

California Department of Health Services

Human Stem Cell Research Advisory Committee



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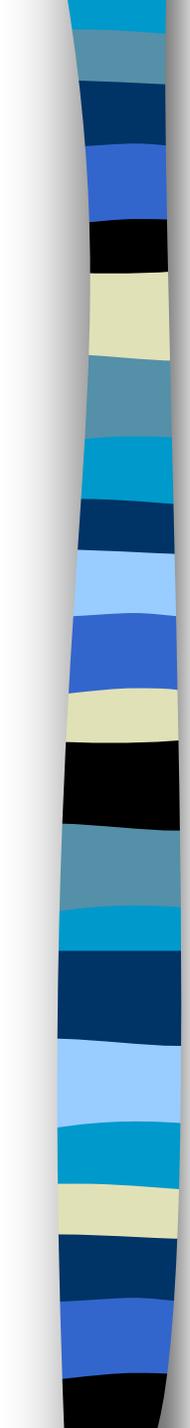
Human Stem Cell Research Unit
Maternal, Child & Adolescent Health/Office of Family Planning Branch
Primary Care and Family Health Division
California Department of Health Services

Children's Hospital Oakland Research Institute (CHORI)
February 24, 2006



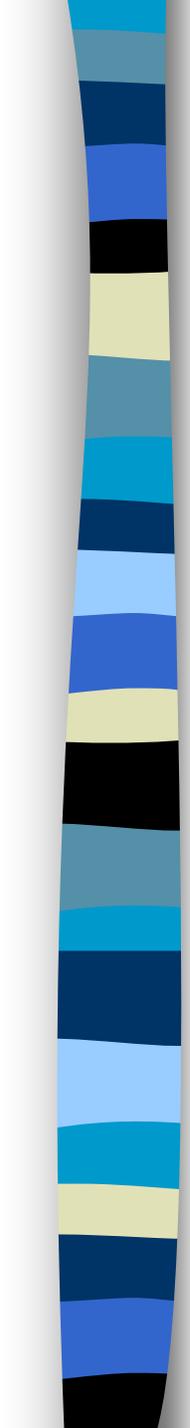
Legislative History: California Stem Cell Research

- **SB 253 (Ortiz)**
 - Implemented State policy that both permitted stem cell research and prohibited the sale of embryonic or fetal tissue.
- **SB 771 (Ortiz)**
 - Established an embryo registry and required advance directives for disposition of embryos produced during fertility treatment.
- **SB 322 (Ortiz)**
 - Required the Director of the DHS to appoint a Human Stem Cell Research Advisory Committee, to develop standards for human embryonic stem cell research in the State, collect data on stem cell research in California, review that data and report annually to the Legislature.
- **Proposition 71**
 - Authorized \$3 billion in state general obligation bonds to provide funding for stem cell research and research facilities in California. Established the California Institute for Regenerative Medicine (CIRM).



Legislative History: California Stem Cell Research

- **SJR 17 (Ortiz)**
 - Memorialized Congress and the President of the US to: (1) Lift restrictions on federal funding for stem cell research, (2) Not impair the ability of researchers to conduct stem cell research applications that hold promise for developing therapies for treating and curing chronic diseases, (3) Develop ethical guidelines for federally funded stem cell research, and (4) Prohibit human cloning.
- **SB 1260 (Ortiz & Runner, Introduced February 9, 2006)**
 - Would require physicians to obtain written consent as well as provide a standardized written summary of health and consumer issues to patients undergoing assisted oocyte production for the purpose of donating eggs for medical research or developing medical therapies.

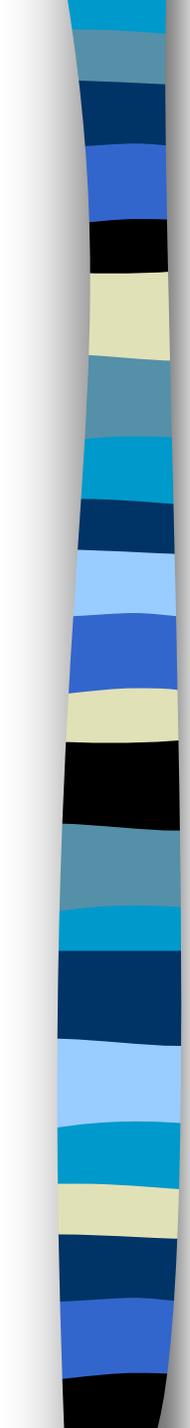


SB 322 (Ortiz)

SB 322 added sections 125118 - 125119.5 to the California Health and Safety Code (Chapter 506) charging the Department of Health Services to:

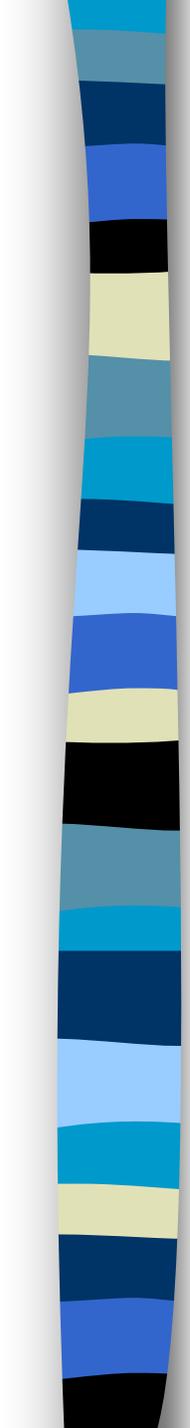
1. Establish a Human Stem Cell Research Advisory Committee consisting of 13 members representing professional specialties as specified in the statute.
2. Develop statewide standards for human embryonic stem cell research.
3. Collect mandated progress reports from all Institutional Review Boards (IRBs) in California regarding the status of approved projects and proposals involving stem cell research.
4. Review all IRB reports, and revise guidelines as necessary.
5. Report annually to the Legislature on human embryonic stem cell research activity in California.

The intent of SB 322 was to provide uniform statewide guidelines and standards as well as to ensure comprehensive monitoring and reporting of all human embryonic stem cell research in California.



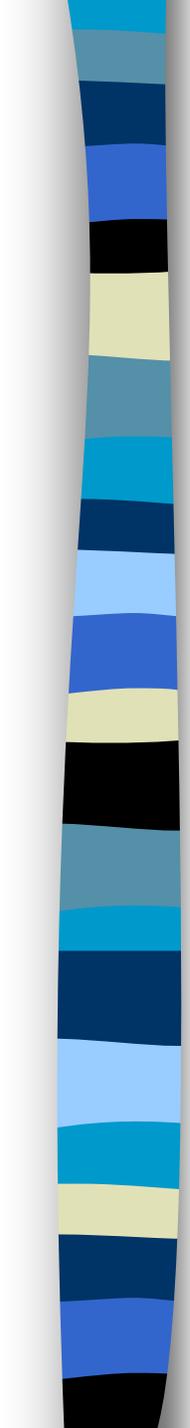
Proposition 71

- 2004 ballot initiative.
- Created a constitutional right to conduct stem cell research in California.
- Authorized the sale of 3 billion dollars in State General Obligation Bonds over 10 years to fund stem cell research and research facilities in California.
- Established the California Institute for Regenerative Medicine (CIRM) and an 29-member Independent Citizen's Oversight Committee to govern CIRM.
- Prohibited CIRM funding of human reproductive cloning research.
- Included language that specifically exempted CIRM and its grantees from the provisions of SB 322 as well as any 'other current or future state laws or regulations (except 125315)'.
- Specified CIRM would develop its own scientific and medical standards.



SB 322: Today

- While funding and other issues have delayed progress, work is now underway to implement the statutes of SB 322.
- Post Proposition 71, the statutes of SB 322 currently apply to all non-CIRM funded research in California including:
 - The DHS Human Embryonic Stem Cell Research Guidelines
 - The Mandated Review of IRB Reports in California, and
 - The Annual Report to the Legislature

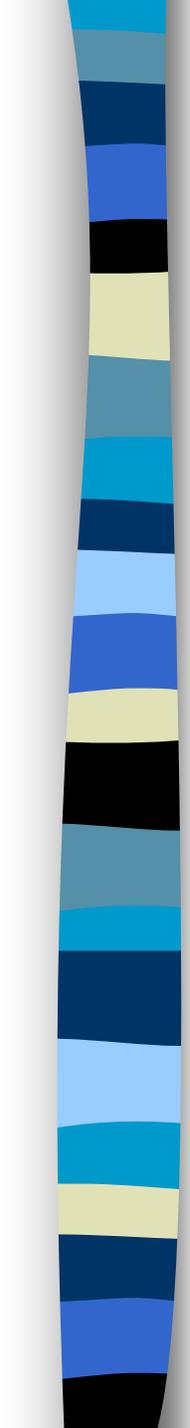


DHS Human Stem Cell Research Advisory Committee (HSCR)

The DHS HSCR Advisory Committee is authorized and organized pursuant to section 125118.5 of the Health and Safety Code enacted by SB 322.

As required by statute, the Committee consists of 13 members from the following specialties:

- Seven scientists with experience in biomedical research in the field of cell differentiation, nuclear reprogramming, tissue formation & regeneration, stem cell biology, developmental biology, regenerative medicine or related fields.
- Two medical ethicists.
- Two persons with backgrounds in legal issues related to human embryonic stem cell research, in vitro fertilization, or family law, as it applies to the donation of embryos.
- Two persons who are members or leaders of religious organizations.



Members of the DHS HSCR Advisory Committee

Elizabeth Helen Blackburn, Ph.D	Science
Samuel H. Cheshier, M.D., Ph.D	Science
Gregory Stock, Ph.D., M.B.A.	Science
Irving Weissman, M.D.	Science
Otoniel Martinez-Masa, Ph.D	Science
Fred Gage, Ph.D	Science
Bertram H. Lubin, M.D.	Science
Henry Greely, J.D.	Law
Radhika Rao, J.D.	Law
Bernard Lo, M.D.	Ethics
David Magnus, Ph.D.	Ethics
Eliliot Dorff, Ph.D.	Religion
Margaret R. McLean, Ph.D.	Religion



DHS Human Stem Cell Research Advisory Committee Charge

Charge:

To recommend to the Department of Health Services (DHS), scientific, medical, ethical and legal guidelines for research involving the derivation or use of human embryonic stem cells in California (notwithstanding CIRM funded projects).

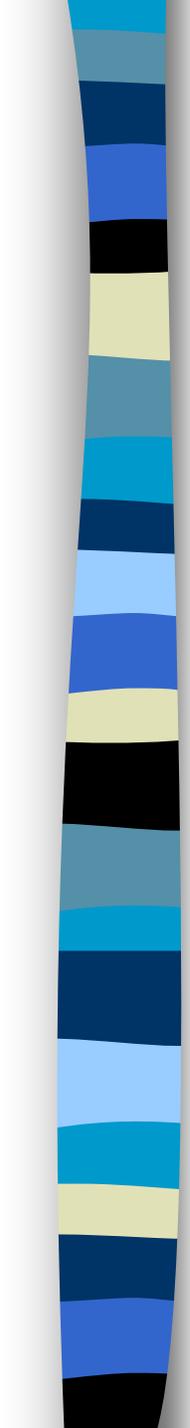
(Final approval of any guidelines adopted lies with the California Department of Health Services and the Health and Human Services Agency).



Current Considerations

- NAS Guidelines: Published in August 2005
- CIRM Regulations: ICOC approved February 10, 2006
- DHS HSCR Advisory Committee Recommendations:
 - GOAL: Compatibility with CIRM and NAS standards*

* Identified as critical during our preliminary discussions with the DHS HSCR Advisory Committee members in January of 2006.



Brief Overview of the Process*

■ First Meeting:

- Conflict of interest policy and disclosure
- Proposed Committee bylaws
- Vote on Committee Chair & Vice Chair
- Discuss of NAS & CIRM standards
- Identify areas requiring additional/modified guidelines

■ Future Meetings:

- Working from established standards, develop guidelines for identified areas requiring addition and/or modification.
- Approve the Committee's draft and final recommendations to the Department.

* Developed based on our preliminary conversations with the DHS HSCR Advisory Committee

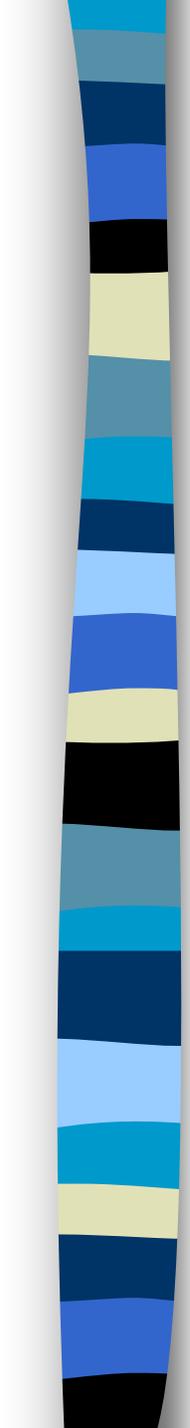
* Subject to change based on the Committee's evolving needs.



Proposed Timeline*

August 15, 2006	Draft guidelines prepared
September 1–30, 2006	Public comment on draft guidelines
October 31, 2006	Final guidelines prepared
November 30, 2006	Committee approved <i>recommended</i> guidelines transmitted to DHS

* Subject to change based on the needs/timetable of the Committee



Committee Organization

- The Committee will act as a whole, independent from but supported by DHS.
- Leadership:
 - Chair and Vice Chair
- DHS Support Staff include:
 - Designated State Officer
 - Executive Coordinator and
 - Clerical Aide
- Informal subcommittees may be formed to address specific issues identified by the HSCR Advisory Committee as a whole.

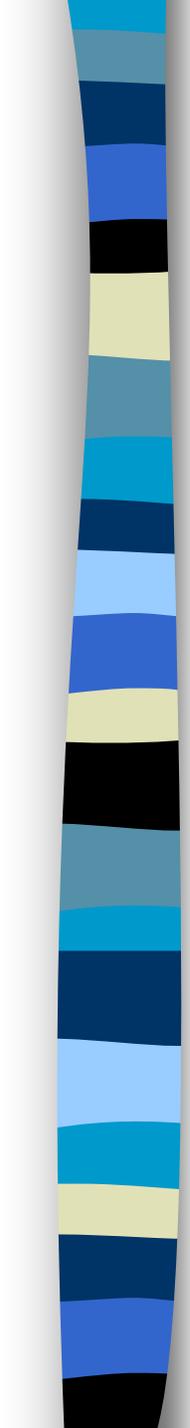


Committee Chair and Vice Chair

- Coordinate the work of the HSCR Advisory Committee:
 - Call Committee meetings (with approval of DHS).
 - Develop meeting agendas (in collaboration with the Committee and the DSO).
 - Certify the accuracy of HSCR Advisory Committee meeting minutes.
 - Preside over meetings of the HSCR Advisory Committee.
 - Oversee the development of the Committee's draft and final recommended guidelines to the Department.

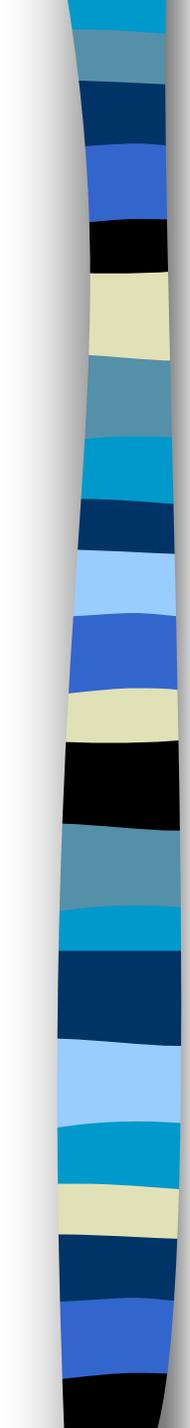
- Provide leadership to the Committee:
 - Provide a liaison between the HSCR Advisory Committee and DHS.
 - Provide a liaison between the HSCR Advisory Committee and CIRM.
 - Act on behalf of the Committee between meetings.
 - Represent the Committee to third parties.

- Forward the Committee's approved formal recommendations and opinions to the Department of Health Services via the DSO.



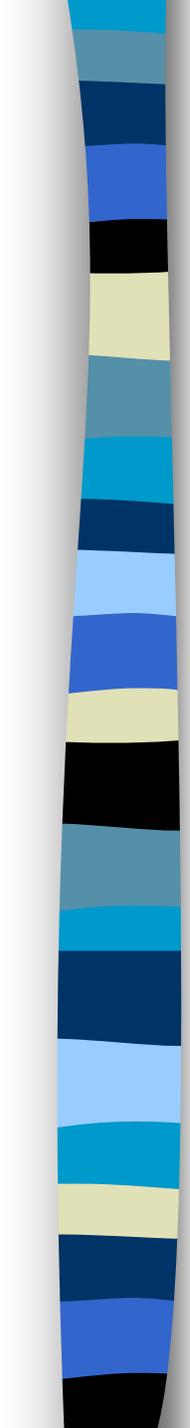
DHS Support Staff

- Facilitate the work of the Committee:
 - Assist the Chair and Vice Chair in meeting planning and agenda development.
 - Provide public notice of HSCR Advisory Committee meetings.
 - Attend all meetings and serve as a liaison between the HSCR Advisory Committee and any of its working groups.
 - Maintain official Committee records and correspondence.
 - Prepare and distribute HSCR Advisory Committee meeting minutes.
 - Process for payment vouchers for approved travel expenditures.
 - Provide materials and assistance to help the Committee fulfill its charge.
- Accept the final guidelines recommended by the Committee and transmit them to the Director of DHS.



THANK YOU

We would like to thank Dr. Lubin and his staff for hosting today's meeting.



Contact Information

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