standards and/or funding.

(iii) Qualified for appointment pursuant to Section 125281.03 (a) (3), (4) or (5).

(iv) Cannot be concurrently employed by or on leave from any prospective grant or loan recipient institutions in California.

(B) **Additional Criteria for Consideration:**

(i) Experience with governmental agencies or institutions (either executive or board position).

(ii) Experience with the process of establishing government standards and procedures.

(iii) Legal experience with the legal review of proper governmental authority for the exercise of government agency or government institutional powers.

(iv) Direct knowledge and experience in bond financing.

The Vice-Chairperson shall satisfy section 125281.03 (a) (6) (A) (i), (iii) and (iv). The Vice-Chairperson shall be selected from among individuals who have attributes and

experience complementary to those of the Chairperson, preferably covering the criteria not represented by the Chairperson's credentials and experience.

(b) Appointment of ICOC Members

(1) All appointments shall be made within 40 days of the effective date of this Act. In the event that any of the appointments are not completed within the permitted timeframe, the ICOC shall proceed to operate with the appointments that are in place, provided that at least 60 percent of the appointments have been made.

(2) 45 days after the effective date of this Act, the State Controller and the State Treasurer, or if only one is available within 45 days, the other shall convene a meeting of the appointed members of the ICOC to elect a Chairperson and Vice Chairperson from among the individuals nominated by the Constitutional Officers pursuant to section 125281.03 (a) (6).

(c) ICOC Member Terms Of Office

(1) The members appointed pursuant to section 125281.03 (a) (1), (a) (3), (a) (4), and (a) (5) shall serve eight-year terms, and all other members shall serve six-year terms. Members shall serve a maximum of two terms.

(2) If a vacancy occurs within a term, the appointing authority shall appoint a replacement member within 30 days to serve the remainder of the term.

(3) When a term expires, the appointing authority shall appoint a member within 30 days. ICOC members shall continue to serve until their replacements are appointed.

125281.04 Majority Vote of Quorum

Actions of the ICOC may be taken only by a majority vote of a quorum of the ICOC.

125281.05 Public and Financial Accountability Standards

(a) Annual Public Report

The Institute shall issue an annual report to the public which sets forth its activities, grants awarded, grants in progress, research accomplishments, and future program directions. Each annual report shall include, but not be limited to, the following: the number and dollar amounts of research and facilities grants; the grantees for the prior year; the Institute's administrative expenses; an assessment of the availability of funding for stem cell research from sources other than the Institute; a summary of research findings, including promising new research areas; an assessment of the relationship between the Institute's grants and the overall strategy of its research program; and a report of the Institute's strategic research and financial plans.

(b) Independent Financial Audit for Review by State Controller

The Institute shall annually commission an independent financial audit of its activities from a certified public accounting firm which shall be provided to the State Controller, who shall review the audit and annually issue a public report of that review.

(c) Citizen's Financial Accountability Oversight Committee

There shall be a Citizen's Financial Accountability Oversight Committee chaired

by the State Controller. This committee shall review the annual financial audit, the State Controller's report and evaluation of that audit, and the financial practices of the Institute. The State Controller, the State Treasurer, the President Pro-Tem of the Senate, the Speaker of the Assembly, and the Chairperson of the ICOC shall each appoint a public member of the committee. Committee members shall have medical backgrounds and knowledge of relevant financial matters. The committee shall provide recommendations on the Institute's financial practices and performance. The State Controller shall provide staff support. The committee shall hold a public meeting, with appropriate notice, and with a formal public comment period. The committee shall evaluate public comments and include appropriate summaries in its annual report. The ICOC shall provide funds for the per diem expenses of the committee members and for publication of the annual report.

(d) Public Meeting Laws

(1) The ICOC shall hold at least two public meetings per year, one of which will be designated as the Institute's annual meeting. The ICOC may hold additional meetings as it determines are necessary or appropriate.

(2) The Bagley-Keene Opening Meeting Act, Article 9 (commencing with section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code, shall apply to all meetings of the ICOC, except as otherwise provided in this section. The ICOC shall award all grants, loans and contracts in public meetings and shall adopt all governance, scientific, medical and regulatory standards in public meetings.

(3) The ICOC may conduct closed sessions as permitted by the Bagley-Keene Open Meeting Act, Government Code section 11126. In addition, the ICOC may conduct closed sessions when it meets to consider or discuss:

(A) Matters involving information relating to patients or medical subjects, the disclosure of which would constitute an unwarranted invasion of personal privacy.

(B) Matters involving 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) Matters involving pre-publication, confidential scientific research or data.

(D) Matters concerning the appointment, employment, performance, compensation, or dismissal of Institute officers and employees. Action on compensation of the Institute's officers and employees shall only be taken in open session.

(4) The meeting required by section 125281.03 (b) (2) shall be deemed to be a special meeting for the purposes of Government Code section 11125.4.

(e) Public Records

(1) The California Public Records Act, Article 1 (commencing with section

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.

(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.

(j) Adopt, amend and rescind rules and regulations to carry out the purposes and provisions of this chapter, and to govern the procedures of the ICOC. Except as provided in subdivision (k), these rules and regulations shall be adopted in accordance with the Administrative Procedure Act (Government Code, Title 2, Division 3, Part 1 , Chapter 4.5, Sections 11371 et seq.)

(k) Notwithstanding the Administrative Procedure Act ("APA"), and in order to facilitate the immediate commencement of research covered by this chapter, the ICOC may adopt interim regulations without compliance with the procedures set forth in the APA. The interim regulations shall remain in effect for 270 days unless earlier superseded by regulations adopted pursuant to the APA.

(l) Request the issuance of bonds from the California Stem Cell Research and Cures Finance Committee and loans from the Pooled Money Investment Board.

(m) May annually modify its funding and finance programs to optimize the Institute's ability to achieve the objective that its activities be revenue-positive for the State of California during its first five years of operation without jeopardizing the progress of its core medical and scientific research program.

(n) Notwithstanding Government Code section 11005, accept additional revenue and real and personal property, including but not limited to gifts, royalties, interest and appropriations that may be used to supplement annual research grant funding and the operations of the Institute.

125281.08 ICOC Operations

(a) Legal Actions and Liability

(1) The Institute may sue and be sued.

(2) Based upon ICOC standards, Institute grantees shall indemnify or insure and hold the Institute harmless against any and all losses, claims, damages, expenses or liabilities, including attorneys' fees, arising from research conducted by the grantee pursuant to the grant, and/or, in the alternative, grantees shall name the Institute as an additional insured and submit proof of such insurance.

(3) Given the scientific, medical and technical nature of the issues facing the ICOC, and notwithstanding Government Code section 11042, the Institute is authorized to retain outside counsel when the ICOC determines that the Institute requires specialized services not provided by the Attorney General's Office.

(4) The Institute may enter into any contracts or obligations which are authorized or permitted by law.

(b) Personnel

(1) The ICOC shall from time to time determine the total number of authorized employees for the Institute, up to a maximum of fifty employees, excluding members of the working groups, who shall not be considered Institute employees. The ICOC shall select a Chairperson, Vice-Chairperson and President who shall exercise all of the powers delegated to them by the ICOC. The following functions apply to the Chairperson, Vice-Chairperson and President:

The Chairperson's primary responsibilities are to manage the ICOC agenda and work flow including all evaluations and approvals of scientific and medical working group grants, loans, facilities, and standards evaluations, and to supervise all annual reports and public accountability requirements; to manage and optimize the Institute's bond financing plans and funding cash flow plan; to interface with the California legislature, the United States Congress, the California healthcare system, and the California public; to optimize all financial leverage opportunities for the Institute; and to lead negotiations for intellectual property agreements, policies, and contract terms. The Chairperson shall also serve as a member of the Scientific and Medical Accountability Standards Working Group and the Scientific and Medical Research Facilities Working Group and as an ex-officio member of the Scientific and Medical Research Funding Working Group. The Vice-Chairperson's primary responsibilities are to support the Chairperson in all duties and to carry out those duties in the Chairperson's absence.

The President's primary responsibilities are to serve as the Chief Executive of the Institute; to recruit the highest scientific and medical talent in the United States to serve the Institute on its working groups; to serve the Institute on its working groups; to direct ICOC staff and participate in the process of supporting all working group requirements to develop recommendations on grants, loans, facilities, and standards as well as to direct and support the ICOC process of evaluating and acting on those recommendations, the implementation of all decisions on these and general matters of the ICOC; to hire, direct, and manage the staff of the Institute; to develop the budgets and cost control programs of the Institute; to manage compliance with all rules and regulations on the ICOC, including the performance of all grant recipients; and to manage and execute all intellectual property agreements and any other contracts pertaining to the Institute or research it funds.

(2) Each member of the ICOC except the Chairperson, Vice Chairperson and President, shall receive a per diem of one hundred dollars ($100) per day (adjusted annually for cost of living) for each day actually spent in the discharge of the member's duties, plus reasonable and necessary travel and other expenses incurred in the performance of the member's duties.

(3) The ICOC shall establish daily consulting rates and expense reimbursement standards for the non-ICOC members of all of its working groups.

(4) Notwithstanding Government Code section 19825, the ICOC shall set compensation for the Chairperson, Vice-Chairperson and President and other officers, and for the scientific, medical, technical, and administrative staff of the Institute within the range of compensation levels for executive officers and scientific, medical, technical, and administrative staff of medical schools within the University of California system and the non-profit academic and research institutions described in section 125281.03 (a) (2).

125281.09 Scientific and Medical Working Groups-General

(a) The Institute shall have, and there is hereby established three separate scientific and medical working groups as follows:

Scientific and Medical Research Funding Working Group;

Scientific and Medical Accountability Standards Working Group; and

Scientific and Medical Research Facilities Working Group

(b) Working Group Members

Appointments of scientific and medical working group members shall be made by a majority vote of a quorum of the ICOC, within 30 days of the election and appointment of the initial ICOC members. The working group members' terms shall be six years except that, after the first six year terms, the members' terms will be staggered so that one-third of the members shall be elected for a term that expires two years later, one third of the members shall be elected for a term that expires four years later, and one-third of the members shall be elected for a term that expires six years later. Subsequent terms are for six years. Working group members may serve a maximum of two consecutive terms.

(c) Working Group Meetings

Each scientific and medical working group shall hold at least four meetings per year, one of which shall be designated as its annual meeting.

(d) Working Group Recommendations to the ICOC

Recommendations of each of the working groups may be forwarded to the ICOC only by a vote of a majority of a quorum of the members of each working group. If 35 percent of the members of any working group join together in a minority position, a minority report may be submitted to the ICOC. The ICOC shall consider the recommendations of the working groups in making its decisions on applications for research and facility grants and loan awards and in adopting regulatory standards. Each working group shall recommend to ICOC rules, procedures and practices for that working group.

(e) Conflict of Interest

(1) The ICOC shall adopt conflict of interest rules, based on standards applicable to members of scientific review committees of the National Institutes of Health, to govern the participation of non-ICOC working group members.

(2) The ICOC shall appoint an ethics officer from among the staff of the Institute.

(3) Because the working groups are purely advisory and have no final decision-making authority, members of the working groups shall not be considered public officials, employees or consultants for purposes of the Political Reform Act (commencing with Government Code section 81000), Government Code sections 1090 and 19990, and Public Contract Code sections 10516 and 10517.

(f) Working Group Records

All records of the working groups submitted as part of the working groups' recommendations to the ICOC for approval shall be subject to the Public Records Act. Except as provided in this subdivision, the working groups shall not be subject to the

provisions of Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code, or Article 1 (commencing with Section 6250) of Chapter 3.5 of Division 7 of Title 1 of the Government Code.

125281.10 Scientific and Medical Accountability Standards Working Group

(a) Membership

The Scientific and Medical Accountability Standards Working Group shall have 19 members as follows:

(1) Five ICOC members from the ten groups that focus on disease-specific areas described in section 125281.03 (a) (3), (a) (4) and (a) (5).

(2) Nine scientists and clinicians nationally recognized in the field of pluripotent and progenitor cell research.

(3) Four medical ethicists.

(4) The chairperson of the ICOC.

(b) Functions

The Scientific and Medical Accountability Standards Working Group shall have the following functions:

(1) To recommend to the ICOC scientific, medical and ethical standards.

(2) To recommend to the ICOC standards for all medical, socio-economic, and financial aspects of clinical trials and therapy delivery to patients, including, among others, standards for safe and ethical procedures for obtaining materials and cells for research and clinical efforts for the appropriate treatment of human subjects in medical research consistent with section 125281.06 (a) (2) herein, and to ensure compliance with patient privacy laws.

(3) To recommend to the ICOC modification of the standards described in sub-paragraphs (1) and (2) as needed.

(4) To make recommendations to the ICOC on the oversight of funded research to ensure compliance with the standards described in subparagraphs (1) and (2).

(5) To advise the ICOC, the Scientific and Medical Research Funding Working Group, and the Scientific and Medical Research Facilities Working Group on an on-going basis on relevant ethical and regulatory issues.

125281.11 Scientific and Medical Research Funding Working Group

(a) Membership

The Scientific and Medical Research Funding Working Group shall have 23 members as follows:

(1) Seven ICOC members from the 10 disease advocacy group members described in sections 125281.03 (a) (3), (a) (4), and (a) (5).

(2) 15 scientists nationally recognized in the field of stem cell research.

(3) The Chairperson of the ICOC.

(b) Functions

The Scientific and Medical Research Funding Working Group shall perform the following functions:

(1) Recommend to the ICOC interim and final criteria, standards and requirements for considering funding applications and for awarding research grants and loans.

(2) Recommend to the ICOC standards for the scientific and medical oversight of awards.

(3) Recommend to the ICOC any modifications of the criteria, standards and requirements described in subparagraphs (1) and (2) above as needed.

(4) Review grant and loan applications based on the criteria, requirements and standards adopted by the ICOC and make recommendations to the ICOC for the award of research, therapy development, and clinical trial grants and loans.

(5) Conduct peer-group progress oversight reviews of grantees to ensure compliance with the terms of the award, and report to the ICOC any recommendations for subsequent action.

(6) Recommend to the ICOC standards for the evaluation of grantees to ensure that they comply with all applicable requirements. Such standards shall mandate periodic reporting by grantees and shall authorize the Scientific and Medical Research Funding Working Group to audit a grantee and forward any recommendations for action to the ICOC.

(7) Recommend its first grant awards within 60 days of the issuance of the interim standards.

(c) Recommendations for Awards

Award recommendations shall be based upon a competitive evaluation as follows.

(1) Only the 15 scientist members of the Scientific and Medical Research Funding Working Group shall score grant and loan award applications for scientific merit. Such scoring shall be based on scientific merit in three separate classifications—research, therapy development and clinical trials, on criteria including the following:

(A) A demonstrated record of achievement in the areas of pluripotent stem cell and progenitor cell biology and medicine, unless the research is determined to be a Vital Research Opportunity.

(B) The quality of the research proposal, the potential for achieving significant research or clinical results, the timetable for realizing such significant results, the importance of the research objectives, and the innovativeness of the proposed research.

(C) In order to ensure that Institute funding does not duplicate or supplant existing funding, a high priority shall be placed on funding pluripotent stem cell and progenitor cell research that cannot, or is unlikely to, receive timely or sufficient federal funding, unencumbered by limitations that would impede the research. In this regard, other research categories funded by the National Institute of Health shall not be funded by the Institute.

(D) Notwithstanding subparagraph (C), other scientific and medical research and technologies and/or any stem cell research proposal not actually funded by the Institute under subparagraph (C) may be funded by the Institute if at least two-thirds of a

quorum of the members of the Scientific and Medical Research Funding Working Group recommend to the ICOC that such a research proposal is a Vital Research Opportunity.

125281.12 Scientific and Medical Facilities Working Group

(a) Membership

The Scientific and Medical Research Facilities Working Group shall have 11 members as follows:

(1) Six members of the Scientific and Medical Research Funding Working Group.

(2) Four real estate specialists. To be eligible to serve on the Scientific and Medical Research Facilities Working Group, a real estate specialist shall be a resident of California, shall be prohibited from receiving compensation from any construction or development entity providing specialized services for medical research facilities, and shall not provide real estate facilities brokerage services for any applicant for, or any funding by the Scientific and Medical Research Facilities Working Group and shall not receive compensation from any recipient of Institute funding grants.

(3) The Chairperson of the ICOC.

(b) Functions

The Scientific and Medical Research Facilities Working Group shall perform the following functions:

(1) Make recommendations to the ICOC on interim and final criteria, requirements and standards for applications for, and the awarding of, grants and loans for buildings, building leases, and capital equipment; those standards and requirements shall include, among others,

(A) facility milestones and timetables for achieving such milestones;

(B) priority for applications that provide for facilities that will be available for research no more than two years after the grant award;

(C) the requirement that all funded facilities and equipment be located solely within California;

(D) the requirement that grantees comply with reimbursable building cost standards, competitive building leasing standards, capital equipment cost standards, and reimbursement standards and terms recommended by the Scientific and Medical Facilities Funding Working Group, and adopted by the ICOC;

(E) the requirement that grantees shall pay all workers employed on construction or modification of the facility funded by facilities grants or loans of the Institute, the general prevailing rate of per-diem wages for work of a similar character in the locality in which work on the facility is performed, and not less than the general prevailing rate of per diem wages for holiday and overtime work fixed as provided in Division 2, Part 7, Chapter 1 of the Labor Code;

(F) the requirement that grantees be not-for-profit entities;

(G) the requirement that awards be made on a competitive basis, with the following minimum requirements:

(i) that the grantee secure matching funds from sources other than the Institute equal to at least 20 percent of the award. Applications of equivalent merit, as determined by the Scientific and Medical Research Funding Working Group, considering research opportunities to be conducted in the proposed research facility, shall receive priority to the extent that they provide higher matching fund amounts. The Scientific and Medical Research Facilities Working Group may recommend waiving the matching fund requirement in extraordinary cases of high merit or urgency;

(ii) that capital equipment costs and capital equipment loans be allocated when equipment costs can be recovered in part by the grantee from other users of the equipment.

(2) Make recommendations to the ICOC on oversight procedures to ensure grantees' compliance with the terms of an award.

125281.13 Appropriation and Allocation of Funding.

(a) Monies in the California Stem Cell Research and Cures Fund shall be allocated as follows:

(1) No less than 97 percent of the proceeds of the bonds authorized pursuant to section 125282.05, after allocation of bond proceeds to purposes described in subsections (a) (iv) and (a) (v) of section 125282.03, shall be used for grants and grant oversight as provided in this chapter.

(A) Not less than 90 percent of the amount used for grants shall be used for research grants, with no more than the following amounts—as stipulated below— to be committed during the first ten years of grant-making by the Institute with each year's commitments to be advanced over a period of one to seven years, except that any such funds that are not committed may be carried over to one or more following years. The maximum amount of research funding to be allocated annually as follows: Year 1, 5.6%; Year 2, 9.4%; Year 3, 9.4%; Year 4, 11.3%; Year 5, 11.3%; Year 6, 11.3%; Year 7, 11.3%; Year 8, 11.3%; Year 9, 11.3%; and Year 10, 7.5%.

(B) Not more than three percent of the proceeds of bonds authorized by section 125282.05 may be used by the Institute for research and research facilities implementation costs, including the development, administration and oversight of the grant-making process and the operations of the working groups.

(2) Not more than three percent of the proceeds of the bonds authorized pursuant to section 125282.05 shall be used for the costs of general administration of the Institute.

(3) In any single year any new research funding to any single grantee for any program year is limited to no more than two percent of the total bond authorization under this Chapter. This limitation shall be considered separately for each new proposal without aggregating any prior year approvals that may fund research activities. This requirement shall be determinative, unless 65 percent of a quorum of the ICOC approves a higher limit for that grantee.

(4) Recognizing the priority of immediately building facilities that ensure the independence of the scientific and medical research of the Institute, up to 10 percent of the proceeds of the bonds authorized pursuant to section 125282.05, net of costs described in clauses (a) (ii), (a) (iv) and (a) (v) of section 125282.03 shall be allocated for grants to build scientific and medical research facilities of non-profit entities which are intended to be constructed in the first five years.

(5) The Institute shall limit indirect costs to 25 percent of a research award, excluding amounts included in a facilities award, except that the indirect cost limitation may be increased by that amount by which the grantee provides matching funds in excess of 20 percent of the grant amount.

(b) To enable the Institute to commence operating during the first six months following the adoption of this measure, there is hereby appropriated from the General Fund as a temporary start-up loan to the Institute three million dollars ($3,000,000) for initial administrative and implementation costs. All loans to the Institute pursuant to this appropriation shall be repaid to the General Fund within twelve months of each loan draw from the proceeds of bonds sold pursuant to section 125282.05.

(c) The Institute's funding schedule is designed to create a positive tax revenue stream for the state of California during the Institute's first five calendar years of operations, without drawing funds from the state general fund for principal and interest payments for those first five calendar years.

ARTICLE 2.

CALIFORNIA STEM CELL RESEARCH AND CURES BOND ACT OF 2004

125282.01. This article shall be known, and may be cited, as the California Stem Cell Research and Cures Bond Act of 2004.

125282.02. As used in this article, the following terms have the following meaning:

(a) "Act" means the California Stem Cell Research and Cures Act" constituting Chapter 3 (commencing with Section 125281.01) of Part 5 of Division 106 of the Health and Safety Code.

(b) "Board" or "Institute" means the California Institute for Regenerative Medicine designated in accordance with subdivision (b) of Section 125282.07.

(c) "Committee" means the California Stem Cell Research and Cures Finance Committee created pursuant to subdivision (a) of Section 125282.07.

(d) "Fund" means the California Stem Cell Research and Cures Fund created pursuant to Section 125282.04.

(e) "Interim Debt" means any interim loans pursuant to Sections 125281.13 (b), 125282.11 and 25282.12, bond anticipation notes or commercial paper notes issued

to make deposits into the Fund and which will be paid from the proceeds of bonds issued pursuant to this article.

125282.03. (a) Notwithstanding Section 13340 of the Government Code or any other provision of law, moneys in the Fund are appropriated without regard to fiscal years to the Institute for the purpose of (i) making grants or loans to fund research and construct facilities for research, all as described in and pursuant to the Act, (ii) paying general administrative costs of the Institute (not to exceed 3% of the net proceeds of each sale of bonds), (iii) paying the annual administration costs of the Interim Debt or bonds after December 31 of the fifth full calendar year after this article takes effect, (iv) paying the costs of issuing Interim Debt, paying the annual administration costs of the Interim Debt until and including December 31 of the fifth full calendar year after this article takes effect, and paying interest on Interim Debt, if such Interim Debt is incurred or issued on or prior to December 31 of the fifth full calendar year after this article takes effect, and (v) paying the costs of issuing bonds, paying the annual administration costs of the bonds until and including December 31 of the fifth full calendar year after this article takes effect, and paying interest on bonds that accrues on or prior to December 31 of the fifth full calendar year after this article takes effect (except that such limitation does not apply to premium and accrued interest as provided in Section 125282.13). In addition, moneys in the Fund or other proceeds of the sale of bonds authorized by this article may be used to pay principal of or redemption premium on any Interim Debt issued prior to the issuance of bonds authorized by this article. Moneys deposited in the Fund from the proceeds of Interim Debt may be used to pay general administrative costs of the Institute without regard to the 3% limit set forth in (ii) above, so long as such 3% limit is satisfied for each issue of bonds.

(b) Repayment of principal and interest on any loans made by the Institute pursuant to this article shall be deposited in the Fund and used to make additional grants and loans for the purposes of this Act or for paying continuing costs of the annual administration of outstanding bonds.

125282.04. The proceeds of Interim Debt and bonds issued and sold pursuant to this article shall be deposited in the State Treasury to the credit of the California Stem Cell Research and Cures Fund, which is hereby created in the State Treasury, except to the extent that proceeds of the issuance of bonds are used directly to repay Interim Debt.

125282.05. Bonds in the total amount of three billion dollars ($3,000,000,000), not including the amount of any refunding bonds issued in accordance with Section 125282.14, or as much thereof as is necessary, may be issued and sold to provide a fund to be used for carrying out the purposes expressed in this article and to be used and sold for carrying out the purposes of Section 125282.03 and to reimburse the General Obligation Bond Expense Revolving Fund pursuant to Section 16724.5 of the Government Code. The bonds, when sold, shall be and shall constitute a valid and binding obligation of the State of California, and the full faith and credit of the State of

California is hereby pledged for the punctual payment of both the principal of, and interest on, the bonds as the principal and interest become due and payable.

125282.06. The bonds authorized by this article shall be prepared, executed, issued, sold, paid, and redeemed as provided in the State General Obligation Bond Law (Chapter 4 (commencing with Section 16720) of Part 3 of Division 4 of Title 2 of the Government Code), and all of the provisions of that law except Section 16727 apply to the bonds and to this article and are hereby incorporated in this article as though set forth in full in this article.

125282.07. (a) Solely for the purpose of authorizing the issuance and sale, pursuant to the State General Obligation Bond Law, of the bonds and Interim Debt authorized by this article, the California Stem Cell Research and Cures Finance Committee is hereby created. For purposes of this article, the California Stem Cell Research and Cures Finance Committee is "the Committee" as that term is used in the State General Obligation Bond Law. The committee consists of the Treasurer, the Controller, the Director of Finance, the Chairperson of the California Institute for Regenerative Medicine, and two other members of the Independent Citizens Oversight Committee (as created by the Act) chosen by the Chairperson of the California Institute for Regenerative Medicine, or their designated representatives. The Treasurer shall serve as chairperson of the Committee. A majority of the Committee may act for the Committee.

(b) For purposes of the State General Obligation Bond Law, the California Institute for Regenerative Medicine is designated the "board."

125282.08. (a) The Committee shall determine whether or not it is necessary or desirable to issue bonds authorized pursuant to this article in order to carry out the actions specified in this article and, if so, the amount of bonds to be issued and sold. Successive issues of bonds may be authorized and sold to carry out those actions progressively, and it is not necessary that all of the bonds authorized to be issued be sold at any one time. The bonds may bear interest which is includable in gross income for federal income tax purposes if the Committee determines that such treatment is necessary in order to provide funds for the purposes of the Act.

(b) The total amount of the bonds authorized by Section 125282.05 which may be issued in any calendar year, commencing in 2005, shall not exceed $350,000,000. If less than this amount of bonds is issued in any year, the remaining permitted amount may be carried over to one or more subsequent years.

(c) An interest-only floating rate bond structure will be implemented for Interim Debt and bonds until at least December 31 of the fifth full calendar year after this article takes effect, with all interest to be paid from proceeds from the sale of Interim Debt or bonds, to minimize debt service payable from the general fund during the initial period of basic research and therapy development, if the Committee determines, with the advice of the Treasurer, that this structure will result in the lowest achievable borrowing costs for the State during that five-year period considering the objective of avoiding any

bond debt service payments, by the State's general fund, during that period. Upon such initial determination, the Committee may delegate, by resolution, to the Treasurer such authority in connection with issuance of bonds as it may determine, including but not limited to the authority to implement and continue this bond financing structure (including during any time following the initial five-year period) and to determine that an alternate financing plan would result in significant lower borrowing costs for the State consistent with the objectives related to the State's general fund and to implement such alternate financing plan.

125282.09. There shall be collected each year and in the same manner and at the same time as other State revenue is collected, in addition to the ordinary revenues of the State, a sum in an amount required to pay the principal of, and interest on, the bonds maturing each year. It is the duty of all officers charged by law with any duty in regard to the collection of the revenue to do and perform each and every act that is necessary to collect that additional sum.

125282.10. Notwithstanding Section 13340 of the Government Code, there is hereby appropriated from the General Fund in the State Treasury, for the purposes of this article, an amount that will equal the total of the following:

(a) The sum annually necessary to pay the principal of, and interest on, bonds issued and sold pursuant to this article, as the principal and interest become due and payable.

(b) The sum necessary to carry out Section 125282.11 appropriated without regard to fiscal years.

125282.11. The Director of Finance may authorize the withdrawal from the General Fund of an amount or amounts not to exceed the amount of the unsold bonds that have been authorized by the Committee to be sold for the purpose of carrying out this article. Any amount withdrawn shall be deposited in the Fund. Any money made available under this section shall be returned to the General Fund, plus an amount equal to the interest that the money would have earned in the Pooled Money Investment Account, from money received from the sale of bonds for the purpose of carrying out this article.

125282.12. The Institute may request the Pooled Money Investment Board to make a loan from the Pooled Money Investment Account in accordance with Section 16312 of the Government Code for the purposes of carrying out this article. The amount of the request shall not exceed the amount of the unsold bonds that the Committee, by resolution, has authorized to be sold for the purpose of carrying out this article. The Institute shall execute any documents required by the Pooled Money Investment Board to obtain and repay the loan. Any amounts loaned shall be deposited in the Fund to be allocated by the Institute in accordance with this article.

125282.13. All money deposited in the Fund that is derived from premium and accrued interest on bonds sold shall be reserved in the Fund and shall be available for transfer to the General Fund as a credit to expenditures for bond interest.

125282.14. The bonds may be refunded in accordance with Article 6 (commencing with Section 16780) of Chapter 4 of Part 3 of Division 4 of Title 2 of the Government Code, which is a part of the State General Obligation Bond Law. Approval by the voters of the State for the issuance of the bonds described in this article includes the approval of the issuance of any bonds issued to refund any bonds originally issued under this article or any previously issued refunding bonds.

125282.15. Notwithstanding any provision of this article or the State General Obligation Bond Law, if the Treasurer sells bonds pursuant to this article that include a bond counsel opinion to the effect that the interest on the bonds is excluded from gross income for federal tax purposes, subject to designated conditions, the Treasurer may maintain separate accounts for the investment of bond proceeds and the investment earnings on those proceeds. The Treasurer may use or direct the use of those proceeds or earnings to pay any rebate, penalty, or other payment required under federal law or to take any other action with respect to the investment and use of bond proceeds required or desirable under federal law to maintain the tax-exempt status of those bonds and to obtain any other advantage under federal law on behalf of the funds of this state.

125282.16. Inasmuch as the proceeds from the sale of bonds authorized by this article are not "proceeds of taxes" as that term is used in Article XIII B of the California Constitution, the disbursement of these proceeds is not subject to the limitations imposed by that article.

ARTICLE 3.

DEFINITIONS

125283.01 As used in this Chapter and in Article XXXV of the California Constitution, the following terms have the following meanings:

(a) "Act" means the California Stem Cell Research and Cures Act constituting Chapter 3 (commencing with Section 125281.01) of Part 5 of Division 106 of the Health and Safety Code.

(b) "Adult Stem Cell" means an undifferentiated cell found in a differentiated tissue in an adult organism that can renew itself and may (with certain limitations) differentiate to yield all the specialized cell types of the tissue from which it originated.

(c) "Capitalized Interest" means interest funded by bond proceeds.

(d) "Committee" means the California Stem Cell Research and Cures Finance Committee created pursuant to subdivision (a) of Section 125282.07.

(e) "Constitutional Officers" means the Governor, Lieutenant Governor, Treasurer and Controller of California.

(f) "Facilities" means buildings, building leases, or capital equipment.

(g) "Floating-rate Bonds" means bonds which do not bear a fixed rate of interest until their final maturity date, including commercial paper notes.

(h) "Fund" means the California Stem Cell Research and Disease Cures Fund created pursuant to Section 125282.04.

(i) "Grant" means a grant, loan or guarantee.

(j) "Grantee" means a recipient of a grant from the Institute. All University of California grantee institutions shall be considered as separate and individual grantee institutions.

(k) "Human Reproductive Cloning" means the practice of creating or attempting to create a human being by transferring the nucleus from a human cell into an egg cell from which the nucleus has been removed for the purpose of implanting the resulting product in a uterus to initiate a pregnancy.

(l) "Indirect Costs" mean the recipient's costs in the administration, accounting, general overhead and general support costs for implementing a grant or loan of the Institute. NIH definitions of indirect costs will be utilized as one of the bases by the Scientific and Medical Research Standards Working Group to create a guideline for recipients on this definition, with modifications to reflect guidance by the ICOC and this Act.

(m) "Institute" means the California Institute for Regenerative Medicine.

(n) "Interim Standards" means temporary standards that perform the same function as "emergency regulations" under the Administrative Procedure Act (Government Code, Title 2, Division 3, Part 1, Chapter 4.5, sections 11371 et seq) except that in order to provide greater opportunity for public comment on the permanent regulations, remain in force for 270 days rather than 180 days.

(o) "Life-Science Commercial Entity" means a firm or organization, headquartered in California, whose business model includes biomedical or biotechnology product development and commercialization.

(p) "Medical Ethicist" means an individual with advanced training in ethics—who holds a PhD, MA or equivalent training and who spends or has spent substantial time (a) researching and writing on ethical issues related to medicine, and (b) administering ethical safeguards during the clinical trial process, particularly through service on institutional review boards.

(q) "Pluripotent Cells" means cells that are capable of self-renewal, and have broad potential to differentiate into multiple adult cell types. Pluripotent stem cells may be derived from somatic cell nuclear transfer or from surplus products of in vitro fertilization treatments when such products are donated under appropriate informed consent procedures. These excess cells from in vitro fertilization treatments would otherwise be intended to be discarded if not utilized for medical research.

(r) "Progenitor Cells" means multipotent or precursor cells that are partially differentiated but retain the ability to divide and give rise to differentiated cells.

(s) "Quorum" means at least 65 percent of the members who are eligible to vote.

(t) "Research Donor" means a human who donates biological materials for research purposes after full disclosure and consent.

(u) "Research Funding" includes interdisciplinary scientific and medical funding for basic research, therapy development, and the development of pharmacologies and treatments through clinical trials. When a facilities grant or loan has not been provided to house all elements of the research, therapy development, and/or clinical trials, research funding shall include an allowance for a market lease rate of reimbursement for the facility. In all cases, operating costs of the facility, including but not limited to library and communication services, utilities, maintenance, janitorial and security, shall be included as direct research funding costs. Legal costs of the Institute incurred in order to negotiate standards with federal and state governments and research institutions; to implement standards or regulations; to resolve disputes; and/or to carry out all other actions necessary to defend and/or advance the Institute's mission shall be considered direct research funding costs.

(v) "Research Participant" means a human enrolled with full disclosure and consent, and participating in clinical trials.

(w) "Revenue Positive" means all state tax revenues generated directly and indirectly by the research and facilities of the Institute are greater than the debt service on the state bonds actually paid by the state general fund in the same year.

(x) "Stem Cells" mean non-specialized cells that have the capacity to divide in culture and to differentiate into more mature cells with specialized functions.

(y) "Vital Research Opportunity" means scientific and medical research and technologies and/or any stem cell research not actually funded by the Institute under Section 125281.11 (c) (1) (C) which provides a substantially superior research opportunity vital to advance medical science as determined by at least a two-thirds vote of a quorum of the members of the Scientific and Medical Research Funding Working Group and recommended as such by that working group to the ICOC. Human reproductive cloning shall not be a vital research opportunity.

SEC. 6. Government Code section 20069 is amended to read as follows:

(a) "State service" means service rendered as an employee or officer (employed, appointed or elected) of the state, the California Institute for Regenerative Medicine and the officers and employees of its governing body, the university, a school employer, or a contracting agency, for compensation, and only while he or she is receiving compensation from that employer therefore, except as provided in Article 4 (commencing with Section 20990) of Chapter 11.

(b) State service," solely for purposes of qualification for benefits and retirement allowances under this system, shall also include service rendered as an officer or employee of a county if the salary for the service constitutes compensation earnable by a member of this system under section 20638.

SEC. 7. Severability

If any provision of this Act, or part thereof, is for any reason held to be invalid or unconstitutional, the remaining provisions shall not be affected, but shall remain in full force and effect, and to this end the provisions of this Act are severable.

SEC. 8. Amendments

The statutory provisions of this measure, except the bond provisions, may be amended to enhance the ability of the Institute to further the purposes of the grant and loan programs created by the measure, by a bill introduced and passed no earlier than the third full calendar year following adoption, by seventy percent of the membership of both houses of the Legislature and signed by the Governor, provided that at least 14 days prior to passage in each house, copies of the bill in final form shall be made available by the clerk of each house to the public and news media.