

AMENDED IN ASSEMBLY APRIL 26, 2006
AMENDED IN ASSEMBLY APRIL 5, 2006
AMENDED IN ASSEMBLY MARCH 7, 2006
AMENDED IN ASSEMBLY JUNE 15, 2005
AMENDED IN SENATE MAY 4, 2005
AMENDED IN SENATE APRIL 12, 2005
AMENDED IN SENATE APRIL 4, 2005

SENATE BILL

No. 401

Introduced by Senators Ortiz and Runner
(Coauthors: Assembly Members Jones and Laird)

February 17, 2005

An act to amend Sections 125290.30 and 125290.50 of the Health and Safety Code, relating to stem cell research, *and calling a special election to be consolidated with the statewide general election of November 7, 2006, to take effect immediately as an act calling an election.*

LEGISLATIVE COUNSEL'S DIGEST

SB 401, as amended, Ortiz. Stem cell research: ICOC procedures.

The California Stem Cell Research and Cures Act, an initiative measure, establishes the California Institute for Regenerative Medicine, the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in the cure for, or substantial mitigation of, diseases and injuries. Existing law establishes the Independent

Citizen's Oversight Committee (ICOC), composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute.

Existing law sets forth public meeting, public records, and conflict-of-interest provisions applicable to the ICOC and requires the ICOC to 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.

Existing law exempts the ICOC working groups from the state open meetings laws and the Public Records Act and, with certain exceptions, makes working group records submitted to the ICOC for approval subject to the Public Records Act.

This bill would delete these working group open meeting and public records provisions and modify the public hearing and public records provisions applicable to the ICOC, the Citizen's Financial Accountability Oversight Committee, and the advisory and working groups established to assist these bodies, and would set forth minimum intellectual property licensing conditions applicable to ICOC standards for research grants and loans. This bill would modify the conflict-of-interest provisions applicable to members of ICOC working or advisory groups.

Existing law prohibits amendment of the initiative measure by the Legislature unless the amendment is approved by the voters, or the amendment is accomplished by a bill introduced after the first 2 full calendar years and approved by a vote of 70% of both houses.

~~This bill would provide for submission of the measure to the voters at the next statewide election, and would condition the changes upon voter approval pursuant to prescribed provisions of law.~~

This bill would call a special election to be consolidated with the statewide general election scheduled for November 7, 2006. It would condition the amendment of the initiative upon voter approval, and would require the Secretary of State to submit the provisions of the bill that amend the initiative statute to the voters for their approval at the November 7, 2006, consolidated statewide general election.

This bill would declare that it is to take effect immediately as an act calling an election.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 125290.30 of the Health and Safety
2 Code is amended to read:
3 125290.30. Public and Financial Accountability Standards
4 (a) Annual Public Report
5 The institute shall issue an annual report to the public which
6 sets forth its activities, grants awarded, grants in progress,
7 research accomplishments, and future program directions. Each
8 annual report shall include, but not be limited to, the following:
9 the number and dollar amounts of research and facilities grants;
10 the grantees for the prior year; the institute’s administrative
11 expenses; an assessment of the availability of funding for stem
12 cell research from sources other than the institute; a summary of
13 research findings, including promising new research areas; an
14 assessment of the relationship between the institute’s grants and
15 the overall strategy of its research program; a report of the
16 institute’s strategic research and financial plans; and the detailed
17 and verifiable progress that the institute has made to promote
18 diversity in the hiring, contracting, and grant and loan making
19 functions of the institute.
20 (b) Independent Financial Audit for Review by State
21 Controller
22 The institute shall annually commission an independent
23 financial audit of its activities from a certified public accounting
24 firm, which shall be provided to the State Controller, who shall
25 review the audit and annually issue a public report of that review.
26 (c) Citizen’s Financial Accountability Oversight Committee
27 There shall be a Citizen’s Financial Accountability Oversight
28 Committee chaired by the State Controller. This committee shall
29 review the annual financial audit, the State Controller’s report
30 and evaluation of that audit, and the financial practices of the
31 institute. The State Controller, the State Treasurer, the President
32 pro Tempore of the Senate, the Speaker of the Assembly, and the
33 Chairperson of the ICOC shall each appoint a public member of
34 the committee. Committee members shall have medical
35 backgrounds and knowledge of relevant financial matters. The

1 committee shall provide recommendations on the institute’s
2 financial practices and performance. The State Controller shall
3 provide staff support. The committee shall hold a public meeting,
4 with appropriate notice, and with a formal public comment
5 period. The committee shall evaluate public comments and
6 include appropriate summaries in its annual report. The ICOC
7 shall provide funds for the per diem expenses of the committee
8 members and for publication of the annual report.

9 (d) Public Meeting Laws

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

14 (2) The Bagley-Keene Open Meeting Act, Article 9
15 (commencing with Section 11120) of Chapter 1 of Part 1 of
16 Division 3 of Title 2 of the Government Code, shall apply to all
17 meetings of the ICOC, the Citizen’s Financial Accountability
18 Oversight Committee, and any working or advisory group
19 established to assist these bodies except as otherwise provided in
20 this section. The ICOC shall award all grants, loans, and
21 contracts in public meetings and shall adopt all governance,
22 scientific, medical, and regulatory standards in public meetings.

23 (3) The ICOC, the Citizen’s Financial Accountability
24 Oversight Committee, and any working or advisory group
25 established to assist these bodies, may conduct closed sessions as
26 permitted by the Bagley-Keene Open Meeting Act, under Section
27 11126 of the Government Code. In addition, these bodies may
28 conduct closed sessions when any of these bodies meets to
29 consider or discuss:

30 (A) Individually identifiable information regarding the
31 medical history of, mental or physical condition of, or treatment
32 of, a patient or medical subject, except to the extent that the
33 person has waived his or her right to confidentiality regarding
34 that information.

35 (B) Confidential intellectual property or work product,
36 whether patentable or not, including, but not limited to, any
37 formula, plan, pattern, process, tool, mechanism, compound,
38 procedure, production data, or compilation of information, which
39 is not patented, which is known only to certain individuals who
40 are using it to fabricate, produce, or compound an article of trade

1 or a service having commercial value and which gives its user an
2 opportunity to obtain a business advantage over competitors who
3 do not know it or use it.

4 (C) Prepublication scientific working papers, or research data.

5 (D) The appointment, employment, performance,
6 compensation, or dismissal of individual institute officers and
7 employees. Action on compensation of the institute's officers and
8 employees shall only be taken in open session.

9 (E) (i) The scientific evaluation of any application for
10 research, training, or facility grants or loans submitted for
11 funding. However, any working or advisory group that is charged
12 with reviewing and recommending applications for research,
13 training, or facility grants or loans shall produce a written
14 summary that shall be a public record of the reasons for
15 recommending or not recommending any application for funding.

16 (ii) The written summaries specified in clause (i) shall be
17 posted on the ICOC's Web site at least 10 days prior to the
18 ICOC's consideration for any recommendations for funding and
19 shall include all of the following:

20 (I) In the case of any application that is recommended for
21 funding: the name of the applicant, the title and subject of the
22 application, a description of how the project proposed in the
23 application could benefit the state, a brief summary of the
24 scientific evaluation of the project, the consolidated scientific
25 score for the project, and the final recommendation of the full
26 working or advisory group on the application.

27 (II) In the case of any application that is not recommended for
28 funding: a short description of the project proposed in the
29 application, the disease category addressed by the proposed
30 project, the geographic region represented by that project, and the
31 general reasons for the decision not to recommend the
32 application for funding.

33 (4) The meeting required by paragraph (2) of subdivision (b)
34 of Section 125290.20 shall be deemed to be a special meeting for
35 the purposes of Section 11125.4 of the Government Code.

36 (e) Public Records

37 (1) The California Public Records Act, Article 1 (commencing
38 with Section 6250) of Chapter 3.5 of Division 7 of Title 1 of the
39 Government Code, shall apply to all records of the institute,
40 except as otherwise provided in this section.

1 (2) This section does not require disclosure of any record
2 exempt from disclosure under the California Public Records Act.
3 Moreover, nothing in this section shall be construed to require
4 disclosure of any records that are any of the following:

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

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

18 (C) Prepublication scientific working papers or research data.

19 (f) Competitive Bidding

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

25 (2) For all institute contracts, the ICOC shall follow the
26 procedures required of the regents by Article 1 (commencing
27 with Section 10500) of Chapter 2.1 of Part 2 of Division 2 of the
28 Public Contract Code with respect to contracts let by the
29 University of California.

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

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

34 (g) Conflicts of Interest

35 (1) The Political Reform Act, Title 9 (commencing with
36 Section 81000) of the Government Code, shall apply to the
37 institute and to the ICOC, except as provided in this section and
38 in subdivision (e) of Section 125290.50.

39 (A) No member of the ICOC shall make, participate in
40 making, or in any way attempt to use his or her official position

1 to influence a decision to approve or award a grant, loan, or
2 contract to his or her employer, but a member may participate in
3 a decision to approve or award a grant, loan, or contract to a
4 nonprofit entity in the same field as his or her employer.

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

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

12 (2) Service as a member of the ICOC by a member of the
13 faculty or administration of any system of the University of
14 California shall not, by itself, be deemed to be inconsistent,
15 incompatible, in conflict with, or inimical to the duties of the
16 ICOC member as a member of the faculty or administration of
17 any system of the University of California and shall not result in
18 the automatic vacation of either such office. Service as a member
19 of the ICOC by a representative or employee of a disease
20 advocacy organization, a nonprofit academic and research
21 institution, or a life science commercial entity shall not be
22 deemed to be inconsistent, incompatible, in conflict with, or
23 inimical to the duties of the ICOC member as a representative or
24 employee of that organization, institution, or entity.

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

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

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

36 (h) Patent Royalties and License Revenues Paid to the State of
37 California

38 (1) The ICOC shall establish standards that require that all
39 grants and loan awards be subject to intellectual property
40 agreements that balance the opportunity of the State of California

1 to benefit from the patents, royalties, and licenses that result from
2 basic research, therapy development, and clinical trials with the
3 need to assure that essential medical research is not unreasonably
4 hindered by the intellectual property agreements. The ICOC shall
5 establish and apply minimum licensing conditions to its grants
6 and loans for research ~~and facilities~~ consisting of the following:

7 (A) A requirement that every recipient of grant or loan awards
8 for research that is a nonprofit research institution provide to the
9 state a portion of net licensing revenues from any invention,
10 research finding or tool, or technology that it develops using
11 funds from the grant or loan award, as follows:

12 (i) The grant or loan recipient shall provide 50 percent of the
13 net licensing revenues beyond a reasonable revenue threshold
14 that the ICOC may establish if the state shares in the expenses of
15 developing and protecting any patent on the invention, research
16 finding or tool, or technology.

17 (ii) The grant or loan recipient shall provide 25 percent of the
18 net licensing revenues beyond a reasonable revenue threshold
19 that the ICOC may establish if the state does not share in the
20 expenses of developing and protecting any patent on the
21 invention, research finding or tool, or technology.

22 (B) For any grant or loan for research that is to be financed
23 with taxable bonds, the ICOC shall require a higher level of
24 royalties than set forth in subparagraph (A), if a higher level is
25 necessary to offset the additional cost of using taxable bonds.

26 (C) For any grant or loan for research that is financed with
27 nontaxable bonds, the ICOC may require that the royalties
28 required by this subdivision be paid directly to a nonprofit
29 organization that is dedicated to enhancing access to clinical
30 trials and therapies for low-income populations, rather than being
31 paid to the state, if the institute determines for tax reasons that
32 receipt of the royalties by the state would preclude the use of
33 nontaxable bonds.

34 (D) A requirement that every recipient of a grant or loan
35 award for research that is a *nonprofit* research institution require
36 every licensee who develops a product, drug, or therapy using
37 any invention, research finding or tool, or technology developed
38 with funds from the grant or loan award to agree to sell the
39 product, drug, or therapy to state and county health programs at a
40 cost not to exceed the federal Medicaid price.

1 (E) A requirement that every recipient of a grant or loan award
2 for research that is a commercial entity agree, as a condition of
3 accepting the funds, to sell any product, drug, or therapy that it
4 develops using grant or loan funds to state and county health
5 programs at a cost not to exceed the federal Medicaid price.

6 (F) A requirement that any recipient of a grant or loan award
7 for research that is a commercial entity provide royalty payments
8 to the state at a rate that is consistent with the rates historically
9 received by the University of California for research agreements
10 with biotechnology and pharmaceutical commercial entities for
11 that type of research.

12 (2) The ICOC shall seek licensing conditions that would
13 provide greater financial benefits to the state than those required
14 by paragraph (1) where it is possible to do so without hindering
15 research and development of promising stem cell therapies and
16 treatments.

17 (3) The ICOC shall impose any licensing conditions in its
18 grants and loans for research that are necessary to ensure the free
19 and open dissemination of basic research tools and findings,
20 including research exemptions, open source and nonexclusive
21 licensing, development of patent pools, and other provisions the
22 ICOC finds are necessary to ensure open dissemination.

23 (4) The ICOC shall require a grantee or licensee to grant a
24 nonexclusive, partially exclusive, or exclusive license to a
25 responsible applicant if the ICOC determines that the grantee or
26 licensee is violating the terms of licensing conditions, or if the
27 grantee or licensee is not making efforts in a reasonable period of
28 time to achieve practical application of an invention developed
29 with grant or loan funds, or if it is necessary to alleviate health
30 and safety needs. With the exception of actions to address health
31 and safety needs, prior to exercising this authority, the institute
32 shall give the grantee or licensee an opportunity to bring its
33 actions into compliance with the licensing conditions.

34 (5) For the purposes of this subdivision, “net licensing
35 revenue” shall include all forms of financial consideration from
36 licensing, including cash and corporate equity, and shall be
37 defined as gross licensing revenues, less patent expenses and
38 reasonable payments to inventors.

39 (6) Any proposed intellectual property agreement between the
40 ICOC and a grantee or loan recipient shall be reviewed by the

1 Attorney General prior to its approval by the ICOC, and the
2 ICOC shall consider any comments by the Attorney General
3 prior to approving the agreement.

4 (i) Preference for California Suppliers

5 The ICOC shall establish standards to ensure that grantees
6 purchase goods and services from California suppliers to the
7 extent reasonably possible, in a good faith effort to achieve a
8 goal of more than 50 percent of such purchases from California
9 suppliers.

10 SEC. 2. Section 125290.50 of the Health and Safety Code is
11 amended to read:

12 125290.50. Scientific and Medical Working
13 Groups—General

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

16 (1) Scientific and Medical Research Funding Working Group.

17 (2) Scientific and Medical Accountability Standards Working
18 Group.

19 (3) Scientific and Medical Research Facilities Working Group.

20 (b) Working Group Members

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

33 (c) Working Group Meetings

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

37 (d) Working Group Recommendations to the ICOC

38 Recommendations of each of the working groups may be
39 forwarded to the ICOC only by a vote of a majority of a quorum
40 of the members of each working group. If 35 percent of the

1 members of any working group join together in a minority
2 position, a minority report may be submitted to the ICOC. The
3 ICOC shall consider the recommendations of the working groups
4 in making its decisions on applications for research and facility
5 grants and loan awards and in adopting regulatory standards.
6 Each working group shall recommend to ICOC rules, procedures,
7 and practices for that working group.

8 (e) Conflict of Interest

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

13 (2) (A) Upon his or her appointment, and each year thereafter
14 at a time specified by the ICOC, each member of a working or
15 advisory group appointed to assist the institute or its governing
16 body shall disclose to the ICOC any income, real property, and
17 investments they or a close family member has in all of the
18 following:

19 (i) A California-based academic or nonprofit research
20 institution.

21 (ii) A biotechnology or pharmaceutical company.

22 (iii) Real property interests in California.

23 (B) In addition to the disclosures in subparagraph (A), a
24 member who is appointed to the facilities working group shall
25 disclose all construction, real estate, and development firms from
26 which they or a family member receives or has received
27 economic benefits.

28 (C) The ICOC shall provide the disclosures to the State
29 Auditor. The State Auditor, or his or her successor, shall review
30 at least annually the disclosures, in addition to the voting record
31 of each working or advisory group member regarding
32 recommendations for applications for research and facility grants
33 and loan awards and regulatory standards, and submit an annual
34 report to the Legislature containing findings on whether any of
35 the votes made by these members may constitute, or has
36 constituted, a *financial* conflict of interest that requires or
37 required the member to recuse himself or herself from
38 consideration of an application or standard if the member is
39 otherwise required under existing law to recuse himself or
40 herself.

1 (D) A working group member shall not vote or participate in
2 the consideration of any grant, loan, or project submitted for
3 funding if he or she has a financial conflict of interest.

4 (3) For purposes of this subdivision, “financial conflict of
5 interest” means that the working or advisory group member, or a
6 close relative or professional associate of the member, has a
7 financial or other monetary interest in an application or standard
8 that is known to the member, including a direct benefit of any
9 amount deriving from an application or standard, or a financial
10 benefit of any type from an applicant institution of over five
11 thousand dollars (\$5,000) per year, including honoraria, fees,
12 stock, or other benefits. For purposes of this paragraph, “close
13 relative” and “professional associate” shall have the same
14 meaning as those terms are defined under the National Institutes
15 of Health Conflict of Interest, Confidentiality and
16 Non-Disclosure Rules.

17 (4) The ICOC shall appoint an ethics officer from among the
18 staff of the institute.

19 (5) Because the working groups are purely advisory and have
20 no final decisionmaking authority, members of the working
21 groups shall not be considered public officials, employees, or
22 consultants for purposes of the Political Reform Act (Title 9
23 commencing with Section 81000) of the Government Code,
24 Sections 1090 and 19990 of the Government Code, and Sections
25 10516 and 10517 of the Public Contract Code.

26 ~~SEC. 3. As an amendment of an initiative, Sections 1 and 2 of~~
27 ~~this act shall become effective only upon approval by the voters~~
28 ~~at a statewide election. The Secretary of State shall submit~~
29 ~~Sections 1 and 2 of this act to the voters at the next statewide~~
30 ~~election pursuant to Section 9040 of the Elections Code.~~

31 *SEC. 3. (a) As an amendment of an initiative statute,*
32 *Sections 1 and 2 of this act shall become effective only upon*
33 *approval by the voters at a statewide election.*

34 *(b) A special election is hereby called, to be held throughout*
35 *the state on November 7, 2006, for approval by the voters of*
36 *Sections 1 and 2 of this act. The special election shall be*
37 *consolidated with the statewide general election to be held on*
38 *that date. The consolidated elections shall be held and conducted*
39 *in all aspects as if there were only one election, and only one*
40 *form of ballot shall be used.*

1 (c) *Notwithstanding Section 9040 of the Elections Code, or*
2 *any other provision of law, the Secretary of State shall, pursuant*
3 *to subdivision (c) of Section 10 of Article II of the Constitution,*
4 *submit Sections 1 and 2 of this act to the voters for their approval*
5 *at the November 7, 2006, consolidated statewide general*
6 *election.*

7 *SEC. 4. This act calls an election within the meaning of*
8 *Article IV of the Constitution and shall go into immediate effect.*

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