

Summary Recommended Revisions CIRM MES Regulations January 2009

#	Section Number	Policy Objective	Revised Language	Rationale
1	§ 100070(c)	Require SCRO review and approval of research involving human gametes and embryos.	(c) CIRM-funded research with the aim to derive or create a covered stem cell line <u>from human gametes, embryos or products of SCNT involving a human donor nucleus</u> may not commence without SCRO committee review and approval in writing.	The SWG recommended that basic research involving the reprogramming of somatic cells be subject to SCRO notification. This modification limits full SCRO review to derivations involving the use gametes, embryos or SCNT.
2	§ 100070(d)	Require SCRO notification (but not full review and approval) of iPS research involving human somatic cells.	CIRM-funded purely in vitro research utilizing covered stem cell lines <u>or the reprogramming human somatic cells with the aim to derive or create a covered stem cell line</u> may not commence without written notification to the designated SCRO committee. <u>Research may include animal assays to evaluate pluripotency; however, subsequent introduction of derived covered stem cell lines in non-human animals shall be reviewed in accordance with section (e).</u>	The SWG recommended that basic research involving the reprogramming of somatic cells be subject to SCRO notification. This modification clarifies that reprogramming is covered under the notification standard including animal assays for the purpose of determining if a line is pluripotent. Stating that subsequent animal transplantation of an established line must be reviewed under the existing standard provides further clarification.
3	§ 100070(f)	Require SCRO review of research involving the transplantation of cells derived from pluripotent cell to human subjects.	(f) CIRM-funded research introducing stem cells from covered stem cell lines into a live born human may not commence without SCRO committee review and approval in writing.	The SWG recommended that transplantation research be subject to full SCRO review. This modification clarified that all research proposing to transplant cells from a covered cell line must be reviewed.
4	§ 100090(a)(1)	Establish a “baseline” level of consent for use of gametes, embryos and somatic cells.	(a) Where CIRM funds are to be used for research intended to derive a covered stem cell line from human gametes, embryos, somatic cells or tissue, the SCRO committee must determine the requirements of Code of California Regulations, title 17, section 100080,	The SWG recommended that “general” consent for research be allowed for gametes, embryos and somatic cells procured prior to the promulgation of the MES regulations. This provision identifies the baseline requirements for consent, payment and oversight. The

Summary Recommended Revisions CIRM MES Regulations January 2009

			subdivision (a)(2) or (a)(3), have been met with the following exceptions:	addition of section 100080(a)(3) allows the use of somatic cell that conform to federal regulations to be utilized.
5	§ 100090(a)(1)	Allow embryos created from gametes from which the donors were paid if the embryo was created for reproductive purposes (IVF) and it was created prior to August 2008.	<u>(1) For embryos created on or before August 13, 2008, “valuable consideration” does not include payments to gamete donors in excess of “permissible expenses,” provided the embryo was originally created for reproductive purposes.</u>	This provision exempts embryos created from gametes from which the donors were paid from the payment restriction in 100080(a)(2)(A).
6	§ 100090(a)(2)	Allow the use of embryos in research if the oocyte donor has provided consent and the sperm donor cannot be identified.	<u>(2) For embryos created before November 22, 2006 consent exclusively from oocyte donors is sufficient provided the sperm donor cannot be identified and the donation was made in accordance with the legal requirements in force at the place and time of donation.</u>	This provision exempts certain embryos from 100080(a)(2)(B).
7	§ 100090(c)	Require explicit consent for cell transplantation.	<u>(c) Where a covered stem cell line is derived from human somatic cells, procured from human subjects after November 22, 2006, and the CIRM-funded research is designed to develop cells for transplantation into a live born human; the SCRO committee must confirm that donors provided voluntary and informed consent including the requirements of Code of California Regulations, title 17, section 100100, subdivision (b)(1)(E).</u>	This provision is requires explicit consent for transplantation of cells to humans.