



MEMORANDUM

TO: Members of the ICOC

FROM: C. Scott Tocher, Counsel to the Chair

RE: **Item 9:** Adoption of Regulation 100801 - Intellectual Property Provisions Applicable to Loan Recipients

DATE: November 1, 2010

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Executive Summary

The ICOC initiated a rulemaking process late last year to propound a regulation (100801) applying certain Intellectual Property regulations to recipients of CIRM loans. The ICOC approved an Interim regulation, which staff used as the basis for initiating the formal adoption process. The process for soliciting and considering public input has concluded and the regulation is now ready for the ICOC's final adoption. No relevant public comment was received and **the proposed language before the ICOC today is materially unchanged from the version the ICOC approved last year. Staff requests the ICOC adopt the final version of 100801.** Staff will then submit the regulation to the Office of Administrative Law, which will conduct a final review.

I. Background

In 2010, the California Institute for Regenerative Medicine (CIRM) began offering research loans to for-profit institutions. The ICOC adopted an Interim Loan Administration Policy to cover various administrative procedures that will apply to the review and administration of research loans and loan applications, and will consider adopting a permanent policy at this meeting. The Loan Task Force, a subcommittee of the ICOC, developed much of the policy goals and the Finance Subcommittee has focused on refining the terms of the loan program.

Early in the task force's meetings in 2008, it was determined that virtually all of the Intellectual Property regulations that applied in the context of grants should also apply to loan recipients. The exception, of course, is the requirement of grantees to share profits

and other revenues with the state. In the context of loans, revenue sharing is superfluous in light of the loan repayment and warrant provisions of the loan program.

Currently, the agency's IP regulations only apply to grants. A new regulation is necessary to extend certain provisions to loan recipients. To that end, and to ensure potential loan recipients in the earlier Disease Team RFA were subject to the agency's IP regulations, the ICOC adopted an interim regulation (100801) and initiated a formal rulemaking process to make that regulation permanent.

Proposed regulation 100801 incorporates the agency's consolidated IP regulations (sections 100600, *et seq.*) with the exception of regulation 100606, addressing revenue sharing. In addition, certain provisions of section 100602, that would require reporting of revenues, are exempted for the same reasons as the revenue sharing requirement. Subdivision (b) of the interim regulation is intended to ensure that a loan recipient cooperates with CIRM in identifying third parties that may be interested in acquiring the loan recipient's intellectual property in the event the loan recipient is otherwise planning to abandon the intellectual property.

The proposed regulation is virtually identical to the version approved by the ICOC to initiate the rulemaking process (save for the correction of typographical errors).

II. Recommendation:

Staff recommends the ICOC adopt proposed Regulation 100801 pursuant to its authority under Proposition 71, and direct staff to finalize the process of permanent adoption pursuant to the Administrative Procedure Act.