Summary of Informal Public Comments on Interim CIRM Guidelines

#	SG	Source	Specific Comment	Staff Comments	Action
1		WC001	Section 100000 (a) (3): I do not understand the rationale for not retrospectively applying the guidelines for oversight to "research involving hESC derived prior to the effective date of this chapter" (even though prospective approval protocols would not, of course, be possible).	This clause was removed.	complete
2	A	WC001	Section 100004: I believe it may be overly restrictive to prohibit item 2 (introduction of hESC into nonhuman primate blastocysts and of any embryonic stem cells into human blastocysts) and to prohibit item 3 (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.	suggested
3	E	WC001	Section 100006 (a): In my opinion, ESCRO 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.	Common Rule indicates required expertise; can suggest membership expertise in regulations	suggested
4	A	WC001	Section 100009 d 3 C: I believe 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	none
5	B	WC001	Section 100010 (c): Again, I ask (as I did regarding item 100000 a 3) Why not require oversight and review of research with "already derived and coded hESC lines" ?	Only work exempt from ESCRO 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	E	WC001	Section 100010 (i): Again: Why not require IRB review of research with existing hESC ?	IRB does not need to review *in vitro* research; ESCRO process sufficient	none
7	A	WC002	I would therefore recommend that the guidelines to be adopted by Prop. 71 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.	May be limited in ability to compensate by law.	none
8	E	PS01	ESCRO membership should include public member(s) and advocates for civil-rigths.	Common Rule indicates required expertise; can suggest membership expertise in regulations	
9	E	PS01	ESCRO should have central oversight with autonomy from CIRM	Possible regional IRB concept	Under consideration

10	D	PS01	Direct expense limitation is a good policy	Currently limited to expenses	none
11	A	PS01	Should not set limits on science by using terms like “prohibited”	Can indicate that such activities are “not eligible” for funding.	Suggested language
12	C	PS01	There should be a mechanism for tracking use, transfer and research involving embryos	Under discussion by Banking study group; state Bank suggested	See Banking Memo
13	C	PS01	IP policy should prevent (1) excessive upstream patenting of materials, and (2) privatizing individuals genetic material	Bank seen as a means of getting materials into public domain; see issue memo 2 on Banking	See Banking Memo
14	E	PS01	There should be an ELSI research component in the CIRM program.	Contemplated, but would be in the grants program may not be written into regulation	Forward to grants group
15	E	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.	Needs Discussion	Forward to Oversight Group
16	E	PS03	Oversight should occur from a centralized ESCRO and there should be a centralized banking structure. See Winickoff White Paper	Proposes very extensive oversight structure with at least 2 additional bodies.	
17	A	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.	No additional changes
18	E		If the ESCRO is intended to provide scientific review and accounting of stem cell research, then why have a member of the public on the ESCRO committee? The ESCRO 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.		
19		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.		
20		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.		
21		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.		