CIRM Scientific and Medical Accountability Standards Working Group: Friday, August 26, 2005

A. Issues Identified by Donor Recruitment and Protection Study Group			
#	Issue	Question or Issue	Comments
[A1]	Levels of Consent	Should donors have to opportunity to consent for certain types of research activities? For example, should a donor have the ability to provide (1) blanket consent or all research or (2) opt out of specific types of research such as: • SCNT, • Injection into non-human animals?	This could be decided by the IRB but any standards for Banking or a Registry would have to capture such requests.
[A2]	Oocyte Generation	NAS prohibits researchers from requesting generation of more oocytes. Should we say that research may not be funded with oocytes from infertility programs that generate more oocytes than would ordinarily be generated during infertility?	
[A3]	Recruitment of Oocyte Donors	Should women in infertility treatment donate unfertilized oocytes to researchers? Could sharing result in setbacks to reproductive goals? Should donation from (a) women who are also donating oocytes for infertility treatment be treated separately from (b) women donating solely for research purposes? Should donors be limited to those whose child-bearing is completed?	
[A4]	Compensation for Injury	What standards should exist for compensation for injuries directly resulting from research interventions?	
[A5]	Institutional Oversight		Note the study group call focused in issues reflected in the memo developed by Steve Peckman. In addition, there was some discussion of how the IRB is mandated to evaluate risk/benefits of research. See Attached.

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B. Issues Identified by Interstate & International Collaboration Study Group			
#	Issue	Question or Issue	Comments
[B1]	Minimum Oversight Standards for "Ethically Derived" Materials	How can we assure that there is adequate oversight in other states and countries? Should we require minimum standards for oversight for cells or cell lines that were not derived from CIRM-funded research? For example, cells that were derived from other states and countries. How do we get the facts needed to make this assessment and what are the criteria? Which protections should be essential?	The issue of certifying that materials are "ethically derived" is closely tied to registry, banking and donor protection issues. Banking/donor protection: What are the non-negotiable requirements for information about cell lines and the original donors that must be attached to banked lines before CIRM will fund research that uses those lines? see Issue Memo 1 for initial suggestions
[B2]	Donor Compensation or Payment	Should CIRM refuse to pay for research that uses lines that were derived by others who had paid for the eggs or embryos?	Note overlap with donor protection issues and need to link standards
[B3]	Collaboration with non-CIRM-funded Partners	What about a collaboration between a California investigator and someone else, where the CA investigator does not work with the foreign lines but provides other services, e.g. data analysis or some other more distant form of collaboration -- can CIRM fund this investigator if he is collaborating with someone who uses lines derived in a fashion that does not match CIRM's own standards?	Not resolved
[B4]	Accepting Outside Reviews	Under what circumstances should reviews performed by a non-California institution regarding animal research or genetic engineering research using hES cells be accepted as sufficient for CIRM-funded work, and when will CIRM insist on its own standards of review?	see Issue Memo 1
[B5]	Other State Laws	Should we explicitly forbid procurement of frozen embryos from states or countries where embryo research or SCNT is not legal?	

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C. Issues Identified by Banking Study Group			
#	Issue	Question or Issue	Comments
[C1]	Stem Cell Registry	Should CIRM maintain a registry of stem cell lines?	Study Group Proposal: 1. CIRM should maintain a registry with information about existing cell lines.
[C2]	Stem Cell Banking	Should there be a California Stem Cell Bank? Is there a role for third party organizations to provide this function?	2. There needs to be a CIRM Bank that can be administered by a third party through grant/contract or other financial arrangement. 3. For CIRM-generated lines there needs to be time frame for providing cells to the Bank.
[C3]	Joint Banking and ESCRO Committees	Should each facility engaged in obtaining and storing HES cell lines create a [separate] Banking committee for policy and oversight purposes or can an ESCRO or IRB sub-committee serve this purpose?	Policy and oversight should be an ESCRO function. There is no need for a separate Banking committee.
[C4]	Materials Stewardship / Responsible of Cell Identifiers	How should identifiable cells or cell lines be tracked, especially if there may be a need to contact donors?	Intuitions that originally derive source materials from donors should be responsible for maintaining personally identifiable information in accordance with HIPAA, IRB requirements or other privacy standards. Cell lines should be coded in a manner where there is a possibility of contacting donors through the institution that maintains the personally identifiable information.

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D. Issues Identified by Pre-Clinical Research Standards Study Group			
#	Issue	Question or Issue	Comments
[D1]	Sources of Stem Cells	Informed consent requirements will very depending on source of materials. a) Adult tissues b) Fetal tissues c) Chord blood and placenta d) Excess IVF-derived embryos e) Eggs fertilized for stem cell derivation f) Eggs transplanted with somatic cell nuclei g) Eggs activated parthenogenetically h) Somatic cells fused with stem cells i) Somatic cells reprogrammed	45 CFR Subtitle A (10–1–04 Edition) provides a useful starting point.
[D2]	Informed Consent	a) Adult tissues b) Fetal tissues c) Chord blood and placenta d) Excess IVF-derived embryos e) Eggs fertilized for stem cell derivation f) Eggs transplanted with somatic cell nuclei g) Eggs activated parthenogenetically h) Somatic cells fused with stem cells i) Somatic cells reprogrammed	a) Individual or surviving family b) All parents c) All parents for child d) All gamete donors e) All gamete donors f) Both donors g) Egg donor h) ? i) ?
[D3]	Other Relevant Laws	For a-h are there any relevant state laws that may provide guidance or any CA laws that may impact regulatory language?	Four states have laws in support: CA, MA, NJ, CN ?? states have laws against
[D4]	Tests in Animal Models	Are there any special considerations for ESCRO, IRB, IACUCs for: a) Introduction of SC into post-natal host b) Introduction of SC into pre-natal, post-implantation, in utero host c) Introduction into pre-implantation "chimera"	a-b generally covered by IACUC and c may need more clarification in guidelines. Should review any existing state laws that cover this activity. Not allowed in NA guidelines.

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