

**STATE OF CALIFORNIA  
OFFICE OF ADMINISTRATIVE LAW**

In re: )  
)  
) DECISION OF PARTIAL DISAPPROVAL  
CALIFORNIA INSTITUTE FOR )  
REGENERATIVE MEDICINE ) OF REGULATORY ACTION  
)  
) (Gov. Code, sec. 11349.3)  
REGULATORY ACTION: )  
Title 17, California Code of )  
Regulations, section 100500 ) OAL File No. 07-0112-01S  
)  
Section VI.E.3.b of the CIRM Grants )  
Administration Policy for Academic )  
and Non-Profit Institutions )  
)  
\_\_\_\_\_)

**SUMMARY OF REGULATORY ACTION**

The California Institute for Regenerative Medicine (“Institute” or “CIRM”) was established in early 2005 with the passage of Proposition 71 (the “Act”), the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides \$3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004 and called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities. This regulatory action establishes standards and criteria for the awarding and oversight of the grant awards.

**DECISION**

On February 28, 2007, the Office of Administrative Law (OAL) approved the adoption of section 100500 of title 17 of the California Code of Regulations and the incorporated CIRM Grants Administration Policy for Academic and Non-Profit Institutions except for section VI.E.3.b. Section VI.E.3.b was disapproved for failure to comply with the requirements for incorporation by reference and failure to comply with the clarity standard of Government Code section 11349.1.

**DISCUSSION**

The adoption of regulations by the California Institute for Regenerative Medicine (“CIRM”) must satisfy requirements established by the part of the California Administrative Procedure Act (“APA”) that governs rulemaking by a state agency. Any rule or regulation adopted by a state

agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, is subject to the APA unless a statute expressly exempts the regulation from APA coverage. (Gov. Code, sec. 11346.)

Before any rule or regulation subject to the APA may become effective, the rule or regulation is reviewed by the Office of Administrative Law (“OAL”) for compliance with the procedural requirements of the APA and for compliance with the standards for administrative regulations in Government Code Section 11349.1. 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.

Section VI.E.3.b of the CIRM Grants Administration Policy for Academic and Non-Profit Institutions incorporated by new section 100500 of title 17 provides:

“The Trainee Termination Form is the basis for validating the total period of support. The Grantee must submit to CIRM a Trainee Termination Form for each trainee within 30 days of the end of the trainee’s support.”

OAL adopted section 20 of Title 1 of the California Code of Regulations to assure that material incorporated by reference in regulations conforms to the requirements of the APA. This section provides the requirements for a state agency that wishes to incorporate another document as part of a regulation by reference to that document. An incorporation by reference of an external document (or part of an external document) into a regulatory provision effectively makes the incorporated text a part of the regulatory provision, as though the incorporated text were printed in its entirety as part of the regulatory provision. (Cal. Code regs., tit.1, section 20(a).) For this reason the incorporated document must be included in the rulemaking record for OAL review and must have been made available to the public for comment. (Cal. Code regs., tit. 1, section 20(b).) In this instance, the Trainee Termination Form was not included in the record, nor alternatively was its content described in section VI.E.3.b. The form was apparently not made available to the public either.

Subsection (c) of section 20 provides:

“An agency may ‘incorporate by reference’ only if the following conditions are met:  
...

- (4) The regulation text states that the document is incorporated by reference and identifies the document by *title and date of publication or issuance*. Where an authorizing California statute or other applicable law requires the adoption or enforcement of the incorporated provisions of the document as well as any subsequent amendments thereto, no specific date is required....” (Emphasis added.)

Failure to specify the date of publication or issuance of the particular version of the form incorporated by reference makes the provision difficult to understand. One cannot know from the text of the regulatory provision which particular revision of the form has been incorporated by reference. Further, since section VI.E.3.b gives no revision date, one might understand this provision to require the use of the most recent version of the form. Such a prospective incorporation by reference (one that automatically incorporates future changes to an incorporated document) is of questionable validity. While prospective incorporation by reference could cut down on periodic rulemaking to incorporate future changes made by the body who originally issued the incorporated document, it also eliminates the opportunity for public participation in the decision to give regulatory effect to those changes. The validity of prospective incorporation by reference has been questioned by the Court of Appeal in a case involving a Department of Health Care Services regulation incorporating by reference standards issued by the Department of Finance.

“There is no procedural barrier prohibiting the enacting agency from adopting by reference a set of standards issued by another agency if supporting evidence is made available at a public hearing, opportunity for refutation is given, the pro and con evidence considered and the evidentiary material assembled in an identifiable record. On the other hand, an attempt to embody by reference future modifications of the incorporated material without additional hearings would have dubious validity. (See *Olive Proration etc. Com. V. Agric. Tec. Com.*, ... , 17 Cal.2d at P. 209, 109 P.2d 918.)” [California Ass’n of Nursing Homes, Etc. v. Williams (1970) 4 Cal.App.3d 800, 814, 84 Cal.Rptr. 590.]

In addition, it may be that the reason the Trainee Termination Form was not included in the rulemaking file, nor identified by revision date, was that it had not yet been developed. If this is the case, a Grantee would not easily understand how to comply with section VI.E.3.b which requires the submittal of the Trainee Termination Form within 30 days of the end of the trainee’s support. OAL is required to review each regulation to determine whether the regulation complies with the “clarity” standard of the APA. “Clarity” as defined by Government Code section 11349(c) means “written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them.” In the absence of a Trainee Termination Form, section VI.E.3.b would not easily be understood.

### **CONCLUSION**

For the reasons set forth above, OAL has disapproved section VI.E.3.b of the CIRM Grants Administration Policy for Academic and Non-Profit Institutions. Upon resubmission, please be sure to make the Trainee Termination Form and any revisions to section VI.E.3.b available to the public pursuant to section 44 of title 1 of the California Code of Regulations. If you have any questions, please contact me at (916) 323-6808.

Date: March 7, 2007

---

CRAIG S. TARPENNING  
Senior Staff Counsel

for: LINDA C. BROWN  
Deputy Director

Original: Dr. Zachary W. Hall, Interim President  
cc: C. Scott Tocher