SCRO Consent Requirements

Bertha deLanda

January 12, 2010

Research Compliance Office

Slide information provided by : Sarah Cho

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:

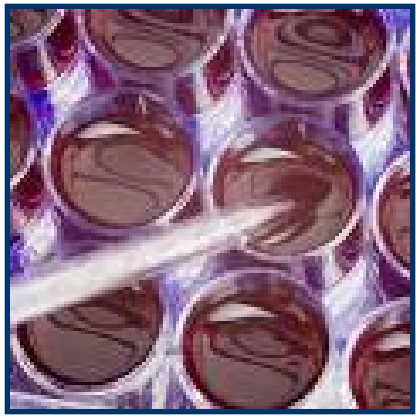
- human gametes
- embryos
- somatic cells or
- tissue for derivation of new covered stem cells lines

CDPH : California Department of Public Health

CIRM : California Institute for Regenerative Medicine

SCRO Consent Requirements, cont.

- **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



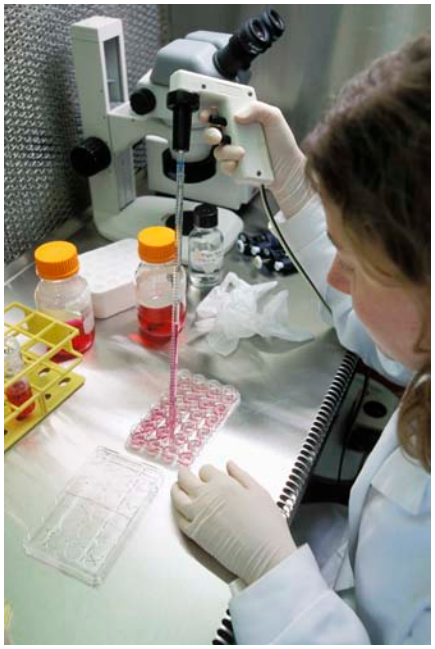
AND must be told

✓ Cells are not intended to provide direct benefit to donor financially

(beyond reimbursement for permissible expenses)

SCRO Consent Requirements, cont.

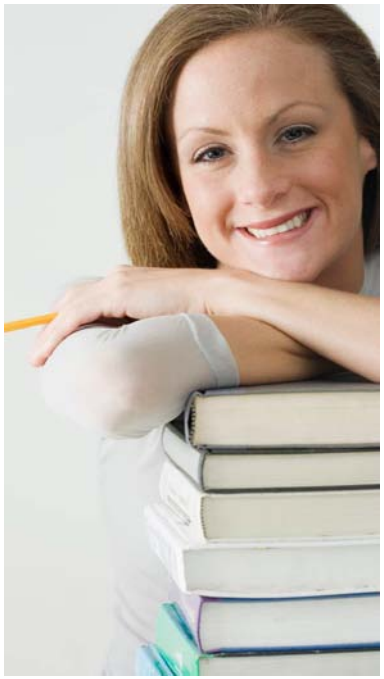
- Donors must also be made aware of:
  - Confidentiality of identity and potential re-contact
  - Possibility of unforeseen uses of the cells
  - No restriction on the recipient of transplanted cells
  - Whether embryos will be destroyed
  - Possible autologous treatment if donated for Somatic Cell Nuclear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



SCRO Consent Requirements, cont.

- 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