

Proposition 71:
Stem Cell Research
- or -
The New California Gold Rush

Claire Pomeroy, MD, MBA
Vice Chancellor for Human Health Sciences
and Dean, UC Davis School of Medicine

Proposition 71

- Passed in November 2004
- Established “California Institute for Regenerative Medicine” (CIRM)
- Regulates and provides funding for stem cell research
- Constitutional right to conduct stem cell research (human reproductive cloning prohibited)
- Oversight committee (ICOC) to govern CIRM
- Issue bonds worth \$3 billion to provide funding over 10 years
- Cost to State: \$6 billion (principal + interest) over 30 years

Proposition 71

- Prioritizes stem cell research that has greatest potential for therapies and cures
- Prioritizes research that is unlikely to receive timely or sufficient federal funding (i.e., human embryonic stem cell research)
- Research eligible for funding from NIH will not be supported

CIRM

- Administrative headquarters
- Temporary headquarters in Emeryville
- Zach Hall appointed as Interim President
- Search for permanent president underway
- First employees hired
- Anticipate total of 50 employees
- Initial policies and procedures being established

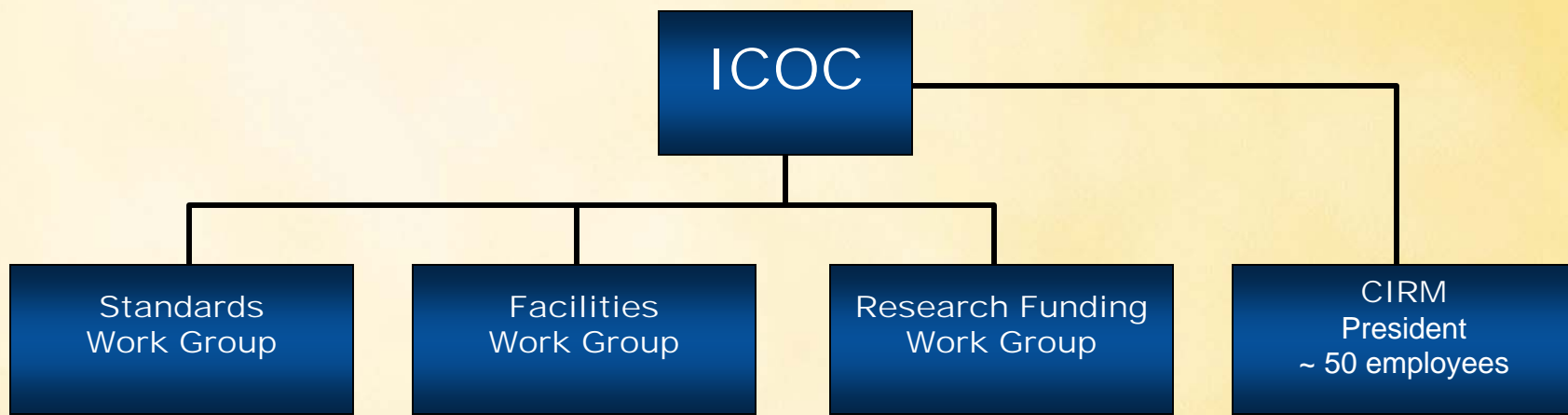
Independent Citizens Oversight Commission

- Five University of California medical school representatives
- Four other university representatives, four research institute representatives, four life science commercial entity representatives
- 10 patient advocate representatives – spinal cord, Alzheimer's, type-II diabetes, type-I diabetes, ALS/MS, heart disease, cancer, Parkinson's, mental illness, HIV/AIDS
- Chairperson (Robert Klein) and Vice Chair (Ed Penhoet), elected by ICOC

Independent Citizens Oversight Commission

- Best practices workshops – e.g. ethics, intellectual property, diversity
- Spotlight on Disease
 - (Sacramento meetings – Aug. 5 and Nov. 3)
- Aug. 5: Focus on Alzheimer's disease
- Collaboration with other groups to advance public education about stem cell research, including basic concepts, potential, and limitations

ICOC Organizational Structure



- 5 ICOC patient advocates*
- 9 stem-cell experts
- 4 ethicists
- ICOC Chair*

- 6 members Research Funding Work Group
- 4 real estate specialists*
- ICOC Chair*

- 7 ICOC patient advocates*
- 15 stem-cell experts**
- ICOC Chair

*Must be from California
**Cannot be from California

CIRM Headquarters Site

- RFP issued and 10 applications received from city-developer partners
- Sacramento City and Tsakopoulos family
- Four semi-finalists
 - San Francisco, Sacramento, San Diego, Emeryville
- Site visits over the next two weeks
- Subcommittee recommends top candidate and runner-up on May 2 to ICOC
- Top proposal endorsed at May 6 ICOC meeting

Training Grants

- Goal: Increase numbers of stem cell researchers in CA, support curriculum development, increase awareness of ethical issues
- Support for trainees, classroom courses, laboratory experiences
- Anticipate awards ~\$500K to \$1.2M per year X 3 years
- Hope to approve release of RFA at May ICOC meeting

Facilities

- Up to \$295 million total (spent in ~first 2 years)
- Limited to non-profit institutions in California
- Preference to proposals that can be completed in two years
- Capital leases, renovation, new construction
- Requires 20% institutional match
- Supports requirement for complete separation from federal funds

Research Grants

- Up to ~\$295 million per year x 10 years
- Non-profit and for-profit eligible
- Academic-industry partnerships encouraged
- First year:
 - Pilot studies
 - Centers of excellence
- Expanded research support later
- Overhead limited to 25%

Challenges

- Issues re: open meetings (Bagley-Keene), conflict of interest, financial disclosure
- Two lawsuits: allege proposition illegally exempts agency members from conflict of interest laws and wrongfully allows ICOC control of tax dollars
- Legislative actions- Ortiz/Runner introduce bill re: conflict of interest/affordable pricing and bill re: banning the harvesting of multiple eggs for 3 years
- Distribution of funds delayed- patient advocates voice concerns

Remaining Issues

- Defining scope of research to be supported
- Conflict-of-interest rules
 - ICOC
 - Grant recipients
- Intellectual property/revenue sharing
 - Bayh-Dole Act regulations
 - Stricter requirements?
 - Returns to state general fund?
- Reasonable pricing of discoveries/therapies/cures
- <http://stemcells.nih.gov>

UC Davis Strategies

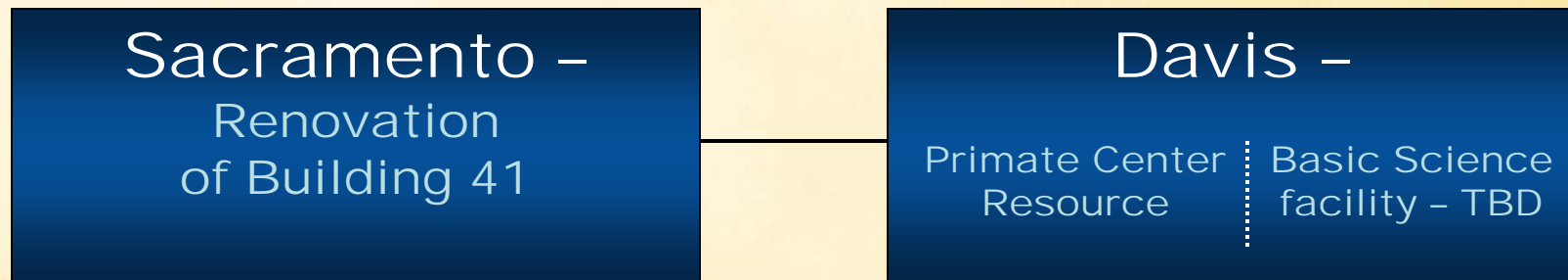
Center for Regenerative Science and Therapies (CReST)

Animal Stem Cells	Human Adult Stem Cells	Human Embryonic Stem Cells
<ul style="list-style-type: none">▪ Embryonic▪ Adult▪ Models	<ul style="list-style-type: none">▪ Basic▪ Clinical	Program in Regenerative Therapies (PIRT)

Prop. 71 Proposals

UC Davis Strategies

Facilities



- Three ~16,000 asf modules
- Adjacent to CRISP

Clinical ↔ Translational ↔ Pre-clinical

UC Davis Strategies

Program in Regenerative Therapies

- Build on strengths in:
 - Neuroscience and aging
 - Cancer and immunobiology
 - Vascular and metabolic diseases
- Leverage special resources at Primate Center
 - Statewide resource
- Combine strong basic science reputation and expanding translational research programs

UC Davis Strategies

- Pilot study funding allocated and RFP issued
- Life science dean collaborative proposal for CReST prepared for Provost
- Planning group for Prop. 71 proposals
 - Training grant application
 - Centers of excellence grant proposal
 - Facilities grant proposal
 - Pilot grant proposals
- Active recruitments of researchers under way
- Meeting with economic development leaders
- Web site – <http://researchnew.ucdavis.edu/stemcell>

Discussion Points

1. How should UC prepare to address ethical questions?
2. How do we manage PR and public education to ensure community support?
3. Given this unique opportunity, how should UC build the best possible stem cell research programs?
4. How should UC partner with industry on stem cell projects?
5. How do we obtain new resources (e.g., faculty, space, etc.) to effectively compete?
6. What advice should we relay to ICOC about California's stem cell initiative?