State of California
Office of Administrative Law

In re: **California Institute for Regenerative Medicine**	**DECISION OF PARTIAL DISAPPROVAL OF REGULATORY ACTION**
Regulatory Action: Title 17 **California Code of Regulations**	**Government Code Section 11349.3**
Adopt sections: **Amend sections: 100500** **Repeal sections:**	**OAL File No. 2009-0806-03 SR**

SUMMARY OF REGULATORY ACTION

The California Institute for Regenerative Medicine (CIRM) was established in early 2005 with the passage of Proposition 71 (The California Stem Cell Research and Cures Initiative). Proposition 71 provided $3 billion in funding to CIRM. CIRM makes grants and provides loans for stem cell research, research facilities and other vital research opportunities.

On January 27, 2009, CIRM submitted a proposed rulemaking (OAL File No. 2009-0127-03 S) to amend the standards and criteria for the awarding and oversight of grants, loans and contracts for academic and non-profit recipients. Specifically, CIRM sought to amend section 100500 of title 17 of the California Code of Regulations (CCR) to update the revision date of and illustrate changes to a document incorporated by reference: the Grants Administration Policy for Academic and Non-Profit Institutions (GAP). The GAP is a 51 page document with a six page appendix and sets forth the standards and criteria for the awarding and oversight of grants, loans, and contracts. Section 100500 provides that all academic and non-profit institutional recipients of CIRM funding must adhere to the terms and conditions of the GAP.

OAL File No. 2009-0127-03 S was withdrawn by CIRM on March 11, 2009. On August 6, 2009, CIRM resubmitted the withdrawn file. The resubmission (OAL File No. 2009-0806-03 SR) again proposed amendments to the GAP, including proposed changes to the *Appeals of Scientific Review* section of the GAP. The *Appeals of Scientific Review* section of the GAP contains the standards for appealing a denial of an Application for CIRM funding of research or research related opportunities.

DECISION

On September 18, 2009, the Office of Administrative Law (OAL) notified CIRM of the approval in part and the disapproval in part of OAL File No. 2009-0806-03 SR. The amendment to section 100500 of title 17 of the CCR, and the amendments to the document incorporated by reference, CIRM's Grants Administration Policy for Academic and Non-Profit Institutions were approved except as to the amendments to the *Appeals of Scientific Review* section, which were disapproved. The amendments to the *Appeals of Scientific Review* section were disapproved for failure to comply with the *clarity* standard of Government Code section 11349.1.

DISCUSSION

Any regulatory action a state agency adopts through the exercise of quasi-legislative power delegated to the agency by statute is subject to the requirements of the Administrative Procedure Act (APA) unless a statute expressly exempts or excludes the act from compliance with the APA. (Gov. Code, sec. 11346.) Accordingly, regulations adopted by CIRM must be adopted pursuant to the APA. No exemption or exclusion applies to the regulatory action under review. Thus, before the proposed regulatory action may become effective, it is subject to a review by OAL for compliance with procedural requirements and substantive standards of the APA. (Gov. Code, sec. 11349.1(a).) Generally, to satisfy the standards a rule or regulation must be legally valid, supported by an adequate record, and easy to understand. In this review OAL is limited to the rulemaking record and may not substitute its judgment for that of the rulemaking agency with regard to the substantive content of the regulation. This review is an independent check on the exercise of rulemaking powers by executive branch agencies intended to improve the quality of rules and regulations that implement, interpret, and make specific statutory law, and to ensure that the public is provided with a meaningful opportunity to comment on rules and regulations before they become effective.

Clarity

In adopting the APA, the Legislature found that the language of many regulations was unclear and confusing to the persons who must comply with the regulations. (Gov. Code, sec. 11340(b).) For this reason, subdivision (a)(3) of Government Code section 11349.1 requires that OAL review all regulations for compliance with the clarity standard. Government Code section 11349, subdivision (c), defines "[c]larity" as meaning "... written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them." Section 16, subdivision (a), of title 1 of the CCR further provides:

> (a) A regulation shall be presumed not to comply with the "clarity" standard if any of the following conditions exists:

> (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
> (2) the language of the regulation conflicts with the agency's description of the effect of the regulation; or
> . . .
> (5) the regulation presents information in a format that is not readily understandable by persons "directly affected;" . . . .

OAL disapproved the amendments proposed with respect to the process for review upon appeal of a denied Application for funding as set forth in the *Appeals of Scientific Review* section of CIRM's GAP. The proposed amendments to the *Appeals of Scientific Review* of CIRM's GAP are as follows (with the 45-day changes from the existing text indicated in single underline and strike-through; changes in the first 15-day text with double underlining, double strike-through and italics (italics used here instead of the yellow highlighting used by CIRM in the noticed text); changes in the second 15-day text with single strike-through and single underlining and bolding (bolding used here instead of the green highlighting used by CIRM in the noticed text)):

> ~~The *aA*~~*The a*pplicant~~*s*~~ should carefully examine the review report provided by CIRM. Any questions about the conduct of the review must first be raised with the SRO responsible for the review meeting in question. **The SRO can discuss the applicant's concerns, answer any questions, and explain the appeals process. Once the applicant has conferred with ~~If an applicant's concern cannot be informally resolved in consultation with~~** the SRO, CIRM will accept a *request for* **~~a~~ formal** appeal.
>
> Grounds for ~~An applicant may then lodge **a formal**~~ appeal ~~*of the review*~~ are strictly limited to circumstances in which ~~only if the applicant can show that~~ *an applicant can show that* a demonstrable financial*, professional or personal* ~~*or scientific*~~ conflict of interest **(as defined in Cal. Code Regs., Title 17, section 100003**) had a negative impact on the review process and resulted in a flawed review. ~~This shall be the only ground for appeal.~~ *This shall be the only ground for appeal.* Differences of scientific opinion between or among PIs and reviewers are not grounds for appeal.
>
> To lodge an appeal, the applicant must submit a written ~~an appeal~~ request ~~in writing~~ to the SRO or to the ~~*Director of Scientific Activities*~~*Chief Scientific Officer*~~*The deadline for submission is*~~ within 30 days from the date that ~~of~~ CIRM~~'s making~~ makes the review report available to the applicant. CIRM staff *will then assess the merits of the appeal* in consultation with the Chair *and Vice-Chair(s)* of the GWG ~~*will then assess the merit of the appeal*~~ request ~~in consultation with the chair of the SMRFWG~~ and present a written

recommendation to the President of CIRM. If the eChair of the ~~SMRF~~GWG has a financial, professional or personal ~~or scientific~~ conflict of interest *(as defined in Cal. Code Regs., Title 17, section 100003) in the* ~~*with the*~~ aApplication that is the subject of the appeal, *staff will consult with an eligible* ~~*as determined by ICOC policy adopted pursuant to Health and Safety Code section 125290. 50(e), a different*~~ scientific member of the ~~SMRF~~GWG *(i.e. a member* who has no financial, professional or personal ~~or scientific~~ conflict of interest*).* ~~*will be consulted.*~~ *If the Vice-Chair(s) of the GWG has a conflict of interest in the Application (as defined in Health & Safety Code section 125290.30(g)), staff will consult with an eligible patient advocate member of the GWG (i.e., a member who has no conflict of interest).* The President of CIRM will consider the appeal and the recommendations and issue a ~~then make the~~ final written decision on the merits of the appeal.

~~*If the President determines that an appeal is meritorious, then the aApplication will be reevaluated for scientific merit by two scientist members of receive a new review by the SMRFGWG.*~~ *If an appeal is meritorious, the Application will receive a new review by the following members of the GWG: (1) the Chair of the GWG; (2) the Vice-Chair(s) of the GWG; (3) at least two, but no more than three, scientific reviewers of the GWG or specialists selected by CIRM staff in consultation with the chair of the GWG; and (4) if the Application is for disease-specific research, the patient advocate member of the GWG who was appointed from an advocacy group for that disease, provided that he or she is eligible to participate.*

If any of the members in categories (1) and (3) above has a conflict of interest in the Application under the applicable conflict of interest policies, staff shall select an eligible scientific or patient advocate member, as appropriate, to serve in his or her place. Members in categories (2) and (4) above may waive their participation, or if they do not have a conflict of interest in the Application, designate another eligible patient advocate member of the GWG to participate in their place.

CIRM staff, in consultation with the members in categories (1) through (4) above, will set a date for the review. At least two weeks before the scheduled review, all eligible patient advocate members of the GWG will be invited to participate. The Application will be reviewed pursuant to the procedures for the review of Applications set forth in the GWG bylaws, provided, however, that the quorum requirements shall not apply. A summary of the ~~*The resulting*~~ new review and recommendation ~~A recommendation based on the new~~

~~review~~ will *~~then~~* be ~~presented~~ submitted to the ICOC, which will make the final decision on funding the ~~a~~Application in question.

The following are examples of the more significant clarity issues presented. All clarity issues identified and discussed with the agency concerning the *Appeals of Scientific Review* section must be addressed prior to resubmission.

A. The proposed amendments are in a format that makes the process for review of an Application not readily understandable by persons directly affected. (1 CCR 16 (a)(5)).

1. It is unclear as to which members are participating in the decision regarding the merit of the Application upon review. The fourth paragraph states that if an appeal is found to be meritorious in a written decision by the President, the Application will receive a new review by the following GWG members (emphasis added): "(1) the Chair of the GWG; (2) the Vice-Chair(s) of the GWG; (3) **at least two, but no more than three, scientific reviewers of the GWG or specialists selected by CIRM staff** in consultation with the chair of the GWG; and (4) if the Application is for disease-specific research, the patient advocate member of the GWG who was appointed from an advocacy group for that disease, provided that he or she is eligible to participate." The fifth paragraph states that if the Chair or any member from category (3) above, has a conflict of interest, staff shall select **an eligible scientist or patient advocate member, as appropriate**, to serve in their place. Members in categories (2) and (4) may waive their participation, or if they do not have a conflict of interest, designate another eligible patient advocate member to participate in their place. At least two weeks before the scheduled review, **all eligible patient advocate members of the GWG will be invited to participate.** The Application will be reviewed pursuant to the procedures for the review of Applications **set forth in the GWG bylaws,** provided, however, that the quorum requirements shall not apply. Then a summary and recommendation will be submitted to the Independent Citizens Oversight Committee (ICOC) for final decision.

2. **In what manner are all eligible patient advocate members of the GWG invited to participate in the review as stated in the sixth paragraph?** The sixth paragraph states: "all eligible patient advocate members of the GWG will be invited to participate." However, in the fourth and fifth paragraphs, it states that the new review will be by the Vice-Chair(s) (who is/are patient advocate member(s)) and the patient advocate member of the GWG who was appointed from the advocacy group for that disease if the Application is disease-specific (and they are eligible, i.e. having no conflict of interest). It is unclear as to which members are allowed to participate and in what capacity in the review, because in the fourth paragraph it specifically sets forth which patient advocate members will be participating, but in the sixth paragraph, it states "**all** patient advocate members of the GWG be invited to participate."

3. **Who are the "specialists" referred to in the fourth paragraph and by what criteria is such selection made?** It states: "(1) the Chair of the GWG; (2) the Vice-Chair(s) of the GWG; (3) at least two, but no more than three, scientific reviewers of the GWG **or specialists** selected by CIRM staff in consultation with the chair of the GWG . . . . (Emphasis added.)"

4. **Bylaws:** "The Application will be reviewed pursuant to the procedures for the review of Applications set forth in the GWG bylaws, provided, however, that the quorum requirements shall not apply." The procedures (Bylaws) are not articulated and are not properly incorporated by reference. If they are to be incorporated into the procedure for review of Applications and are going to apply generally to those seeking review of their denied Applications, then such procedures would necessarily have to be adopted pursuant to the APA and would have to be properly incorporated.

5. **Presentation of text.** The text presented in the second 15-day notice had both underlining and strike-through in a number of places. It is unclear as to what exactly is intended to be retained as final text and what is being deleted.

B. Noncompliance with Government Code, section 11346.8(c) and 1 CCR 46.

CIRM did not comply with Government Code section 11346.8(c) and title 1 section 46 of the CCR. Government Code section 11346.8(c) provides:

> No state agency may adopt, amend, or repeal a regulation which has been changed from that which was originally made available to the public pursuant to Section 11346.5, unless the change is . . . (2) sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action. If a sufficiently related change is made, the full text of the resulting adoption, amendment, or repeal, **with the change clearly indicated, shall be made available to the public for at least 15 days** before the agency adopts, amends, or repeals the resulting regulation. . . . (Gov. Code, sec. 11346.8(c). Emphasis added.)

Title 1, section 46 of the CCR states:

> (a) Changes to regulations in accordance with Government Code Section 11346.8(c) shall be made using a uniform method and **shall illustrate accurately all changes to the original text.** (Emphasis added.)

Although the last paragraph in the submitted text appeared for the first time in the third 15 -text, the text was not underlined or highlighted and the amendments were not discussed in the notice. The public was not adequately apprised that it was a newly proposed amendment. It appeared as if it were existing text (with amendments proposed to the last sentence), when in actuality only the last sentence was existing text.

C. Failure to meet the requirements of title 1, section 20 of the CCR.

According to the proposed amendments, the review during the appeal of the rejected Application is to be pursuant to "GWG bylaws." However, those bylaws were not included in the rulemaking file and were not made available to the public as part of this rulemaking. In essence, the incorporated document is incorporating another document by reference, which is treated similarly. Title 1, section 20 of the CCR states:

> . . .
> (b) Material proposed for "incorporation by reference" shall be reviewed in accordance with procedures and standards for a regulation published in the California Code of Regulations. . . .

Section 20 further states that an agency may "incorporate by reference" only if certain conditions are met. CIRM did not meet these conditions as it relates to the bylaws. One cannot know from the text of the regulatory provision which standards will be applied during the review. In the absence of the bylaws being part of the rulemaking file, the public is not only denied an opportunity to comment on them, but even to know what they are.

CONCLUSION

For the reasons set forth above, OAL has disapproved the amendments to the *Appeals of Scientific Review* section of the CIRM Grants Administration Policy for Academic and Non-Profit Institutions. Prior to resubmission, please be sure to make the revisions to this section available to the public pursuant to section 44 of title 1 of the CCR. If you have any questions, please contact me at (916) 323-6800.

Date: September 25, 2009

Elizabeth A. Heidig
Staff Counsel

for: SUSAN LAPSLEY
Director

Original: Dr. Alan Trounson
cc: Ian K. Sweedler