CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Scientific and Medical Accountability Standards
Working Group Briefing Paper:
Oversight for iPS-Related Research

Background Oversight for iPS Research

The CIRM MES regulations contain provisions requiring SCRO review and approval of research intended to derive a pluripotent ("covered") stem cell line – Section 100070(c). Experiments involving somatic cell reprogramming have become common in basic- (*in vitro*) research. In many cases, such research may result in the generation of cells with pluripotent-like characteristics. SCRO committees tend to consider such experiments as *in vitro* research requiring only notification or expedited review rather than full SCRO review. Grantees have requested that CIRM clarify this position (see Section 3 of interviews summary).

iPS Experiments and the NAS Guidelines

In the 2008 amendments, the NAS hESC Research Committee indicated that ESCRO review is not necessary for non-embryo-derived iPS cell line derivations and *in vitro* experiments. The committee reasoned that since iPS cells are derived from human material, their use in research is covered by existing IRB regulations concerning review and informed consent and do not raise any special ethical concerns. One exception to the review standard is *in vitro* experiments to yield gametes. Such experiments are subject to ESCRO committee review.

Policy Considerations

CIRM has a general SCRO "notification" requirement for *in vitro* research utilizing a covered stem cell line – Section 100070(d), and SCRO committees are required to confirm documentation of compliance with any required IRB review. The notification standard could be applied to iPS experiments. Alternatively, expedited review might also be considered.

The full SCRO review and approval requirements in Section 100070(c) could be limited in scope to research intended to "create or utilize human gametes and embryos." This modification in scope would subject all gamete or embryo work to full review and *in vitro* work with somatic cells would be subject to a notification standard. Such clarification would be consistent with the NAS guidelines.

This modification in scope would be limited to *in vitro* work with human somatic cells. Experiments proposing to transplant cells with pluripotent characteristics to humans or animals would still require full review.