Updates to Stem Cell Research Oversight

IRB/SCRO Panel Meeting
August 10, 2010

Mario McKay Garcia
FDA lifts hold on Geron’s hESC Clinical Trial

- The Clinical Trial tests cells in patients with new spinal cord injuries
- FDA placed hold in August 2009 due to cysts forming on animals treated with the therapy
- Geron developed new markers and assays to ensure safety
- FDA lifted clinical hold July 30, 2010

Photo: M. W. Lensch, Children’s Hospital, Boston, MA
Effective Date is July 29, 2010

Research involving

– purely in vitro research
– with the aim to create or use a covered stem cell line
– from non-identifiable cells
– and animal assays may be used to evaluate pluripotency

may not commence until IRB/SCRO receives written notification (rather than review)
CIRM Final Rule: SCRO Notification

Research involving

– CIRM-funded human subjects research
– with the aim to create or use a covered stem cell line from sources other than human gametes, blastocysts or embryos
– and animal assays may be used to evaluate pluripotency

may not commence until IRB/SCRO receives written notification (rather than review)
CIRM Final Rule: Informed Consent

• For embryos procured after November 22, 2006 consent is required from the oocyte and sperm donor
  – Prior to this date, consent from only the oocyte donor is sufficient if sperm donor is unknown

• For CIRM funded research with somatic cells collected after November 22, 2006
  – When CIRM-funded somatic cell research is for transplantation into humans, SCRO must confirm donors provided informed consent that fulfills section 100100.
• Derived cells or products may be kept for many years

• Plan to recontact donor if identity is retained

• Cell lines may be used in future studies not now foreseeable

• Cell lines may be used in research involving genetic manipulation

• Derived cells may be transplanted into humans or animals

• Donation is made without restriction on recipient

• Neither consent nor refusal to donate will affect medical care

• Donor will have no legal or financial interest from donation

• Donor may impose restrictions, but donated cells may not be used