2006 California Stem Cell Research-Related Active Bill Update
As of May 25, 2006

Assembly Bill (AB) 2721 (Mullin)
Office of Intellectual Property

- Establishes the Office of Intellectual Property in the Business, Transportation and Housing Agency. The office would be responsible to:
    - track intellectual property generated by state employees and by state funded research,
    - develop a database to track intellectual property,
    - establish and update guidelines for use by state agencies in administering their intellectual property, including:
        - Policies concerning the criteria for determining which products will be treated as intellectual property.
        - Policies concerning the criteria for determining which products should be placed into the public domain.
        - Factors that state agencies should consider when deciding whether to sell an intellectual property or license it to others.
    - develop an outreach campaign informing state agencies of their rights and abilities concerning intellectual property, and
    - develop sample invention assignment agreements that state agencies can consider if they believe it is necessary to secure the rights to potentially patentable items created by their employees on work time using state resources;
    - develop sample language for licenses or terms-of-use agreements that state agencies can use to limit the use of their intellectual property by others to only appropriate purposes
- Creates criteria for IP contracts, grants, and agreements entered into by a state agency on and after January 1, 2008 including:
    - Permits grantees to own intellectual property rights from state-funded research, provided a state agency can decide that, in appropriate cases, the intellectual property rights shall be dedicated to the public domain.
    - Requires that grantees, including institutions, individuals, or both, provide a plan describing how intellectual property will be managed for the benefit to California.
    - Requires that grantees, including institutions, individuals, or both, make research tools developed with any state funds widely available to other researchers.
    - Requires diligent efforts by grantees to develop state-funded intellectual property subject to the federal Patent Act into applications and products that benefit the public.
    - Reserves the right to use the intellectual property by, or on behalf of, the state for research or noncommercial purposes.
- Applies to IP policies established on and after January 1, 2008 that with respect to any subject invention in which a grantee has acquired title under this chapter, the state agency under whose funding agreement the subject invention was made shall have the right, in accordance with procedures specified in regulations adopted pursuant to this chapter, provided that these regulations shall promote, and not hinder, the availability of the state's rights under this subdivision, to require the contractor, an assignee, or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in

any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances.

- States that if the contractor, assignee, or exclusive licensee refuses the request, the state agency may grant the license itself, notwithstanding the contract, grant, or agreement, if the state agency determines that action is necessary based upon one or more of the following factors:
    - The contractor or assignee has not taken, or is not expected to take, within a reasonable time, effective steps to achieve practical application of the subject invention in that field of use.
    - To alleviate health or safety needs that are not reasonably satisfied by the contractor, assignee, or their licensees.
    - To meet requirements for public use specified by state regulations, and these requirements are not reasonably satisfied by the contractor, assignee, or licensees.
- Applies IP policies established on and after January 1, 2008: State agencies and state grantees, contractors, assignees, and licensees shall grant exclusive licenses involving state-funded patented inventions, where the state funding is not minimal, relevant to therapies and diagnostics only to organizations with plans to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, these licensees will agree to provide to patients whose therapies and diagnostics will be purchased in California by public funds the therapies and diagnostics at a cost not to exceed the federal Medicaid price. The state agency may make access plans available for review by the Office of Intellectual Property annually.
- States that every contract, grant, or agreement for research funded by a grant from a state agency is required that, if a revenue stream develops from research or as a product of the research, the state agency shall receive a royalty from that revenue, provided that the royalty is proportional to the state investment and payable on net revenue.
- States that when royalties are limited by application of the federal Bayh-Dole Act, all revenue derived from royalties shall be deposited into a fund within the granting state agency. The revenue shall be reinvested into the research program funded by the grant, or invested into education in the area researched.-
- Requires that State agencies or departments shall submit an annual report regarding these
- royalties to the Office of Intellectual Property.
- CIRM exemption – "This chapter shall not apply to intellectual property agreements governed by the California Stem Cell Research and Cures Bond Act (Chapter 3 (commencing with Section 125290.10) of Part 5 of Division 106 of the Health and Safety Code)."

Status: Introduced on February 25, 2006 and passed out of Assembly Judiciary Committee. Voted out of the Appropriations Committee on May 25, 2006 and now on the Assembly floor.

Senate Bill (SB) 401 (Ortiz/Runner)
Amendments to the California Stem Cell Research & Cures Act

Note: Amendments to SB 401 were presented by Sen. Ortiz on 5/17 but they are not yet in print. This summary covers the measure based upon the most available version in print.

This bill, if passed by a majority in both houses and signed by the Governor, would be placed on the next statewide ballot. It would modify the public hearing and conflict-of-interest procedures of members of 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 and facilities grants and loans.

- Requires that the Bagley-Keene Open Meeting Act, shall apply to all meetings of the Citizen's Financial Accountability Oversight Committee, and any working or advisory group established to assist these bodies.
- Allows for closed session of these committees for:
    - Individually identifiable information regarding the medical history of, mental or physical condition of, or treatment of, a patient or medical subject, except to the extent that the person has waived his or her right to confidentiality regarding that information;
    - 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;
    - Prepublication scientific working papers or research data;
    - The scientific evaluation of any application for research, training, or facility grants or loans submitted for funding. However, any working or advisory group that is charged with reviewing and recommending applications for research, training, or facility grants or loans shall produce a written summary that shall be a public record of the reasons for recommending or not recommending any application for funding;
- Requires that the written summaries shall be posted on the ICOC's Web site at least 10 days prior to the ICOC's consideration for any recommendations for funding and shall include all of the following:
    - In the case of any application that is recommended for funding: the name of the applicant, the title and subject of the application, a description of how the project proposed in the application could benefit the state, a brief summary of the scientific evaluation of the project, the consolidated scientific score for the project, and the final recommendation of the full working or advisory group on the application;
    - In the case of any application that is <u>not</u> recommended for funding: a short description of the project proposed in the application, the disease category addressed by the proposed project, the geographic region represented by that project, and the general reasons for the decision not to recommend the application for funding.
- Requires that the ICOC establish and apply minimum licensing conditions to its grants and loans for research and facilities consisting of the following:
    - Every recipient of grant or loan awards for research that is a research institution provide to the state a portion of net licensing revenues from any invention, research finding or tool, or technology that it develops using funds from the grant or loan award, as follows:

        - The grant or loan recipient will provide 50 percent of net licensing revenues if the state shares in the expenses of developing and protecting any patent on the invention, research finding or tool, or technology.
        - The grant or loan recipient will provide 25 percent of the net licensing revenues if the state does not share in the expenses of developing and protecting any patent on the invention, research finding or tool, or technology.
    - For any grant or loan for research that is to be financed with taxable bonds, the ICOC shall require a higher level of royalties than set forth above, if a higher level is necessary to offset the additional cost of using taxable bonds.
    - For any grant or loan for research that is financed with nontaxable bonds, the ICOC may require that the royalties required by this subdivision be paid directly to a nonprofit organization that is dedicated to enhancing access to clinical trials and therapies for low-income populations, rather than being paid to the state, if the institute determines for tax reasons that receipt of the royalties by the state would preclude the use of nontaxable bonds.
    - For every recipient of a grant or loan award for research that is a nonprofit research institution, requires every licensee who develops a product, drug, or therapy using any invention, research finding or tool, or technology developed with funds from the grant or loan award to agree to sell the product, drug, or therapy to state and county health programs at a cost not to exceed the federal Medicaid price.
    - For every recipient of a grant or loan award for research that is a commercial entity agree, as a condition of accepting the funds, to sell any product, drug, or therapy that it develops using grant or loan funds to state and county health programs at a cost not to exceed the federal Medicaid price.
    - For any recipient of a grant or loan award for research that is a commercial entity, to provide royalty payments to the state at a rate that is consistent with the rates historically received by the University of California for research agreements with biotechnology and pharmaceutical commercial entities for that type of research.
- Requires that the ICOC seek licensing conditions that would provide greater financial benefits to the state than those required above where it is possible to do so without hindering research and development of promising stem cell therapies and treatments.
- Requires that the ICOC impose any licensing conditions in its grants and loans for research that are necessary to ensure the free and open dissemination of basic research tools and findings, including research exemptions, open source and nonexclusive licensing , development of patent pools, and other provisions the ICOC finds are necessary to ensure open dissemination.
- Requires that the ICOC require a grantee or licensee to grant a nonexclusive, partially exclusive, or exclusive license to a responsible applicant if the ICOC determines that the grantee or licensee is violating the terms of licensing conditions, or if the grantee or licensee is not making efforts in a reasonable period of time to achieve practical application of an invention developed with grant or loan funds, or if it is necessary to alleviate health and safety needs. Requires, with the exception of actions to address health and safety needs, prior to exercising this authority, the institute to give the grantee or licensee an opportunity to bring its actions into compliance with the licensing conditions.

- Defines "net licensing revenue" as to include all forms of financial consideration from licensing, including cash and corporate equity, and shall be defined as gross licensing revenues, less patent expenses, and reasonable payments to inventors.
- Requires that any proposed intellectual property agreement between the ICOC and a grantee or loan recipient to be reviewed by the Attorney General prior to its approval by the ICOC, and the ICOC shall consider any comments by the Attorney General prior to approving the agreement.
- Requires that each member of a working or advisory group appointed to assist the institute or its governing body shall disclose to the ICOC any income, real property, and investments they or a close family member has in all of the following:
    - A California-based academic or nonprofit research institutions.
    - A biotechnology or pharmaceutical company.
    - Real property interests in California.
- Requires that Facilities Working Group members to disclose all construction, real estate, and development firms from which they or a family member receives or has received economic benefits.
- Requires that the ICOC to provide the disclosures to the State Auditor and that the State Auditor will review at least annually the disclosures, in addition to the voting record of each working or advisory group member regarding recommendations for applications for research and facility grants and loan awards and regulatory standards, and submit an annual report to the Legislature containing findings on conflicts of interest. .
- Defines "financial conflict of interest" as that the working or advisory group member, or a close relative or professional associate of the member, has a financial or other monetary interest in an application or standard that is known to the member, including a direct benefit of any amount deriving from an application or standard, or a financial benefit of any type from an applicant institution of over five thousand dollars ($5,000) per year, including honoraria, fees, stock, or other benefits.
- Removes exemption of working group records from the Public Records Act.
- Requires that this measure will become effective only upon approval by the voters at a statewide election.
- Calls for a special election on November 7, 2006 for approval of the measure. If approved, the bill would go into effect immediately.

Status: Amended to current focus on March 7, 2006 of a measure that previously focused on other subject matter. In 2005, the bill (with the earlier focus) passed the Senate. SB 401 passed the Assembly Health Committee on April 18, 2006 by a vote of 9 to 2 with 3 not voting. The Assembly Appropriations Committee placed the measure on the suspense file on May 17, 2006.

Senate Bill (SB) 1260 (Ortiz/Runner)
Human Egg Donation Consent

- Removes the sunset provision for the Department of Health Services administered Human Stem Cell Research Advisory Committee [created by SB 322 in 2003] to develop guidelines for research involving the derivation or use of human embryonic stem cells in California.

- Defines "assisted oocyte production" or "AOP" as surgical extraction of oocytes following pharmaceutically induced manipulation of oocyte production through the use of ovarian stimulation.
- Defines "alternate method of oocyte retrieval" as a method of oocyte retrieval that does not involve the pharmaceutically induced manipulation of oocyte production.
- Requires that prior to conducting AOP or any alternative method of ovarian retrieval on a subject for the purpose of procuring oocytes for research, a physician and surgeon provide to the subject a standardized written summary of health and consumer issues associated with AOP and any alternative methods of oocyte retrieval. States that the failure to provide this summary constitutes unprofessional conduct.
- Provides that the summary must include medically accurate disclosures concerning the potential risks of AOP or any alternative method of oocyte retrieval, including the risks associated with the surgical procedure and with using the drugs, medications, and hormones prescribed for ovarian stimulation during the AOP process or any alternative method of oocyte retrieval.
- Defines "written summary of health and consumer issues" as the guide published and updated by the American Society for Reproductive Medicine entitled, "Assisted Reproductive Technology: A Guide for Patients" or an alternative written medically accurate document prepared by a recognized authority on oocyte retrieval. Specifies that the alternative document may be one that has been approved and recommended by the State Department of Health Services with the following information:
    - Declares that the document adheres to simplified reading standards, including, but not limited to, those generally accepted and required for government publications and written in lay language and in languages spoken by subjects.
    - Declares that the document must include additional resources for, or list additional sources of, medical information on health and safety issues surrounding oocyte retrieval.
- Requires that prior to providing AOP or any alternative method of ovarian retrieval to a subject for the purposes of medical research, a physician and surgeon obtain written and oral informed consent for the procedure from the subject in compliance with the informed consent requirements of the Protection of Human Subjects in Medical Experimentation Act.
    - States that the failure to obtain written informed consent from the subject constitutes unprofessional conduct.
- Declares that this section does not affect the suitability or availability of oocytes procured for research before January 1, 2006, if the oocytes were donated pursuant to protocols or standards that are generally recognized and accepted by national or international scientific bodies.
- Requires that any written document required pursuant to this section shall adhere to simplified reading standards, including those generally accepted and required for government publications, and in layperson's language. Requires that the document shall be made available in languages spoken by subjects in the study if their proficiency is largely in a language other than English. All information in the written informed consent document shall also be conveyed to the subject orally in easy to understand and non-technical terms.
- Requires that an institutional review board (IRB) that reviews and approves medical and scientific research require all of the following of any research program or project that

comes under its review that involves AOP or any alternative method of oocyte retrieval to:

- Include a written summary as required under that would include information on health risks and potential adverse consequences of the procedure and describe the manner in which the subject will receive and review this written summary.
- Obtain informed consent in compliance with the Protection of Human Subjects in Medical Experimentation Act.
- Provide the subject with an objective and accurate statement about the existing state of the research for which the subject is providing oocytes.
- Perform psychological and physical screening for all subjects prior to the oocyte retrieval procedure.
- Ensure that after conducting AOP or any alternative method of oocyte retrieval on a subject, the subject be given a post-procedure medical examination at a time within the standard of care to determine if the subject has experienced an adverse health effect that is a result of the procedure. Requires that the subject shall be informed that she has the right to a second opinion if she has any medical concerns.
- Ensures that the subject has access to and coverage for medical care for any adverse consequence that is a direct result of the procedure. The research program or project must ensure that payment or coverage of resulting medical expenses be provided by the program or project and that a summary of the arrangements the procuring entity has made for coverage or payment for medical care related to AOP or any alternative method of oocyte retrieval is provided to the subject prior to the procedure.
- Provide a summary informing the subject that oocytes may not be sold or transferred for valuable consideration with exceptions.
- Provide disclosure if the physician and surgeon and his or her immediate family members have any professional interest in the outcome of the research or of the oocyte retrieval procedure and, if so, that it provide disclosure that he or she carries the interest of both the subject and the success of the research.
- Establish and maintain a written record to include all of the following components, which information shall be made publicly available, on at least a biennial basis:

  (1) The demographics of subjects, including, but not limited to, their age, race, primary language, ethnicity, income bracket, and ZIP Code of current residence.

  (2) Information for every oocyte, sperm, gamete, somatic cell, embryo donation, or product of somatic cell nuclear transfer that has been donated, created, or used. This record should be sufficient to determine the provenance and disposition of those materials.

  (3) A record of all adverse health outcomes, including, but not limited to, incidences and degrees of severity, resulting from the AOP or any alternative method of oocyte retrieval

- States that any employee or relative of an employee of a research organization or body is prohibited from being a subject in the research.
- States that the physician and surgeon performing the AOP or any alternative method of oocyte retrieval shall not have a financial interest in the outcome of the research.
- Requires researchers offer subjects an opportunity to document their preferences regarding future uses of their donated materials. The consent process shall fully explore

whether donors have objections to any specific forms of research to ensure that their wishes are honored.

- Requires that any procedures for procuring oocytes in this state for research or the development of medical therapies shall meet all of the standards for subjects included in this chapter. All eggs
- procured outside of this state for research taking place in this state shall meet these same standards. All egg extractions for research shall be approved by an institutional review board.
- Limits payment for reimbursement to direct, out-of-pocket expenses for any research subject to encourage her to produce human oocytes for the purposes of medical research, and specifically states that there shall be no reimbursement for lost wages.
- Provides that no human oocyte or embryo may be acquired, sold, received, or otherwise transferred for valuable consideration for the purposes of medical research or development of medical therapies, excluding reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of oocytes or embryos.
- Encourages the ICOC to review existing studies concerning the health risks and benefits of ovarian stimulation drugs used for assisted oocyte production, identify gaps in existing knowledge concerning health risks and benefits, and undertake further research as necessary to characterize the risks and benefits of those drugs.
- Specifies that the bill does amend Proposition 71, approved by the voters at the November 2, 2004, general election.

Status: Passed Senate Health Committee on April 19, 2006. Passed by the Senate Appropriations Committee on May 25, 2006.

Senate Bill (SB) 1822 (Bowen)
Task Force for Organ, Tissue, and Bone Marrow Donor Programs

- Establishes a task force appointed by the Governor to analyze the state's education and recruitment efforts to recruit individuals to become organ, tissue, and bone marrow donors.
- Requires the task force to report its findings and recommendations on these efforts, including how best to overcome cultural, linguistic, religious, social, and economic barriers to increase participation in these programs to the Legislature no later than July 1, 2008.

Status: Passed Senate on May 11, 2006 and now is in the Assembly Health Committee.

Visit www.leginfo.ca.gov for more details.