Draft – CIRM MES Compliance Plan 2007-08

Introduction

In April 2007, CIRM staff was charged by the CIRM President to develop a plan by which CIRM will oversee and ensure the compliance of grantee institutions with CIRM policies. The Senior Officer for Medical and Ethical Standards was charged with developing a plan to address compliance with the CIRM's Medical and Ethical Standards (MES) regulations. This draft plan identifies specific requirements of the MES regulations and outlines procedures and protocols for ensuring compliance.

Summary of MES Requirements

The CIRM MES regulations section 100070 describes stem cell research oversight (SCRO) committee review and notification requirements for CIRM-funded research. Review and notification requirements vary depending on the nature of the funded research. Attachment 1 summarizes the requirements based on the type of research proposed. In advance of CIRM issuing a notice of grant award, the CIRM Grants Administration Policy (GAP) requires documentation of any approval or notification required by the MES regulations.

The CIRM MES regulations section 100095 describes additional requirement for CIRM-funded research involving the procurement of oocytes. This section includes procedural requirements designed ensure donors have access to medical care required as a direct result of oocyte donation. In addition to these requirements, section 100080(e)(2) limits payments to gamete donors to "permissible expenses." Permissible expenses are defined to be necessary and reasonable costs directly incurred as a result of donation or participation in research activities. Permissible expenses may include but are not limited to cost associated with travel, housing, child care, medical care, health insurance, and actual lost wages.

Compliance Activities

CIRM reserves the right to conduct MES compliance oversight evaluations. Institutions are selected for not-for-cause evaluation based on a range of considerations, including:

- Being a current recipient of CIRM-funding
- Geographic location
- Complaints about the conduct of research at the institution
- Compliance status reported in audit or evaluation by other regulatory agency

When CIRM decides to undertake a compliance oversight evaluation, it proceeds as follows:

(1) CIRM advises institutional officials in writing that it intends to conduct an oversight evaluation at the institution. CIRM's notice requests that the institution provide to CIRM, by a specified date, relevant information concerning the institution's compliance with the CIRM MES regulations, including but not limited to:

(a) SCRO membership, policies and procedures;
(b) A list of active CIRM-funded research indicating review or notification status;
(c) Minutes and resulting investigator notification letters from SCRO committee meetings where specified CIRM-funded research was reviewed;

In the event of shared institutional SCRO, the institution subject to a compliance oversight evaluation need only retain SCRO committee meeting minutes and notification letters pertaining to the institution's CIRM-funded research.

(2) For research involving the donation of human oocytes for CIRM-funded research, CIRM may require the following:

(a) For procurement of oocytes initially provided for reproductive uses, a copy of the protocol for determining oocyte disposition;
(b) Documentation of procedures for ensuring access to medical care pursuant to section 100095(c);
(c) The protocol for determining permissible expenses pursuant to section 100080(e)(2)

(3) For research involving human subjects or live animals, CIRM will require documentation of approval by any relevant oversight committee.

In the event of shared institutional oversight committee, the institution subject to a compliance oversight evaluation need only retain documentation pertaining to the institution's CIRM-funded research.

(4) For research involving fetal tissue, CIRM will require documentation of compliance with section Health and Safety Code 100085 use of fetal tissue.

Following its evaluation, CIRM issues a letter to the institution containing CIRM's findings regarding the institution's compliance. If CIRM identifies noncompliance, it will describe in its letter any relevant corrective actions proposed or implemented by the institution and the extent to which these corrective actions adequately address the noncompliance. If the institution has not proposed an adequate corrective action plan to address one or more of CIRM's findings, CIRM may initiate compliance activities pursuant to section 100050.

Table A: Research Oversight Requirements for 100070 SCRO Review and Notification

Section Reference	Type of Research	SCRO Review & Approval	IRB Review & Approval	Other Review
(a)	Procurement of human oocytes	Yes	Yes	
	Use of human oocytes	Yes	Yes, if human subjects involved	Yes, if animal subjects involved
(b)	Use of human embryo	Yes	Yes, if human subjects involved	Yes, if animal subjects involved
(c)	Research intended to create a covered stem cell line	Yes	Yes, if human subjects involved (note SCNT would generally trigger)	
(d)	in vitro research	Only notification no review requirement	No	No
(e)	Introducing covered stem cell lines to animals or neural-progenitors	Yes	Yes, if human subjects involved	IACUC
(f)	Introducing covered stem cells into a live born human	Yes	Yes	

Note the CIRM MES regulations generally apply when a covered stem cell line is utilized. The one exception is introduction of neural-progenitors into the brain of animals. Research involving adult stem cells may involve human subjects and require IRB approval and conform to CIRM informed consent requirements in section 100100.