12.1.05 Standards Working Group Meeting
AGENDA ITEM # 7
Summary of Public Comment on Informed Consent and Ethically Derived

11/21/2005

To: SWG

Fr: CIRM

Re: Summary of Public Comments Related to Informed Consent and Ethically Derived Materials for 12/1 Meeting

This memo list public comments received to date on topics to be discussed at the 12/1 SWG meeting. Comments are summarized in relation to applicable sections in the Draft CIRM Regulations.

Section 100007: Informed Consent Requirements:

- Beware of "therapeutic misconception" where donors feel they will derive direct benefit from stem cell donation.

- In informed consent provide a statement as to which group characteristics of the donor, if any, will be kept, such as race or ethnicity, and a request for self-identification of this information where appropriate.

- In informed consent ask donors if they would like to be informed of results of infectious disease screening, or evidence of chromosomal anomalies, or genetic disease markers found in their gametes or embryos or somatic cells during preparation of hES cell lines. If this information is requested, their identity will remain secure.

- In informed consent ask donors if they would like to be informed of any scientific results arising from the research for which their tissue is donated. If this information is requested, their identity will remain secure.

Section 100006: Ethically Derived Materials:

- What if stem cells can be derived from surplus embryos from IVF clinics where the clinic had a practice of paying donors? The IVF clinic may be willing to provide the materials to the researcher free of charge, but there was compensation originally.

- Women who undergo hormonal induction to generate oocytes specifically for research purposes (such as for NT) should be given medical care relating directly to the ovarian stimulation protocol and oocyte extraction before, during, and after the procurement as necessary, without regard to their medical insurance status.

- Recruitment procedures and materials for embryo, oocyte, sperm, and somatic cell donation should be approved by the ESCRO committee or by written approval of an IRB. Reasonable efforts should be made to target recruitment of donors to ensure diversity in resultant hES lines, reflecting the tissue characteristics of the ambient population, and off-setting over-sampling of the reproductive IVF donor population.

- To facilitate autonomous choice and to protect against conflict of interest, decisions related to the creation of embryos for infertility treatment shall be free of the influence of investigators who propose to derive or use hES cells in research. Any hES researcher who is also an infertility attending physician shall attain hES cell lines through a well recognized stem cell bank or quality research cell line repository, without knowledge of the provenance of those cell lines.