M E M O R A N D U M

TO: INDEPENDENT CITIZENS OVERSIGHT COMMITTEE

FROM: IAN K. SWEEDLER, INTERIM GENERAL COUNSEL TO THE PRESIDENT

SUBJECT: AMENDMENTS TO GRANTS ADMINISTRATION POLICY FOR ACADEMIC AND NON-PROFIT INSTITUTIONS

DATE: **APRIL 27, 2009**

This memorandum supersedes my April 22, 2009 memorandum regarding this item on the agenda.

At your December 2008 meeting, you adopted a set of amendments to the Grants Administration Policy for Academic and Non-Profit Institutions (Non-Profit GAP). The approved amendments updated the original Non-Profit GAP. Those amendments addressed issues that had been identified by CIRM staff, applicants and grantees after two years of experience with the original Non-Profit GAP. The amendments also incorporated into the Non-Profit GAP several policies the ICOC had adopted after the original Non-Profit GAP was completed.

As required by the Administrative Procedure Act, staff submitted the amendments for review by the Office of Administrative Law (OAL). OAL has requested a number of additional changes, for which we now seek your approval. The new amendments clarify or correct terminology and references to other regulations. Adoption of these additional amendments will not result in any substantive change to policies that were previously approved by the ICOC. The proposed amendments have been posted for public comment, and the comment period has now closed.

The attached documents (Items 5B and 5C) show the Non-Profit GAP and Section 100500 of CIRM's regulations, the provision that incorporates the Non-Profit GAP into CIRM's codified regulations. As required by OAL, these documents are marked up to show all pending amendments, including those you have already approved. The new changes are highlighted in green.

Last week, when we sent you the new proposed changes, Jeff Sheehy raised a question about one of the changes that had been approved earlier in the process. We have taken another look at that provision, and agree that an additional change is appropriate.

Section III.C.6., "Research Involving Human Subjects," lists documentation that CIRM may request from a grantee. The earlier amendment deleted two items from that list. We propose to restore those items, in order to preserve CIRM's ability to verify that CIRM-funded research meets the highest ethical standards.

With this change, Section III.C.6. would read as follows:

> **c.** The Grantee bears ultimate responsibility for protecting Human Subjects involved in CIRM-funded research, including Human Subjects at all participating and collaborating sites. At CIRM's request, the prospective Grantee must provide the following documentation regarding itself and each collaborating site to the GMO:
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> **i.** Documentation of IRB review and approval (specifying the name of the PI, the name of the Grantee and any collaborating organization or site, the CIRM Application number, the project title, and inclusive dates for which IRB approval has been granted);
> **ii.** Sample Human Subject (patient) information and informed consent documents;
> **iii.** Documentation of human research subject education of key personnel;
> **iv.** For clinical trials, a data safety monitoring plan;
> **v.** Institutional assurance that the research is conducted in accordance with relevant national, state, and local laws; and
> **vi.** A copy of the FDA-IND or IDE letter, where applicable when a clinical investigation involves the use of any drugs or devices.

This version restores items (ii) and (iii).

If, with this revision, the new changes meet with your approval, staff requests adoption of the following motion:

> **MOTION: To adopt proposed amendments to Section 100500 of Title 17 of the California Code of Regulations (Agenda Item #5B), and to the Grants Administration Policy for Academic and Non-Profit Institutions (Agenda Item #5C), and to incorporate the revised Section III.C.6. set out above .**

If you have any questions about the amendments, please feel free to contact me at 415-396-9122 or isweedler@cirm.ca.gov.