

DRAFT

Summary of Public Comments—California Department of Health Services Human Stem Cell Research
 Proposed Guidelines
 Prepared by HSCR Unit, MCAH/OFP Branch, CDHS
 December 4, 2006

Public Comments and Changes to CIRM Regulations Matrix

Location	Comment Summary	
General	Guidelines should be entirely consistent with SB 1260, rather than with conflicting or different policies that CIRM has adopted.	
General	Include data collection language from Section 125342.	
General	Suggest replacing “regulations” language with “guidelines” in order to clarify the intended non-regulatory status of the guidelines.	
General	If “must” is used for regulations and “should” is used for guidelines, where does “shall” fit in?	
Preface	Emphasize consistency of guidelines with SB 1260, in addition to CIRM.	
p. 3, line 10-12	Clarify that not ALL research involving derivation or use of hESCs will require approval by both a SCRO and IRB, as <i>in vitro</i> research involving use of previously derived hESCs does not require IRB review. Revise to “ <u>some</u> research involving the derivation or use of hESCs...”	
p. 4, line 7-19	Place prohibition against “the transfer to a uterus of a genetically modified human embryo” into the guidelines (Section 3, p. 7).	
p. 7, Section 4	Majority of SCRO members should not be research scientists and should include “at least one community member”.	
p. 8, line 3-4	“permissible expenses, as defined in Section 2” was cut from CIRM regulations.	CIRM change
p. 8, line 6-7	“In addition, a SCRO committee shall have...” sentence was deleted from CIRM regulations, as it was already included.	CIRM change
p. 8, line 9	“professional or financial stake” was cut from CIRM regulations.	CIRM change
p. 8, line 9	Definition of “professional or financial stake” is unclear; suggest cutting this and only keeping “conflicting interest”.	
p. 8, line 10	“IRB” was deleted from CIRM regulations.	CIRM change
p. 9, line16-18	“For such SCRO...” sentence was deleted from CIRM regulations.	CIRM change
p. 9, line17	Change “the” to “a” so it is not implied there can be only one expert in assisted reproduction.	
p. 10, line 23	Change “confidentiality of the donor(s) is protected” to “privacy of the donor is protected and the confidentiality of identifiable information is maintained”.	
p. 12, line 2-5	These 2 sentences were cut from CIRM regulations.	CIRM change
p. 14, Section 7	Language should be directly from SB 1260, Chapter 2, Sections 125330-125355.	
	Consider reordering Sections 7 & 8 so it is clear which provisions apply to ALL covered stem cell research vs. research only involving derivation of new human stem cell lines.	
p. 14, line 11	Include “knowingly” as CIRM regulations do.	

p. 14, line 13-14	Delete sentence since it does not allow institutions to negotiate medical costs with commercial sponsors of the research, instead only keep Section 8(c), p. 15.	
p. 14, line 14; p. 15, line 23	Wording should match SB 1260 and read “required as a direct result of the procedure”.	
p. 16, Section 9	Provide definition of “clinical trial” in Section 2: Definitions	
	Give careful consideration to delineation of functions between SCROs and IRBs; some SCRO responsibilities overlap with traditional role of IRBs; institutions should retain flexibility to assign responsibility for certain aspects of review.	
	For IRB and SCRO responsibilities, suggest listing the elements of review and allowing the institutions to assure that review is carried out by a committee with appropriate expertise.	
	Consider including a requirement to register clinical trials in a registry, such as clinicaltrials.gov .	
p. 17, line 15-17	Consider changing wording to "donors of the biological materials used to produce the covered cells used in the trial".	
p. 18, line 2	Change “involved” to “that involve...”	
p. 18, line 8	Consider inserting “adequate” before “Data Safety Monitoring Board”.	
p. 18, line 21	“8” was cut from CIRM regulations.	CIRM change
p. 21, line 1	“additional” was cut from CIRM regulations.	CIRM change
p. 21, line 2	Clarify what “subdivision (a)” is.	
p. 21, line 23	Sentence changed in CIRM regulations to “The research is not intended to benefit...”	CIRM change
p. 22, line 4-5	These 2 sentences were cut from the Record Keeping Section of the CIRM regulations.	CIRM change

Commenting Parties:

Susan Fogel, Pro-choice Alliance for Responsible Research
Ellen Auriti, University of California, Office of the President
Emily Galpern, Center for Genetics and Society
Senator Ortiz, Author of SB 322 and SB 1260
Bernard Lo, HSCR Advisory Committee member