

THE CALIFORNIA STEM CELL RESEARCH, TREATMENTS, AND CURES
INITIATIVE OF 2020

SEC. 1. Title.

This measure shall be known and may be cited as “The California Stem Cell Research, Treatments, and Cures Initiative of 2020.”

SEC. 2. Findings and Declarations.

The People of the State of California hereby find and declare all the following:

A. In 2004, California voters rejected efforts by the federal government to limit stem cell research by establishing California’s own stem cell research and therapy development funding agency, catapulting California into a worldwide leadership position in the cutting-edge field of stem cell research.

B. Since then, the California Institute for Regenerative Medicine (California’s stem cell research institute), which was established by California voters, has funded more than 1,000 research projects at 70 institutions and businesses across the state, which have led to more than 2,500 peer-reviewed medical research discoveries, including discoveries that have contributed to more than 70 human clinical trials aimed at finding treatments and cures for chronic injuries and diseases. Many other discoveries are in the translational pipeline awaiting additional funds to move them towards clinical trials. Approximately 2,000 patients are expected to be treated in institute-funded clinical trials or at the institute’s centers of excellence, and more than 4,000 patients are expected to be enrolled in human clinical trials in which the California stem cell research institute has funded research or therapy development.

C. Researchers funded by California’s stem cell research institute are working to develop therapies and cures for devastating diseases and injuries, including without limitation, cancer, diabetes, heart disease, lower respiratory diseases, kidney disease, Alzheimer’s, Parkinson’s, spinal cord injuries, blindness, amyotrophic lateral sclerosis (ALS), HIV/AIDS, multiple sclerosis, and mental health disorders, such as schizophrenia, depression, and autism.

D. Institute-funded researchers are making significant progress in developing therapies for many devastating diseases, ranging from cancer treatments to helping to find a cure for “bubble baby” disease, which has already saved the lives of many children, but many of these projects require additional funds to move from the research stage to the clinic.

E. Treatments developed with support from California’s stem cell research institute are changing lives. Thanks to this research, a high school student who was paralyzed in a diving accident was able to regain function in his upper body and go on to college; a mother who went blind from a genetic disease recovered her sight; and a cure has been found for a disease that causes fetal death.

F. To date, institute-funded research projects are estimated to have generated more than \$3.5 billion in matching funds, created more than 55,000 (FTE) jobs in California, and to have resulted in

approximately \$641 million in state and local tax revenues. California's stem cell research institute has drawn hundreds of out-of-state researchers and many companies to California, making California a worldwide leader in the field. The \$3.5 billion dollars in matching funds generated by these projects validate the value of the voters' decision to invest in research and therapies to treat and cure chronic disease and injury.

G. Although California's stem cell research funding institute has made great gains, much work remains to be done. With new federal restrictions on important research, an anti-science agenda on the rise, and threats to reduce federal research and development funding, California once again must take the lead to ensure that this promising area of research continues and to advance projects from the research stage to the clinic.

H. Without additional funding, many of these promising research and development projects will be forced to stop work on potentially life-changing medical therapies. California's stem cell research institute needs additional funding to help bring promising discoveries through the development process, including clinical trials, with the goal of making treatments available to California patients with chronic diseases and injuries.

SEC. 3. Purpose and Intent.

In enacting this Initiative, it is the purpose and intent of the people of the State of California to continue to support stem cell research to mitigate and/or cure chronic disease and injury and thereby reduce or mitigate human suffering and the cost of care and improve the health and productivity of Californians by:

A. Providing \$5.5 billion in bond funding to allow California's stem cell research institute to continue funding stem cell and other vital research to develop treatments and cures for serious diseases and conditions like diabetes, cancer, HIV/AIDs, heart disease, paralysis, blindness, kidney disease, respiratory illnesses, and many more.

B. Dedicating \$1.5 billion (one billion, five hundred million dollars) for the support of research and the development of treatments for brain diseases and conditions, such as Alzheimer's disease, Parkinson's disease, stroke, dementia, epilepsy, depression, brain cancer, schizophrenia, autism, and other diseases and conditions of the brain.

C. Promoting the accessibility and affordability of treatments and cures by ensuring that more Californians have the opportunity to participate in clinical trials for promising new treatments for chronic disease and injury, expanding the number and geographic reach of clinics where specialized treatments and cures can be provided, including centers of excellence like Alpha Clinics and Community Care Centers of Excellence, which support clinical trials and will serve as the foundation for the delivery of future treatments, and by helping California patients obtain treatments and cures that arise from institute-funded research and development.

D. Creating the workforce necessary to ensure that promising research developments are advanced to the clinic and that resulting treatments are made available to California patients.

E. Reinforcing California's position as a world leader in the development of stem cell treatments and cures for patients.

F. Promoting private investment in institute-funded projects to leverage institute funding so that this critical research can advance new treatments faster towards the goal of making them available to California patients.

G. Requiring strict accountability and transparency, including rigorous conflict of interest rules that are updated every four years, a limit on the number of employees the institute may hire, and a cap on administrative funding to ensure that at least 92.5% of the of the bond proceeds are spent on research and the development and delivery of treatments and cures.

H. Protecting the General Fund by postponing general fund payments on the bonds for the first five years, restricting the issuance of bonds in any one year to no more than one half of one percent of the total amount of the state's outstanding and authorized General Obligation bonds, in the aggregate total, as of January 1, 2020, requiring that bonds be sold over a period of no less than ten years, and spreading the cost of the bonds over a period of up to 40 years, so that the repayment is aligned with the period of time over which California patients are expected to benefit from institute-funded research.

SEC. 4. Section 125290.72 is added to the Health and Safety Code to read as follows:

125290.72. Expand Alpha Stem Cell Clinic Program and Establish Community Care Centers of Excellence Program.

(a) The institute shall expand the Alpha Stem Cell Clinic Program and establish the Community Care Centers of Excellence Program to fund the establishment of centers of excellence at which clinical trials are conducted and treatments and cures made available for all patients. The goal of the Community Care Centers of Excellence Program is to expand the capacity of the Alpha Stem Cell Clinic Program to promote access to human clinical trials and the accessibility of treatments and cures arising from institute-funded research for patients in California by establishing geographically diverse centers of excellence to conduct clinical trials and to seek to make the resulting treatments and cures broadly available to California patients.

(b) The institute shall prioritize the funding of applications for Community Care Centers of Excellence that ensure the geographic distribution of Community Care Centers of Excellence across the state, considering the location of the Alpha Stem Cell Clinics, to promote patient access. The institute shall prioritize applications for Alpha Stem Cell Clinics and Community Care Centers of Excellence that offer matching funds and/or verified in-kind support, consistent with the highest medical standards, as established by the Governing Board of the institute.

(c) Applications for Alpha Stem Cell Clinic and Community Care Centers of Excellence grants shall be required to include a plan for enhancing access to clinical trials for California patients and making treatments and cures that arise from institute-funded research more widely available to California patients, including addressing how the applicant will support the ancillary hospital and access costs of patients participating in clinical trials to enhance access to trials for California patients, regardless of their economic means and geographical location.

(d) Alpha Stem Clinic and Community Care Centers of Excellence awards shall be made pursuant to the procedures set forth in Article I, Chapter 3, Division 106, Part 5 of the Health and Safety Code.

SEC. 5. Section 125290.73 is added to the Health and Safety Code to read as follows:

125290.73. Scientific and Medical Training and Fellowship Programs.

(a) The institute shall establish training and fellowship programs. The goal of the training and fellowship programs shall be to: (1) ensure that California has the workforce necessary to move new discoveries from the research stage to the clinic; (2) accelerate the accessibility of treatments and cures, and to make treatments and cures arising from institute-funded research available to California patients; (3) prepare California undergraduates and master's students for careers in stem cell research and other vital research opportunities and in the development and delivery of treatments and cures; and (4) to support graduate students, post-doctoral students, and medical residents who work in the fields of stem cell and other vital research opportunities and in the development and delivery of treatments and cures, with fellowships.

(1) (A) The program shall provide awards to California community colleges and California State University campuses to establish training programs to prepare undergraduate and provide fellowships for master's graduate students for advanced degrees and technical careers in stem cell research and other vital research opportunities and the development and delivery of treatments and cures, including hands-on training and education in stem cell research and other vital research opportunities and in the development and delivery of treatments and cures. Direct patient engagement and outreach activities that engage California's diverse communities to ensure that all communities are aware of, and have access to, institute-funded treatments and cures shall be a priority outcome of this program.

(B) The institute may establish co-investment, sponsored apprenticeships as part of the training program in order to leverage the institute's funding and create employment opportunities for students in technical positions that advance the fields of stem cell and other vital research opportunities and the development and delivery of treatments and cures.

(2) (A) The fellowship program shall provide awards to academic and nonprofit research institutions in California to administer fellowship awards to graduate and post-doctoral students and medical residents engaged in stem cell research and other vital research opportunities and the development and delivery of treatments and cures. Fellowship awards may be free-standing or supplemental of other sources of funding.

(B) The institute may establish a program to empower fellows to work in Alpha Stem Cell Clinics and Community Care Centers of Excellence as part of their participation in the fellowship program.

(b) The institute shall prioritize the funding of applications from institutions that ensure the geographic distribution of training and research opportunities across the state to promote patient access and applications that offer matching funds or verified in-kind support.

(c) Training and fellowship program awards shall be made pursuant to the procedures set forth in Article I, Chapter 3, Division 106, Part 5 of the Health and Safety Code.

SEC. 6. Section 125290.74 is added to the Health and Safety Code to read as follows:

125290.74. Shared Research Laboratory Program.

(a) The institute shall re-establish a Shared Research Laboratory Program to provide funding to academic and nonprofit research institutions in California for specialized instrumentation, a supply of cell lines, culture materials, and instruction and training in research methods and techniques. Awardees of Shared Research Laboratory grants shall be required to offer use of the research laboratory to investigators conducting research at the awardee institution and to provide a reasonable access plan for neighboring research institutions, and to offer instruction and training opportunities to students and investigators at the awardee institution and to provide a reasonable access plan for neighboring research institutions.

(b) The institute shall prioritize the funding of applications that ensure the geographic distribution of Shared Research Laboratories across the state and applications that offer matching funds or verified in-kind support.

(c) Shared Research Laboratory Program awards shall be made pursuant to the procedures set forth in Article I, Chapter 3, Division 106, Part 5 of the Health and Safety Code.

SEC. 7. Section 125290.75 is added to the Health and Safety Code to read as follows:

125290.75. Treatments and Cures Accessibility and Affordability Working Group.

(a) Membership

The Treatments and Cures Accessibility and Affordability Working Group shall have 17 members nominated by the Chair or Vice Chair and approved by the Board as follows:

(1) five members of the ICOC (the "Governing Board"), with at least two of those members drawn from the patient advocate appointments.

(2) An individual who has private sector experience in innovative therapy medical coverage terms, qualifications, and the process for reimbursement, including, if possible, experience with coverage negotiations with private insurers, health management organizations, or corporate self-insurance health plans.

(3) an expert or a highly knowledgeable individual with experience in federal therapy coverage, qualifications, and process for reimbursement, including, if possible, experience with the Centers for Medicare and Medicaid Services.

(4) an expert or a highly knowledgeable individual with experience in California's public insurance program (Covered California), coverage, qualifications, and the process for reimbursement of innovative therapies.

(5) two representatives from hospitals in California that are participating in stem cell clinical trials or that are treating patients with Federal Drug Administration-approved stem cell or genetic therapies.

(6) a representative from a philanthropic organization who has experience assisting patients with clinical trial access and affordability, or with access to, and the affordability of, innovative therapies.

(7) two representatives from patient advocacy organizations who have technical expertise or experience in coverage, qualifications, and the process for reimbursement of innovative therapies.

(8) a health care economist, with experience in advising or negotiating with private insurers, government insurers, or corporate self-insurance programs on coverage for innovative therapies or human trials, including experience in assisting hospitals and clinics in covering financial gaps in coverage of the direct and indirect costs of innovative therapies.

(9) a patient navigator with training and experience helping patients obtain financial support from private insurers, public support, or nonprofit support, and helping patients obtain social service support to facilitate their participation in Federal Drug Administration-approved human trials or their qualification for access and financial assistance for innovative therapies.

(10) The chairperson and vice chairperson of the Governing Board.

(b) Functions

The Treatments and Cures Accessibility and Affordability Working Group shall have the following functions:

(1) To examine, develop, and assist with the implementation of financial models to enhance the accessibility and affordability of treatments and cures arising from institute-funded research for Californians, and to enhance access to clinical trials, including reimbursement alternatives for patient-qualified costs to help achieve the objective that reimbursement covers patient expenses, including but not limited to, medical expenses, lodging, meals, and travel for research participants and their caregivers.

(2) To recommend to the Governing Board policies and programs to help Californians obtain access to human clinical trials and to make treatments and cures arising from institute-funded research available to California patients throughout California.

(3) To recommend to the Governing Board policies and programs to help Californians afford to participate in human clinical trials and to make treatments and cures arising from institute-funded research affordable to California patients, regardless of their financial means.

(4) To work with the Alpha Clinics and Community Care Centers of Excellence and other California healthcare institutions, and healthcare payors, including private insurers, government programs, and foundations, to develop model programs and coverage models to promote the access and affordability of treatments and cures arising from institute-funded research for California patients, regardless of their financial means, or the disease, injury, or health condition from which they suffer.

(5) To advise the Governing Board regarding the coverage criteria and the process for reimbursement of innovative therapies and cures arising from institute-funded research and made available to patients through publicly or privately funded programs in California with the goal of expanding access and affordability.

SEC. 8. Section 125290.76 is added to the Health and Safety Code to read as follows:

125290.76. Advisory Task Forces.

(a) Membership

The Chair and the President may appoint one or more advisory task forces to provide expert guidance in areas under the institute’s jurisdiction, including scientific, policy, ethical, financial, and technical matters. The Chair and President shall each appoint an equal number of members with expertise in the area or areas for which advice is sought, including at least one member who has a patient advocate perspective, with at least fifty percent of the members appointed from outside California.

(b) Functions

(1) The advisory task forces shall advise the Board through the Chair and the President, regarding scientific, policy, financial, ethical, and technical matters under the institute’s jurisdiction.

(c) Operations

(1) The advisory task forces shall be advisory only and their operations shall be subject to the requirements applicable to working groups pursuant to Section 125290.50.

(2), Members of the advisory task forces shall be subject to the conflict of interest requirements applicable to members of the working groups, provided that the advisory task forces shall not review, comment upon, or have jurisdiction over any individual grant or loan approval.

SEC. 9. Section 125290.20 of the Health and Safety Code is hereby amended to read as follows:

125290.20. ICOC Membership; Appointments; Terms of Office.

(a) ICOC Membership

The ICOC shall have 35 members, appointed as follows:

(1) The Chancellors of the University of California at San Francisco, Davis, San Diego, Los Angeles, Irvine, and Riverside shall each appoint an executive officer from his or her campus. In addition, the Chancellor of the University of California at San Francisco shall also appoint a faculty member, physician/scientist, researcher, or executive officer from the UCSF Fresno/Clovis campus to promote geographic diversity and access.

(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 seven campuses of the University of California described in paragraph (1), that has demonstrated success and leadership in stem cell research, other vital research opportunities, therapy development, or therapy delivery, 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.

(iv) For purposes of this category, the Governor may appoint an executive officer from the California State University system who has an advanced degree in biological 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, other vital research opportunities, therapy development, or therapy delivery, 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 life sciences exceeding \$20 million annually.

(C) A California life-science commercial entity that is not actively engaged in researching or developing therapies or therapy delivery with pluripotent or progenitor stem cells or genetic medical treatments, that has a background in implementing or developing experimental medical therapies, including conducting human clinical trials, and that has not been awarded, or applied for, funding by the Institute at the time of appointment. A board member of such entity who generally meets the same qualifications 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 nonprofit 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 three members, one from each of the following disease advocacy groups: spinal cord injury; Alzheimer's disease; and mental health conditions.

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

(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 and/or mental health conditions advocacy group.

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

(6) The Treasurer and Controller shall each appoint a nurse with experience in clinical trial management and/or stem cell or genetic therapy delivery.

(7) A chairperson and vice chairperson who shall be elected by the ICOC members. 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 or other vital research opportunity in therapy development and/or therapy delivery 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 paragraph (3), (4), or (5) of subdivision (a).

(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 clauses (i), (iii), and (iv) of subparagraph (A). 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) Forty-five days after the effective date of this act, the Controller and the 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 paragraph (7) of subdivision (a).

(c) ICOC Member Terms of Office

(1) The members appointed pursuant to paragraphs (1), (3), (4), and (5) of subdivision (a) 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.

(4) Notwithstanding paragraph (1), the appointing authority may replace a member, other than the Chair or Vice Chair, who has served, as of the effective date of the Act adding this paragraph, at least half of the member's current term by appointing a new member, who shall be eligible to serve a full term. Such appointments shall be made within 90 days of the effective date of the Initiative adding this paragraph.

SEC. 10. Section 125290.30 of the Health and Safety Code is hereby amended to read as follows:

125290.30. 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 Controller, who shall review the audit and annually issue a public report of that review.

(c) A performance audit shall be commissioned by the institute every three years beginning with the audit for the 2010–11 fiscal year. The performance audit, which may be performed by the Bureau of State Audits, shall examine the functions, operations, management systems, and policies and procedures of the institute to assess whether the institute is achieving economy, efficiency, and effectiveness in the employment of available resources. The performance audit shall be conducted in accordance with government auditing standards, and shall include a review of whether the institute is complying with ICOC policies and procedures. The performance audit shall not be required to include a review of scientific performance. The first performance audit shall include, but not be limited to, all of the following:

(1) Policies and procedures for the issuance of contracts and grants and a review of a representative sample of contracts, grants, and loans executed by the institute.

(2) Policies and procedures relating to the protection or treatment of intellectual property rights associated with research funded or commissioned by the institute.

(d) All administrative costs of the audits required by subdivisions (b) and (c) shall be paid by the institute.

(e) Citizen's Financial Accountability Oversight Committee

There shall be a Citizen's Financial Accountability Oversight Committee chaired by the Controller. This committee shall review the annual financial audit, the Controller's report and evaluation of that audit, and the financial practices of the institute. The Controller, the Treasurer, the President pro Tempore 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 or patient advocacy backgrounds and knowledge of relevant financial matters. The committee shall provide recommendations on the institute's financial practices and performance. The 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 all costs associated with the per diem expenses of the committee members and for publication of the annual report.

(f) Public Meeting Laws

(1) The ICOC shall hold at least four 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 Open 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, under Section 11126 of the Government Code. 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 prepublication, 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 paragraph (2) of subdivision (b) of Section 125290.20 shall be deemed to be a special meeting for the purposes of Section 11125.4 of the Government Code.

(g) 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) Prepublication scientific working papers or research data, including but not limited to applications and progress reports.

(3) The institute shall include, in all meeting minutes, a summary of vote tallies and disclosure of each board member's votes and recusals on all action items.

(h) 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 through 5 (commencing with Section 10500) of Chapter 2.1 of Part 2 of 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 through 5 (commencing with Section 10500) of Chapter 2.1 of Part 2 of 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.

(i) 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 subdivision (e) of Section 125290.50.

(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 an 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, including but not limited to strategic plans, concept plans, and research budgets, 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 nonprofit 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) Section 1090 of the Government Code 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.

(j) Patent Royalties and License Revenues Paid to the State of California

(1) 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 ensure that essential medical research is not unreasonably hindered by the intellectual property agreements. All royalty revenues received through the intellectual property agreements established pursuant to this subdivision shall be deposited into in an interest bearing account in the General Fund, and to the extent permitted by law, the principal and interest shall be appropriated for the purpose of offsetting the costs of providing treatments and cures arising from institute-funded research to California patients who have insufficient means to purchase the treatment or cure, including the reimbursement of patient-qualified costs for research participants.

(2) These standards shall include, at a minimum, a requirement that CIRM grantees, other than loan recipients and facilities grant recipients, share a fraction of the revenue they receive from licensing or self-commercializing an invention or technology that arises from research funded by CIRM, as set forth below.

(A) (i) A grantee that licenses an invention or technology that arises from a research program funded by CIRM, regardless of the number of grants awarded to that research program, shall pay 25 percent of the revenues it receives in excess of five hundred thousand dollars (\$500,000), in the aggregate, to the General Fund. The threshold amount of five hundred thousand dollars (\$500,000) shall be adjusted annually by a multiple of a fraction, the denominator of which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the Bureau of Labor Statistics of the United States Department of Labor and published for the month of October 2009, and the numerator of which is that index published for the month in which the grantee accepts the grant. For awards made on or after November 5, 2020, the threshold amount of five hundred thousand dollars (\$500,000) shall be adjusted annually by a multiple of a fraction, the denominator of which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the Bureau of Labor Statistics of the United States Department of Labor and published for the month of October 2020, and the numerator of which is that index published for the month in which the grantee accepts the grant.

(ii) If funding sources other than CIRM directly contributed to the development of the invention or

technology, then the return to the General Fund shall be calculated as follows: The amount of CIRM funding for the invention or technology shall be divided by the total of funding provided by all sources, and that fraction shall be multiplied by 25. That numeral is the percentage due to the General Fund.

(B) (i) A grantee that self-commercializes a product that results from an invention or technology that arises from research funded by CIRM shall pay an amount to the General Fund equal to three times the total amount of the CIRM grant or grants received by the grantee in support of the research that contributed to the creation of the product. The rate of payback of the royalty shall be at a rate of 3 percent of the annual net revenue received by the grantee from the product.

(ii) In addition to the payment required by clause (i), the first time that net commercial revenues earned by the grantee from the product exceed two hundred fifty million dollars (\$250,000,000) in a calendar year, the grantee shall make a one-time payment to the General Fund equal to three times the total amount of the grant or grants awarded by CIRM to the grantee in support of the research that contributed to the creation of the product.

(iii) In addition to the payments required by clauses (i) and (ii), the first time that net commercial revenues earned by the grantee from the product exceed five hundred million dollars (\$500,000,000) in a calendar year, the grantee shall make an additional one-time payment to the General Fund equal to three times the total amount of the grant or grants awarded by CIRM to the grantee in support of the research that contributed to the creation of the product.

(iv) In addition to the payments required by clauses (i), (ii), and (iii), the first time that net commercial revenues earned by the grantee from the product equal or exceed five hundred million dollars (\$500,000,000) in a calendar year, the grantee shall pay the General Fund 1 percent annually of net commercial revenue in excess of five hundred million dollars (\$500,000,000) for the life of any patent covering the invention or technology, if the grantee patented its invention or technology and received a CIRM grant or grants amounting to more than five million dollars (\$5,000,000) in support of the research that contributed to the creation of the product.

(3) The ICOC shall have the authority to adopt regulations to implement this subdivision. The ICOC shall also have the authority to modify the formulas specified in subparagraphs (A) and (B) of paragraph (2) through regulations if the ICOC determines pursuant to paragraph (1) that a modification is required either in order to ensure that essential medical research, including, but not limited to, therapy development and the broad delivery of therapies to patients, is not unreasonably hindered, or to ensure that the State of California has an opportunity to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials. The ICOC shall notify the appropriate fiscal and policy committees of the Legislature 10 calendar days before exercising its authority to vote on the modification of the formulas specified in subparagraphs (A) and (B) of paragraph (2). The amendments made to this subdivision (j) are not intended to affect the institute's authority to modify the provisions set forth in this subdivision (j) pursuant to this paragraph, including but not limited to any modifications that occurred prior to the effective date of the Initiative amending this subdivision.

(k) 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 percent of such purchases from California suppliers.

(l) Additional Accountability Requirements

To assure strict accountability and transparency, including rigorous conflict of interest rules, ethical research and treatment standards, and independent financial audits, every four years the ICOC shall update, at its discretion, the standards relating to conflict of interest rules, ethical research and treatment, and independent financial audits, to be generally potentially aligned with standards adopted by the National Academy of Sciences to the extent that such standards are consistent with constitutional and statutory requirements applicable to the institute.

SEC. 11. Section 125290.35 of the Health and Safety Code is hereby amended to read as follows:

125290.35. 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 Sections 125300, 125320, 125118, , 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 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.

(b) 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) Permitted Reimbursement

Standards permitting reimbursement for expenses, which shall include but not be limited to medical expenses and lodging, meals, and travel expenses for research participants and caregivers in order to ensure functional access to clinical trials. For purposes of this paragraph, "caregivers" includes family members, friends, and professional caregivers providing supportive care.

~~(4)~~ (5) Patient Privacy Laws

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

(6) 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 costs 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.

(7) Time Limits for Obtaining Cells

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

(8) Standards for Genetic Medical Treatments and Research

Standards for research involving genetic medical treatments which shall generally be based on the standards adopted by the National Academy of Sciences.

SEC. 12. Section 125290.40 of the Health and Safety Code is hereby amended to read as follows:

125290.40. 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 across the research and therapy development and delivery spectrum, from basic research and tools and technology to clinical trials and therapy delivery.
- (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) Develop and implement programs to enhance patient access to affordable stem cell and related

treatments and cures through public hospitals and clinics and establish policies regarding intellectual property rights arising from research funded by the institute.

(g) Establish and oversee the institute’s research, therapy development, and therapy delivery programs, including but not limited to the Alpha Stem Cell Clinics and Community Care Centers of Excellence, training and fellowship, and shared research laboratory programs.

(h) Establish and oversee the development of policies and programs to help make treatments and cures arising from institute-funded research available and affordable for California patients, through engagement with healthcare providers, research and therapy development institutions, businesses, governmental agencies, philanthropists, foundations, and patient advocacy groups, and based on recommendations made by the Treatments and Cures Accessibility and Affordability Working Group.

(i) Establish rules and guidelines for the operation of the ICOC and its working groups.

(j) Perform all other acts necessary or appropriate in the exercise of its power, authority, and jurisdiction over the institute.

(k) Select members of the working groups.

(l) 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~~ 11340 et seq.).

(m) 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. For purposes of subdivision (l), requests for applications, program announcements, and notices of award shall not be considered regulations.

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

(o) 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.

(p) Notwithstanding Section 11005 of the Government Code, 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.

(q) Subject to the restrictions set forth in this article, develop conflict of interest standards and at its discretion, consult with the National Academy of Sciences and the Scientific and Medical Accountability Standards Working Group, for the consideration of funding awards based on best practices established by the National Academies of Sciences to prevent conflicts of interest in the award of research funding and update those standards no less than every four years generally potentially align with standards

adopted by the National Academies of Sciences, subject to the constitutional and statutory requirements applicable to the institute.

SEC. 13. Section 125290.45 of the Health and Safety Code is hereby amended as follows:

125290.45. 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 Section 11042 of the Government Code, 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, which number shall not exceed 70 employees (FTE), excluding members of the working groups who shall not be considered institute employees, and excluding up to 15 additional institute employees (FTE) to support the development of policies and programs to help make treatments and cures arising from institute-funded research available and affordable for Californians. The cap on employees shall not apply to employees funded through sources other than bond proceeds or the General Fund. 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:

(A) The chairperson's primary responsibilities are to manage the ICOC agenda and workflow 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 cashflow plan; to interface with the California Legislature, the United States Congress, the California health care system, and the California public; to optimize all financial leverage opportunities for the institute, including without limitation generating matching or supplemental funds through collaborations with other states, nations, territories, or institutions; 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.

(B) 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 of 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 members of all of its working groups.

(4) Notwithstanding Section 19825 of the Government Code, 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 nonprofit academic and research institutions described in paragraph (2) of subdivision (a) of Section 125290.20, and travel expense reimbursement rates and moving and relocation expense limits.

SEC. 14. Section 125290.50 of the Health and Safety Code is hereby amended as follows:

125290.50. Scientific and Medical Working Groups - General.

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

- (1) Scientific and Medical Research Funding Working Group.
- (2) Scientific and Medical Accountability Standards Working Group.
- (3) Scientific and Medical Research Facilities Working Group.
- (4) Treatments and Cures Accessibility and Affordability Working Group.

(b) Working Group Members

(1) 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, provided that the ICOC may, by a two-thirds vote, reappoint working group members to serve more than two consecutive terms.

(2) Appointments of members of the Treatments and Cures Accessibility and Affordability Working Group shall be made by a majority vote of a quorum of the ICOC, within 90 days of the effective date of the Initiative adding this paragraph. The working group members' terms shall be six years, and members may serve a maximum of two consecutive terms., provided that the ICOC may, by a two-thirds vote, reappoint working group members to serve more than two consecutive terms.

(3) The ICOC may appoint ad hoc voting members to each working group as necessary to obtain expertise for a particular expert review session, not to exceed three members for any one expert review session.

(c) Working Group Meetings

Each group shall hold at least four meetings per year, one of which shall be designated as its annual meeting, except as otherwise determined by the institute.

(d) Working Group Recommendations to the ICOC

Recommendations of each panel 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 panel for that working group. If 35 percent of the members of any working group panel award scores in the funding range, a minority recommendation report, including a summary of the strengths and weaknesses of the application and a rebuttal to the majority recommendation, shall 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 and policies and programs. 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 (Title 9 (commencing with Section 81000) of the Government Code) Sections 1090 and 19990 of the Government Code, and Sections 10516 and 10517 of the Public Contract Code.

(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.

SEC. 15. Section 125290.60 of the Health and Safety Code is hereby amended to read as follows:

125290.60. Scientific and Medical Research Funding Working Group.

(a) Membership

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

(1) Seven ICOC members from the 12 disease advocacy group members described in paragraphs (3), (4), and (5) of subdivision (a) of Section 125290.20 or the members described in paragraph (6) of subdivision (a) of Section 125290.20.

(2) At least 15 scientists nationally recognized in the field of stem cell research or other vital research opportunities, 15 of whom shall be designated to serve on each expert review panel.

(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 paragraphs (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, clinical trial, and therapy delivery grants and loans.

(5) Conduct expert peer review and 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:

An expert review panel shall consist of both scientists and patent advocates. There shall be 15 scientists on each expert peer review panel. Only the 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:

- (1) A demonstrated record of achievement in the areas of pluripotent stem cell and progenitor cell biology and medicine, or in other vital research opportunities.
- (2) 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.
- (3) 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 Institutes of Health shall not be funded by the institute, unless such research funding is not timely or sufficient.
- (4) Notwithstanding paragraph (3), other scientific and medical research and technologies and/or any stem cell research proposal not actually funded by the institute under paragraph (3) 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, or if a majority of a quorum of the members of the ICOC determine, that such a research proposal is a vital research opportunity.

SEC. 16. Section 125290.70.5 is added to the Health and Safety Code to read as follows:

125290.70.5. Appropriation and Allocation of Funding.

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

(1) (A) No less than ninety-five and one half percent (95.5%) of the proceeds of the bonds authorized pursuant to Section 125291.30.5, after allocation of bond proceeds to purposes described in paragraphs (4) and (5) of subdivision (a) of Section 125291.20.5, shall be used for grants and grant oversight as provided in this chapter.

(B) Not less than 98 percent (98%) of the proceeds of bonds used for grants shall be used for research, therapy development, and therapy delivery grants, with no more than the following amounts—as stipulated below— to be committed during the first ten years following the effective date of the Initiative adding this subparagraph, with each year’s funding 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 is as follows: Year 1, 11%; Year 2, 11%; Years 3 through 10, 9%; Year 11 and thereafter, 6% cumulatively. To accomplish the goals of Section 125290.75, up to two percent (2%) of the amount available for grants may be used for research consulting in support of access to, and the affordability of, treatments and cures arising from institute-funded research and therapy development and delivery, as determined by the Governing Board of the institute based on the recommendations of the Treatment and Cures Accessibility and Affordability Working Group and the President.

(C) Not more than three percent (3%) of the proceeds of bonds authorized by Section 125291.30.5 may be used by the institute for research and research facilities implementation costs, including the development, administration and oversight of the grant-making process.

(2) (A) Not more than three and one half percent (3.5%) of the proceeds of the bonds authorized pursuant to Section 125291.30.5 shall be used for the costs of general administration of the Institute.

(B) Not more than one percent (1%) of the proceeds of the bonds authorized pursuant to Section 125291.30.5 may be used by the institute to pay for the costs of up to 15 (FTE) employees over ten to 15 or more years, including but not limited to administrative support, facilities costs, salary, benefits, travel reimbursement, and meeting costs, to support the work of the institute to develop policies and programs to help Californians obtain access to human clinical trials, therapies, mitigating treatments, and cures arising from institute-funded research and to promote the accessibility and affordability of such human clinical trials, treatments, and cures for Californians.

(3) In any single year any new research funding to any single grantee for any program year is limited to no more than one percent of the total bonds authorized pursuant to Section 125291.30.5. 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) Up to one and one half percent (1.5%) of the proceeds of the bonds authorized pursuant to Section 125291.30.5, net of costs described in paragraphs (2), (4) and (5) of subdivision (a) of Section 125291.20.5 shall be allocated for grants to build, equip, or fund operations of Community Care Centers of Excellence and up to one half of one percent (0.5%) shall be allocated to build or equip Shared Labs, which are intended to be operational in the first five years following the effective date of the Initiative adding this Section. Funding received by a grantee from an institute award for construction shall be subject to prevailing wage laws.

(5) The institute shall limit indirect costs to no more than 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) The institute's funding schedule is designed to create a positive tax revenue stream for the state of California during first five calendar years following the voters' approval of the initiative adding this section, without drawing funds from the state general fund for principal and interest payments for those first five calendar years.

(c) The institute shall allocate at least \$1.5 billion of the proceeds of the bonds authorized pursuant to Section 125291.30.5 to make grants for research, therapy development, and therapy delivery involving diseases and conditions of the brain, including but not limited to Alzheimer's disease, Parkinson's disease, stroke, dementia, epilepsy, schizophrenia, depression, traumatic brain injury, brain cancer and autism, and for grant oversight and general administration costs associated with such grants and loans, subject to the limits in subparagraph (C) of paragraph (1) of subdivision (a) of this Section and in subparagraph (A) of paragraph (2) of subdivision (a) of this Section.

(d) The allocation of the proceeds of bonds authorized pursuant to Section 125291.30 shall continue to be governed by Section 125290.70.

SEC. 17. Section 125291.20.5 is added to the Health and Safety Code to read as follows:

125291.20.5. Allocation of Bond Proceeds.

125291.20.5 (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 (1) making grants or loans to fund research and construct facilities for research, all as described in and pursuant to the Initiative adding this Section, (2) paying general administrative costs of the institute (not to exceed three and one half percent (3.5%) of the net proceeds of each sale of bonds), (3) paying the annual administration costs of the interim debt or bonds after December 31 of the fifth full calendar year after the Initiative adding this Section takes effect, (4) 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 the Initiative adding this Section 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 the Initiative adding this Section takes effect, and (5) 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 the Initiative adding this Section takes effect, and paying interest on bonds that accrues on or prior to December 31 of the fifth full calendar year after the Initiative adding this Section takes effect (except that such limitation does not apply to premium and accrued interest as provided in Section 125291.70). 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 3.5 percent limit set forth in (ii) above, so long as such three and one half percent (3.5%) 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 for the purposes of the Initiative adding this Section, including the institute's administrative costs, or for paying continuing costs of the annual administration of outstanding bonds.

SEC. 18. Section 125291.30.5 is added to the Health and Safety Code to read as follows:

125291.30.5. Authorization of Bonds.

125291.30.5. Bonds in the total amount of five billion and five hundred million dollars (\$5,500,000,000), not including the amount of any refunding bonds issued in accordance with Section 125291.75, 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 125291.20.5 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.

SEC. 19. Section 125291.45 of the Health and Safety Code is hereby amended to read as follows:

125291.45. Bond Issuance Terms.

125291.45 (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. The committee shall use reasonable efforts to issue bonds with pricing at par or better and to pay the issuance costs out of premium if reasonably achievable. 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. The costs of each bond issue sold on or after the sixty-first month after the Initiative amending this article takes effect shall be spread over a period of time of up to a maturity of 40 years at the discretion of the Treasurer.

(b) The total amount of the bonds authorized by Section 125291.30 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) For purposes of Section 125291.30, 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 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 General Fund and to implement such alternate financing plan.

(d) The total amount of the bonds authorized by Section 125291.30.5 which may be issued in any calendar year, commencing in 2021, shall not exceed the higher of five hundred fifty million dollars (\$550,000,000) or one half of one percent (0.5%) of the total amount of the state's outstanding and authorized General Obligation bonds, in the aggregate total, as of January 1, 2020. 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. Pursuant to Section 125291.60, the Director of Finance may authorize a loan from the General Fund to the institute on or after the effective date of the Initiative adding this paragraph.

SEC. 20. Section 125292.10 of the Health and Safety Code is hereby amended to read as follows:

125292.10. Definitions.

125292.10. 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 125290.10) 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, such as a cell which is committed to make all of the functional cells of the tissue or organ in which it resides and regenerates but which is itself undifferentiated.

(c) “Basic research” means the investigation of basic mechanisms underlying stem cell biology, cellular plasticity, cellular differentiation and other vital research opportunities.

(d) “Capitalized interest” means interest funded by bond proceeds.

(e) “Committee” means the California Stem Cell Research and Cures Finance Committee created pursuant to subdivision (a) of Section 125291.40.

“(f) Constitutional officers” means the Governor, Lieutenant Governor, Treasurer, and Controller of California.

(g) “Early development” means discovery of promising new stem-cell based technologies that could be translated to enable broad use and ultimately improve patient care.

(h) “Facilities” means buildings, building leases, or capital equipment.

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

(j) “Fund” means the California Stem Cell Research and Disease Cures Fund created pursuant to Section 125291.25.

(k) “Grant” means a grant, loan, or guarantee.

(l) “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.

(m) “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.

(n) “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.

(o) “Institute” means the California Institute for Regenerative Medicine.

(p) “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 11340 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.

(q) “Life science commercial entity” means a firm or organization, headquartered in California, whose business model includes biomedical or biotechnology product development and commercialization.

(r) “Medical ethicist” means an individual with advanced training in ethics who holds a Ph.D., MA, or equivalent training and who spends or has spent substantial time (1) researching and writing on ethical issues related to medicine, and (2) administering ethical safeguards during the clinical trial process, particularly through service on institutional review boards.

(s) “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.

(t) “Progenitor cells” means multipotent or precursor cells that are partially differentiated but retain the ability to divide and give rise to differentiated cells.

(u) “Quorum” means at least 65 percent of the members who are eligible to vote.

(v) “Research donor” means a human who donates biological materials for research purposes after full disclosure and consent.

(x) “Research funding” includes interdisciplinary scientific and medical funding for basic research, tools and technologies, therapy development, and the development of treatments through clinical trials, including without limitation the reimbursement of patient-qualified costs for research participants and their caregivers pursuant to paragraph (4) of subdivision (b) of Section 125290.35; the operations of the Working Groups, including the costs associated with the expert review of applications; the costs of advisory groups and consultants established or retained to evaluate and advise the Governing Board, the Working Groups, and awardees; and research conferences. When a facility’s 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.

(y) “Research participant” means a human enrolled with full disclosure and consent, and participating in clinical trials.

(z) “Research program” means research projects that are designed to advance the same ultimate goal along the research continuum and that are conducted by the same or overlapping investigators.

(aa) “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 General Fund in the same year.

(ab) “Stem cells” mean nonspecialized cells that have the capacity to divide in culture and to differentiate into more mature cells with specialized functions.

(ac) “Stem cell discovery research” means basic research, early development, and the discovery, evaluation, or improvement of tools and technologies in the fields of stem cell and genetic research and other vital research opportunities.

(ad) “Vital research opportunity” means scientific and medical research and technologies, including but not limited to genetics, personalized medicine, and aging as a pathology, and/or any stem cell research not actually funded by the institute under paragraph (3) of subdivision (c) of Section 125290.60 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, or as determined by the vote of a majority of a quorum of members of the ICOC. Human reproductive cloning shall not be a vital research opportunity.

SEC. 21. Amendment.

The provisions of this Initiative, except the bond provisions, may not be amended before the measure is approved by the voters. The provisions of this Initiative may be amended after its approval by the voters by a statute that is passed by a vote of seventy percent of the members of each house of the Legislature and signed by the Governor, provided that such amendments are consistent with and further the intent of the grant and loan programs created by this Initiative.

SEC. 22. Severability.

If any provision of this Initiative, or part of this Initiative, or the application of any provision or part to any person or circumstances, is for any reason held to be invalid, the remaining provisions, or applications of provisions, shall not be affected, but shall remain in full force and effect, and to this end the provisions of this Initiative are severable. If a court were to find in a final, unreviewable judgment that the exclusion of one or more entities or activities from the applicability of the Initiative renders the Initiative unconstitutional, those exceptions should be severed, and the Initiative should be made applicable to the entities or activities formerly exempt from the Initiative. It is the intent of the voters that this Initiative would have been enacted regardless of whether any invalid provision had been included or any invalid application had been made.

SEC. 23. Conflicting Initiatives.

(a) In the event that this Initiative and another measure addressing medical research or therapy development shall appear on the same statewide ballot, the provisions of the other measure or measures shall be deemed to conflict with this measure. In the event that this Initiative receives a greater number of affirmative votes than a measure deemed to conflict with it, the provisions of this Initiative shall prevail in their entirety, and the other measure or measures shall be null and void.

(b) If this Initiative is approved by the voters but superseded by law by any other conflicting measure approved by voters by a greater number of votes at the same election, and the conflicting ballot measure is later held invalid, this Initiative shall be self-executing and given full force and effect.

SEC. 24. Standing.

Notwithstanding any other provision of law, if the State, or any of its officials fail to defend the constitutionality of this Initiative, following its approval by the voters, any other state governmental agency of this State shall have the authority to intervene in any court action challenging the constitutionality of this Initiative for the purpose of defending its constitutionality, whether such action is in state or federal trial court, on appeal, or on discretionary review by the Supreme Court of California and/or the Supreme Court of the United States. The reasonable fees and costs of defending the action shall be a charge on funds appropriated to the California Department of Justice, which shall be satisfied promptly.

SEC. 25. Liberal Construction.

This Initiative shall be liberally construed to effectuate its purposes.