

Regulations for CIRM-funded research

Bernard Lo, M.D.

University of California San Francisco

March 17, 2006

March 24, 2006



California Institute of Regenerative Medicine (CIRM) timeline

May 2005

NAS report

Nov 2005

Interim CIRM regulations

Feb 2006

Draft final regulations

Ongoing

Public comment

March 24, 2006



Guiding Principles

- **NAS guidelines as interim regulations.**
- **Incorporate state and federal laws**
- **Go beyond existing standards**
- **Public participation**

March 24, 2006



Additional protections for oocyte donors in CIRM-funded research

- **Extensive disclosure**
- **Ascertain that donor understands essential aspects of research**

March 24, 2006



Additional protections for oocyte donors in CIRM-funded research

- **Institution assumes cost of care required as direct and proximate result of donation**
- **Physician attending donor may not be principal investigator nor have financial stake in outcome of research**
- **Keep record of every oocyte, product of SCNT**

March 24, 2006



March 24, 2006



March 24, 2006



Disclosure for donors of materials for new stem cell lines

- **Future studies, which cannot be predicted at this time**
- **May be transplanted into humans or animals**
- **Results may be patentable or commercial potential; not receive financial benefit**

March 24, 2006



Heightened informed consent in CIRM-funded research

- **Researchers may not violate documented preferences of donors**
 - **Donors have opportunity to document preferences**
 - **Researchers may use only donors who agree to all future uses**

March 24, 2006



Additional disclosure to oocyte donors

- **Risks of**
 - **Hyperovulation syndrome**
 - **Bleeding**
 - **Infection**
 - **Anesthesia**
 - **Pregnancy**

March 24, 2006



Oocyte donor in CIRM-funded derivation must understand:

- **Eggs not used for reproductive purposes**
- **Specific medical risks**
- **Whether stem cell lines derived through fertilization, SCNT, other method**
- **hSC lines shared with other researchers**

March 24, 2006



Oocyte donor in CIRM-funded derivation must understand:

- **Not benefit them or others directly**
- **Might be recontacted**
- **No reimbursement beyond expenses**
- **May be patented or commercialize; donors not share**

March 24, 2006



March 24, 2006



March 24, 2006



March 24, 2006



March 24, 2006



March 24, 2006



March 24, 2006

