SCRO Consent Requirements

CDPH Health and Safety Code section 125118, 125330-125355, CIRM 100080, 100100

Applies to all stem cell research performed in CA involving donation of:

- human gametes
- embryos
- somatic cells or
- tissue for derivation of new covered stem cells lines

CDPH: California Department of Public Health
CIRM: California Institute for Regenerative Medicine
• Donors must be informed that derived cells or products may be:
  – Kept for years
  – Used in research involving genetic manipulation
  – Transplanted into humans or animals

AND must be told

✓ Cells are not intended to provide direct benefit to donor financially
  (beyond reimbursement for permissible expenses)
SCRO Consent Requirements, cont.

- Donors must also be made aware of:
  - Confidentiality of identity and potential re-contact
  - Possibility of unforeseen uses of the cells
  - No restriction on the recipient of transplanted cells
  - Whether embryos will be destroyed
  - Possible autologous treatment if donated for Somatic Cell Nuclear Transfer (SCNT)
Donors may impose restriction on use of donated materials

Oocyte donation from donors must meet the following criteria:

- Reasonable risk
- Option to deliberate before giving consent
- Donors made aware of non-reproductive use, risks, no direct benefit or payment, research methods, possible re-contact

Stem cell research that uses human umbilical cord, cord blood or placenta must have consent of the birth mother