CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

MEMORANDUM

TO: Members of the ICOC

FROM: C. Scott Tocher, Counsel to the Chair

RE: **Item 3:** Adoption of Remaining Consolidated Intellectual Property Regulations for For-Profit and Non-Profit Grantees

DATE: October 13, 2009

Executive Summary

At the ICOC's September 25, 2008 meeting, the Board gave its approval for a project that (a) consolidates the intellectual property regulations for Non-Profit Grantees and the intellectual property regulations for For-Profit Grantees into a single set of regulations, and (b) clarifies the scope of certain regulations. The ICOC tasked the Intellectual Property Task Force (IPTF) with drafting the revisions to the regulations and initiating the formal adoption process with the Office of Administrative Law. The task force completed its work and the ICOC last month adopted all but one of the proposed consolidated regulations.[1] The ICOC directed staff to redraft a portion of proposed regulation 100601 and bring the regulation back for adoption at its September 15th meeting. At the September meeting additional issues were raised and staff reposted section 100601 with clarifications sought by some board members. Staff presents the regulation today, amended as requested by the ICOC, and presents further (some related) amendments for the Board's consideration. Once finalized by the ICOC, these regulations will be submitted to the Office of Administrative Law immediately to ensure the regulations are applicable to recipients of Disease Team grants later this year.

I. Background

The adoption of policies and their transformation into formal regulations is a complicated process governed by the Administrative Procedures Act ("APA"), which is administered by the Office of Administrative Law ("OAL"). Generally speaking, this multi-step process begins with the preparation by a task force of a draft policy, which in

[1] The consolidated IP regulations comprise eleven regulations: sections 100600 – 100611. The Board adopted proposed regulations 100600, and 100602-100611.

turn is approved by the ICOC as an interim policy. From that document, staff translates the elements of the policy into formal regulatory language and submits the regulations ("notices") to the OAL. This commences the one-year period for the agency to fine-tune the regulations through a series of drafts and changes developed in light of public comment and input. When all the comments have been received and there are no further changes to the draft regulations, they are brought before the ICOC for final adoption and then sent to the OAL, which conducts an exhaustive review of the regulations. If approved by the OAL, the regulations are published by the Secretary of State and have the force and effect of law.

In the development of the original IP policies governing non- and for-profit grantees, the IP Task Force and ICOC held at least 15 public meetings devoted to the policy development, observed 18 public presentations by experts and stakeholders, surveyed the best practices of more than 20 funding entities, conducted over 100 interviews, refined the regulations over 12 public comment rounds and responded in detail to more than 100 comment letters in accordance with the APA. As required by Prop 71, the ICOC propounded policies and regulations that "balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development and clinical trials with the need to assure that essential medical research is not unreasonably hindered…."

The application of the existing regulations turns largely on the type of grant recipient – commercial versus noncommercial. The ICOC first approved an intellectual property policy for non-profit and academic research institutions, as those institutions were the first recipients of CIRM grants. That policy, initially adopted in February of 2006, completed the formal regulatory adoption process and went into effect in 2007. The formal adoption of regulations governing for-profit institutions began during the development of the non-profit policy and concluded in early 2008.

CIRM received feedback from many sources concerning the IP regulations from several perspectives after the regulations were adopted. Prospective grant applicants asked numerous questions and some grantees sought clarification. In addition, staff conducted two public (and well attended) IP workshops in September of 2008 intended to familiarize the for-profit community with how the regulations work. This feedback, coupled with internal legal analysis and consultation with outside counsel, suggests that consolidating and clarifying the existing IP regulations would eliminate confusion, make the regulations more user-friendly and ease administration. In addition, collaborative projects funded by CIRM will involve efforts of both non-profit and for-profit entities on the same grant. In September of 2008, the ICOC directed the IP Task Force to consider consolidating the two sets of IP regulations into one regulatory scheme.

II. Project Principles

The purpose of the consolidation project was not to reexamine fundamental concepts and issues already considered by the ICOC in promulgating the existing IP regulations. In other words, the intent of the project was not to reconsider basic requirements relating

to access plans and pricing provisions for uninsured and underinsured Californians. Nor was the project intended to revisit the threshold requirement that grantees are bound by the regulations with receipt of the first CIRM dollar or whether CIRM should require its grantees to share publication-related biomedical materials. Rather, the focus of the project was to identify those regulations that would benefit from further clarification as to their scope and give further meaning to the ICOC's intent in circumstances not explicitly addressed in the existing regulations.

The consolidation regulations do essentially four things: 1) consolidate and harmonize the two existing sets of regulations to eliminate the potential for unintended differences in application; 2) clarify the reach of the IP regulations to better illuminate what happens when non-grantee/licensees use or benefit from CIRM-funded intellectual property; 3) clarify how the regulations will operate in collaborative research environments consisting of multiple for- and non-profit organizations; and 4) improve existing language or concepts to address inadvertent ambiguities and omissions in the existing language.

III. Proposed Amendments

At the August ICOC meeting the Board instructed staff to return with a redraft of section 100601, which is discussed below in the context of "Decision 1." In the meantime, staff identified several other changes that the Board may wish to consider making. In order to preserve the *option* of making the recommended changes at the September 14th meeting, staff prepared the recommended changes as "options" within the regulatory text. Doing so provides the Board the opportunity to accept or reject the proposed change when it adopts the regulations without delaying the submission of the regulations to OAL for final review. *In order to ensure that successful Disease Team applicants are subject to the consolidated IP regulations, these remaining regulations must be finalized as soon as possible.* Each of the suggested changes is discussed below, accompanied by a staff recommendation.

Decision 1: Section 100601(k) – "Exclusive Licensee"

At the ICOC's last meeting in August, the Board approved for final adoption all of the regulations proposed for adoption except for one – section 100601. This section defines terms used throughout the consolidated regulations. The term "Exclusive Licensee," defined in subdivision (k) of 100601, is a critical term used in section 100607, which requires certain entities to provide an access plan to uninsured Californians and participate in the CalRx prescription drug discount program when commercializing in California.[2] The Board directed staff to return to a prior version of the definition of "Exclusive Licensee" that did not require an exclusive license to be received "directly"

[2] "Grantees," "Collaborators" and "Exclusive Licensees" must provide an access plan for uninsured Californians and comply with the CalRx prescription drug discount program for individual Californians eligible under that program, and provide the CalRx pricing options to purchasers (typically entities) that use public funds. (§ 100607.)

from a Grantee, Grantee Personnel or Collaborator. That prior version had already been the subject of prior notice and opportunity for public comment.

To that end, Page 3 of the draft regulations contains optional language in **Decision 1**. The pre-August definition that the ICOC requested is found in **Option B**. Staff proposes two improvements to that language, however, and those improvements are found in **Option A**. Because the term itself defines the entity or person receiving a type of "license" (exclusive), Option A includes the words "by license" at line 2. In addition to being obvious by virtue of the term itself, clarifying that this is a conveyance "by license" is also internally consistent with other terms in section 100601 – specifically, "Exclusive License," which references a "License Agreement." (§ 100601, subd. (j).)

The second change in **Option A** compliments this clarification by omitting the words found in Option B, "…whether by assignment, license, or other mechanism." As stated above, the term is intended to define an "Exclusive License," which by its nature would be expected by custom and practice to be a conveyance of rights in the form of a "license." The omitted language is superfluous in light of this fact, and also because the consequences of "assignment" are addressed in section 100611, as discussed below.[3] Including the omitted language may lead to confusion over how licensees are treated by the regulations and where the obligations are spelled out. Leaving out the language results in no substantive change in the application of these rules and makes the entire regulatory scheme clearer and more intuitive.

Recommendation: *Staff recommends the Board* ***adopt "Option A"*** *to define "Exclusive License."*

Decision 2: Section 100601 - Definitions: "Non-Exclusive License."

Staff proposes a clarification to the definition of "Non-Exclusive Licensee," found at page 5 of the draft regulations. The proposed change, while arguably non-substantive, is more precise wording that more accurately reflects the scope of the term. Generally speaking, a non-exclusive license is one where the rights transferred to a licensee may also be transferred by the licensor to another party. "**Option A**" replaces the word "other" with "one or more." In doing so, the change clarifies that a non-exclusive license may exist *not only* if the rights are transferred to more than one party, but also where the rights transferred by license have already been or remain available to be transferred to at least "one" other entity. **Option B** retains the existing wording.

Recommendation: *Staff recommends the Board* ***adopt "Option A"*** *to define "Non-Exclusive License."*

[3] Generally speaking, a transfer by "assignment" transfers all ownership rights forever, whereas a "license" is usually shorter in duration and scope and ultimate ownership remains with the licensor.

<u>Decision 3</u>: Section 100606 – Licensing and Assignment of CIRM-Funded Inventions and Technology

Section 100606 addresses the responsibilities of CIRM grantees in the event CIRM-funded technologies and inventions are licensed or assigned. Subdivision (h), at page 10 of the draft regulations, requires Grantees to notify CIRM if an Exclusive Licensee materially breaches an exclusive license. This notification is critical to CIRM's ability to monitor compliance with the regulations. That said, some observers note that not all material breaches are necessarily relevant to the agency, and have counseled that the reporting burden could be lessened at no expense to CIRM if the scope is narrowed to require reporting only with respect to breaches of obligations relating to the regulations. This common sense accommodation of CIRM grantees is embodied in the proposed amendment to subdivision (h), as highlighted by "**Decision 3**." By narrowing the reporting to CIRM of breaches "affecting any of the obligations under these regulations," the regulation ensures that CIRM is able to monitor compliance while minimizing the burden on grantees.

<u>Recommendation:</u> *Staff recommends the Board* ***adopt the proposed amendment*** *to section 100606.*

<u>Decisions 4 and 5</u>: Section 100611 – Assurance of Third-Party Compliance

Section 100611 addresses the responsibilities of an entity that becomes a successor in interest – other than by license – of CIRM-funded IP by virtue of merger, purchase or other means. his regulation applies when one entity merges with or acquires a Grantee or Collaborator. In this instance, the acquiring entity assumes all of the same obligations as the acquired Grantee or Collaborator.

In **Decision 4**, staff proposes the word "assignment" be added to the circumstances that trigger this provision. By relocating the issue of assignation of rights from the definition of "Exclusive Licensee" (in section 100601, subdivision (k)) to this section, the myriad circumstances of potential successors in interest are addressed logically in one place. While one may argue that "or any other means" would include assignation, including the term "assignment" ensures there will be no room for competing interpretations in this circumstance.

In **Decision 5**, staff proposes the term "Exclusive Licensee" be included in two instances to ensure that the ICOC's August determination about the scope of these regulations is fulfilled. It will be recalled that the ICOC decided in August that an entity that acquires an Exclusive Licensee of a CIRM-Funded Invention or Technology or is itself a follow-on Exclusive Licensee of that IP should be bound by the access and pricing requirements of the policy. The proposed changes are necessary to ensure that a an entity that becomes a successor in interest of a Grantee, Collaborator "or Exclusive Licensee" assumes all obligations of the Grantee, Collaborator "or Exclusive Licensee."

Recommendation: *Staff recommends the Board* ***adopt the proposed changes*** *to section 100611.*

Decision 6: Section 100601(c) - "CIRM-Funded Invention"

In **Decision 6**, staff addresses concerns raised during the September ICOC meeting. At issue is the definition in subdivision (c) of the term "CIRM-Funded Invention." This term is important because it helps define the universe of new discoveries and research results of CIRM-funded research to which our regulations may apply. The proposed language present before the ICOC at the September meeting is set forth in "**Option A**." As a result of comments from members of the board regarding the clarity of that language, staff redrafted that provision to make the intent clearer – as contain in "**Option B**." The amended language reaches those inventions which our Grantee *either* reduces to practice during our grant, *or* conceives during our grant and reduces to practice within 12 months of the close of the grant. The new language clarifies that the regulation is intended to reach only the work of our Grantees, Collaborators, or Grantee Personnel. **Option B** also narrows the application of the 12-month post-grant reach to circumstances where the invention is conceived *during* as opposed to *prior* to our grant.

Recommendation: *Staff recommends the Board* ***adopt "Option B"*** *to define "CIRM-Funded Invention.*