Summary of Informal Public Comments on Interim CIRM Guidelines

#	draft	Source	Specific Comment	Staff Comments	Action
1	9/9	WC001	What is the rationale for not retrospectively applying the guidelines for oversight to "research involving hESC derived prior to the effective date of this chapter".	The regulations apply a differential standard to previously derived lines, but all materials used must be "ethically derived".	complete
2	9/9	WC001	It may be overly restrictive to prohibit the introduction of hESC into nonhuman primate blastocysts and of any embryonic stem cells into human blastocysts and to prohibit item breeding of an animal into which hESC have been introduced even though these may not be appropriate undertakings scientifically at this time.	Can indicate that such activities are "not eligible" for funding. Regulations can be revised at future date, or appeal mechanism can be considered.	Regulations not revised to maintain consistency with NAS.
3	9/9	WC001	SCRO committees should have both ethical and legal expertise represented independently: i.e., there should be at least one member with expertise in ethics and at least one member with legal expertise, not a single individual with expertise in both ethics and the law.	SCRO committee is focused on science and ethics; legal capacity is available elsewhere in institution and will not be required on SCRO.	Legal requirement dropped.
4	9/9	WC001	It should be mandatory for clinically significant information to be provided to donors unless they have moved and left no contact information (which they should be warned not to do).	Poses logistical challenges; may need to consider on a study-by-study basis. The issue become more salient in clinical trials.	none
5	9/9	WC001	Why not require oversight and review of research with "already derived and coded hESC lines" ?	Only work exempt from SCRO notification or review is *in vitro* using existing lines; given new language on existing lines (NIH & UK) it is feasible to have a standard for ethically derived.	suggested
6	9/9	WC001	Why not require IRB review of research with existing hESC?	Neither IRB or SCRO needs to perform a full review *in vitro* research; provided materials are ethically derived.	none
7	9/9	WC002	The guidelines to be adopted by Prop. 71 should be revised to include the possibility of financial incentives with reasonable payment at marketplace rates for healthy young women to serve as egg-donor volunteers for research purposes. See comment 10.	Proposition 71 limits payments to reimbursement of expenses.	Expenses have been defined in regulation.
8	9/9	PS01	SCRO membership should include public member(s) and advocates for civil-rigths.	Working Group did not see need to be overly prescriptive in membership; individual institutions can develop specific membership policies.	Member of the public included as a requirement, civil-rights.

					advocate not specified.
9	9/9	PS01	SCRO should have central oversight with autonomy from CIRM	Statewide SCRO concept under consideration; CIRM would likely be obligated to fund such activity.	Under consideration.
10	9/9	PS01	Direct expense limitation is a good policy	Currently limited to expenses	None
11	9/9	PS01	Should not set strict limits on science by using terms like "prohibited."	Can indicate that such activities are "not eligible" for funding.	Language revised.
12	9/9	PS01	There should be a mechanism for tracking use, transfer and research involving blastocysts.	Materials tracking requirements are in regulations and will be included in Grants Administration Policy	Tracking is integral part of regulations.
13	NA	PS01	IP policy should prevent (1) excessive upstream patenting of materials, and (2) privatizing individuals genetic material	This is a priority of the IP Task Force	Addressed in IP policy.
14	NA	PS01	There should be an ELSI research component in the CIRM program.	Contemplated, but this is a grants policy issue and may not be written into regulation	Forward to grants group.
15	9/9	PS02	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.	CIRM Regulations do not cover IVF clinics; blastocysts cannot be sold for research purposes by regulation.	Regulation specifies blastocysts cannot be sold for research purposes.
16	NA	PS03	Oversight should occur from a centralized SCRO and there should be a centralized banking structure. See Winickoff White Paper	Oversight is an institutional responsibility. Proposes very extensive oversight structure with at least 2 additional bodies.	Policy is to rely on institutional SCRO.
17	NA	PS03	Beware of "therapeutic misconception" where donors feel they will derive direct benefit from stem cell donation.	There is a statement to this regard in the informed consent requirements of the draft standards, and an evaluation requirement.	Addressed in regulations.
18	9/9		If the SCRO is intended to provide scientific review and accounting of stem cell research, then why have a member of the public on the SCRO committee? The SCRO should be comprised of members who can provide scientific review. Ethical review involving a member of the public is performed by IRBs; this would still be the case under the proposed guidelines. See comment #8.	Charge is scientific and ethical review, and public member is in the interest of ethical oversight and including individual without institutional affiliation.	No action.

19	NA	WC003	Institutions will want to be able to comply with both the CIRM regulations and the NAS guidelines. CIRM can be stricter or more restrictive, but compliance with the CIRM regulations should not put institutions in conflict with the NAS guidelines.	Regulations drafted to be compatible with NAS requirements.	NA
20	NA	WC003	Have a lengthy "preamble" which is actually a detailed explanation of why we are doing what we are doing, and how CIRM will interpret the regulations, which he thought should be terse.	Will make some of these statements in the official Statement of Reasons.	NA
21	9/9	WC003	Consider "process" regulations to make explicit that (and how) CIRM will be using other mechanisms than regulations to achieve the goal of best practices that are not explicitly set out in the regulations themselves.	May contradict with APA, may not be able to play this role.	Performance standards used to accomplish this objective.
22	NA	WC004	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.	Not able to identify applicable CA polices that prescribe requirements for providing medical care to research participant.	
23	9/9	WC004	Recruitment procedures and materials for embryo, oocyte, sperm, and somatic cell donation should be approved by the SCRO 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.	SCRO and IRB have authority in Draft Regulations to review, modify and approve recruitment procedures.	CA regulations regarding diversity in research cited.
24	12/1	WC004	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.	12/1 SWG focused on principle of "not compromising reproductive success." And separation of researcher from clinical donation. See transcript.	Concepts incorporated into draft regulations.
25	12/1	WC004	(f) (1) (M) 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 (f) (3) Donors may be asked 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. (f) (4) Donors may be asked 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.		
26	12/1	WC005	Section 100007(a)(1)(C): "An assurance that participants in research projects will follow applicable and appropriate best practices for donation, procurement, culture, and storage of stem cells...." This is from the NAS Guidelines and it didn't make any sense in their guidelines either. As written, such statements should NOT be part of the CIRM regulations	It is not appropriate to place assurance requirements on participants; institutions are responsible for all compliance.	Requirement deleted.
27	12/1	WC006	The Guidelines have dramatically shifted from "embryonic stem cells" to simply "stem cells." I am very concerned about expanding the scope of SCRO review, and possibly increasing IRB responsibilities for review, to include any research use of adult stem cells. And if this expansion is necessary, then we need some explicit mechanisms to ensure that the minimum possible burden is placed on investigators and reviewers if the research is minimally problematic.	"Stem cells" is overly broad scope. The regulations were revised to include "covered stem cell lines." Review would be required for most derivation and chimera research anyway.	Revised to cover "stem cell lines."
28	12/1	WC006	The focus on stem cells may open a loophole in which problematic research (involving human gametes, zygotes, and embryos) could move forward without SCRO review because it is not conducted for the purpose of deriving stem cells.	Now covered in definition of "covered stem cell lines" and requirement that research involving oocytes and blastocysts be reviewed by SCRO.	Revised by definition and in review requirements.
29	12/1	WC006	Section 100005 seems to greatly limit the scope of what is to be reviewed by SCRO Committees. Para. (a) limits review to "funded research attempting to *derive* human stem cells." Para. (b) describes a somewhat less restrictive review process for research in which human stem cells are introduced into nonhuman animals. Para. (c) describes a still less restrictive review process for in vitro research with stem cells.	Yes, trying to distinguish between review and notification, see comment #27. All work with oocytes and blastocysts now covered by SCRO.	Revised by definition and in review requirements.
30	12/1	WC006	It isn't clear that the CIRM guidelines can require review processes for non-CIRM research.	Not trying to regulate all research; this section talks about materials used in CIRM-funded research which we can regulate.	Limited to CIRM-funded research.

31	12/1	WC006	It would be exceedingly helpful if there was a statewide "certification" process for (a) stem cell lines that might be imported into California institutions and (b) investigators/institutions that might be receiving materials from California institutions. It could be extremely risky for all of us if we rely on each SCRO committee to independently determine whether or not another institution's procedures are ethically (and legally) sound.	The concept of "ethically derived" is attempting to create such a standard. It is difficult to be prescriptive with this type of standard.	Comment flagged for future discussion of stem cell banking.
32	12/1	WC007	If your intent is to require institutions to set up or designate a body that will review ALL types of human stem cell research, regardless of whether it is embryonic, perhaps you should use a term other than SCRO committee (maybe SCRO?).	Changed to SCRO; note multiple comments on this point.	SCRO committee is operational term.
33	12/1	WC007	The SCRO could approve a research project that institutional authorities may decide not to approve. Perhaps it would be clearer to reword something along the lines of the following: "The designated SCRO committee must review all funded hESC research involving derivation. Funded hESC research regarding derivation cannot commence without SCRO committee approval. The designated SCRO committee can require that modifications be made to proposed funded hESC research as a condition of granting its approval."	Changed language in draft regulations to reflect comment.	Conditional approval is acceptable.
34	12/1	WC008	A focus on "stem cells" includes both too much (e.g., adult hematopoietic cells) and too little (e.g., not gametes, embryos, or blastocysts). Perhaps the focus should be on 3 areas: (1) the circumstances of human gamete or embryo donation to protect the interests of the human donors; (2) the derivation or uses of human embryos, cells that are totipotent, or pluripotent cell lines derived from such cells to ensure that we grant special respect to the human embryo; and (3) any clinical trials involving the products of such research to protect the interests of the research subjects.	Preamble modified to focus on CIRM-funded research; and SCRO and Ethically Derived now focus on "human subjects" and "gamete" or "blastocysts" work.	Comment incorporated in revised draft.