



MEMORANDUM

TO: Members of the ICOC

FROM: C. Scott Tocher, Counsel to the Chair

RE: **Item 16:** Interim Regulation 100801 - Intellectual Property Provisions
Applicable to Loan Recipients

DATE: August 11, 2009

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In 2009, the California Institute for Regenerative Medicine (CIRM) will begin offering research loans to for-profit institutions. Earlier this year, the ICOC adopted a Loan Administration Policy to cover various administrative procedures that will apply to the review and administration of research loans and loan applications. The Loan Task Force, a subcommittee of the ICOC, developed much of the policy.¹

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 upcoming Disease Team RFA are subject to the agency's IP regulations, staff proposes the ICOC adopt an interim regulation (100801) that describes the provisions applicable to loan recipients. This regulation will remain in effect for 270 days or until superseded by a final regulation adopted pursuant to the Administrative Procedure Act (APA). Staff proposes to use the interim regulation as the basis for initiating a formal rulemaking under the APA.

Proposed regulation 100801 incorporates the agency's consolidated IP regulations (sections 100600, *et seq.*) that are also on this agenda for consideration, with the

¹ The members of the Loan Task Force are Floyd Bloom, Marcy Feit, Michael Goldberg, Bob Klein, Ted Love, Ed Penhoet, Duane Roth (Chair), Jeff Sheehy and Os Steward.

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.

Recommendation: Staff recommends the ICOC adopt proposed interim Regulation 100801 pursuant to its authority under Proposition 71, and direct staff to initiate the process to permanently adopt the regulation pursuant to the APA.