Regulations for CIRM-funded research

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## California Institute of Regenerative Medicine (CIRM) timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>May 2005</td>
<td>NAS report</td>
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<tr>
<td>Nov 2005</td>
<td>Interim CIRM regulations</td>
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<tr>
<td>Feb 2006</td>
<td>Draft final regulations</td>
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<tr>
<td>Ongoing</td>
<td>Public comment</td>
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Guiding Principles

• NAS guidelines as interim regulations.
• Incorporate state and federal laws
• Go beyond existing standards
• Public participation
Additional protections for oocyte donors in CIRM-funded research

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