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May 8, 2017

C. Scott Tocher
Deputy General Counsel
California Institute of Regenerative Medicine
1999 Harrison Street, Suite 1650
Oakland, CA 94612

SUBJECT: Notice of Proposed Regulation Amendments: Addition of Section 100650 to Chapter 6 of Title 17 of the California Code of Regulations, and the California Institute of Regenerative Medicine ("CIRM") IP Policy incorporated by reference into Section 100650

Dear Mr. Tocher,

The University of California ("UC") appreciates the opportunity to respond to the March 24, 2017 Notice of Proposed Regulation Amendments seeking comments on the addition of 17 CCR §100650 which would incorporate CIRM's revised intellectual property policy ("Proposed Policy"). CIRM has proposed new terms to support its mission of accelerating stem cell treatments to patients with unmet medical needs. UC, as the world's largest academic research system, comprised of ten research-intensive campuses, conducts significant medical research spanning from discovery to translational progression to human clinical studies. CIRM and UC have partnered on over 400 individual research endeavors advancing scientific knowledge and pursuing novel treatments in regenerative medicine. CIRM and UC further align in their goals to strengthen California's biotechnology industry, creating collateral economic benefits for the State of California and excelling in their respective public service missions.

One important element of UC's public service mission is to ensure that its research innovations create public benefit by transferring knowledge. This transfer is accomplished in several ways – by educating students who end up working in industry, publishing research results so that others can build on them to further advance the science in this cutting edge field, collaborating with other researchers to advance the state of the art, and licensing inventions to companies to create products and services that can

become available to the public. There is a careful balancing act among these activities to achieve the greatest public benefit. UC is successful in these endeavors, in no small part due to the assistance and support of sponsors that fund research at our campuses, drive publications and knowledge dissemination, and support our pursuit of patents and commercialization through licensing. CIRM, UC and taxpayers alike intend for early investments in research to yield, over the long term, positive business and employment development as well as medical treatments and cures for chronic disease and injury. UC is concerned that the Proposed Policy's far reaching encumbrances upon data, materials, inventions, research results and know-how will hamper research and commercialization, reducing the possibility that such long term goals will be met.

To that end, we take this opportunity to provide feedback on certain points of the Proposed Policy and how the Proposed Policy would affect UC's ability to accept future CIRM funding.

<u>The Proposed Policy reaches beyond technology directly funded by CIRM and will deter future research and commercialization partners</u>

Awardees' obligations to CIRM with respect to research results should be limited to the specific results directly generated with CIRM funding. The absence of a clear link between respective sponsored projects and sponsor-owed obligations impedes awardees' ability to manage contractual conditions and deters future sponsors and collaborators who would be bound to CIRM requirements despite not receiving a cent of CIRM funding, nor agreeing to the terms of CIRM funding.

Obligations associated with research results made under sponsored research awards should not conflict with obligations to past, current, or future supporters of research (including to the Federal Government), material providers, third party collaborators, and licensees of UC innovations. While the existing definition of CIRM-Funded Technology is bounded by a CIRM project period and the use of CIRM funding, the revised definition abandons such parameters and reaches indefinitely through to any future project, whether CIRM funds that future research or not. Tracking and managing project-specific award obligations far into the future becomes an unmanageable endeavor. Further, the expansive obligations "contaminate" all future collaborations, projects, licenses, and ability to obtain research material necessary to advance studies.

<u>Obligation to pursue commercial licenses for non-patentable results interferes with open collaboration and academic freedom</u>

Article VI of the Proposed Policy *requires* awardees who themselves may not commercialize CIRM-Funded Inventions and CIRM-Funded Technologies to make reasonable efforts to negotiate Licenses for third-party development of CIRM-Funded Inventions and CIRM-Funded Technologies (including data, material and know-how). The Proposed Policy now eliminates the existing condition at §100606 whereby an awardee may forego commercial licensing efforts if the awardee shares or otherwise makes publicly available the CIRM-Funded Inventions or Technologies. Favoring dissemination of data, materials and results over monetization of data, materials and results is part of the careful balancing act necessary to translate research results for the greatest public benefit. UC strikes this balance by licensing *patentable* innovations, as patented technologies provide the most value for commercial development and public sale. In fact, UC has over 1,400 active license agreements at the time of this writing and over 930 startup companies have been founded on UC patents to date. Confining licensing efforts to *patentable* inventions preserves, for industry and academia, the ability for others to replicate and validate UC research, use unique tangible research tools to make new discoveries, and conduct follow-on research resulting in new innovations for public consumption,

while simultaneously enabling a licensee to develop a product or service based on that patentable invention. For decades, UC has managed state assets with this thoughtful and deliberate approach which starkly contrasts with the Proposed Policy's blanket obligation to pursue licensing for any and all inventions, data, materials, research results and know-how *arising* from CIRM awards.

We asked, at the April 11th public hearing, whether CIRM would consider an Awardee's publication of *all* research results from a CIRM-funded project a violation of the Awardee's licensing obligation under the Proposed Policy given that broadly disseminating results may diminish the financial value that could be obtained from licensing results to commercial entities. We did not receive a clear answer to this inquiry. The Proposed Policy should permit awardees to prioritize publication and dissemination for the good of the stem cell research community over the occasional monetization of non-patentable results. The Proposed Policy should encourage the open exchange of ideas within academia and industry to advance scientific knowledge. Award conditions that limit or restrict researchers' abilities to do so compromise the fundamental tenet of academic freedom.

Broad definitions of "Commercializing Entities," "Drug" and "Regulatory Use" may inappropriately capture routine non-profit activities

The proposed new definition of "Commercializing Entities", under Article I of the Proposed Policy, would include any entity that sells, offers for sale or transfers a Drug (a) resulting in whole or in part from Regulatory Use; or (b) that consists of, in whole or in part, of a CIRM-Funded Invention. UC routinely transfers materials that meet the spaciously defined term of "Drug"[1], to academic and industry collaborators for further research; to biological repositories (which can be a requirement of publication, in certain instances); to data warehouses; to journals (both open access and traditional); to peers for scientific validation and experiment replications; and to students for learning exercises. Such transfers may include a "Drug" that results in whole or part from "Regulatory Use" (the use of any CIRM-Funded Research in an FDA or equivalent foreign regulatory body submission or filing). Although most IND and IDE filings are conducted by industry, some are performed by universities. As an example, when UC faculty design a new clinical trial protocol to initiate a study, UC files INDs and IDEs as a normal course of preparing and conducting clinical research. Thus, typical scientific activities such as material transfers and clinical regulatory filings result in UC's categorization as a Commercializing Entity, contrary to UC's non-profit identity. This is concerning because, as discussed below, all Commercializing Entities must share with the State of California a fraction of Net Commercial Revenue[2] which, if broadly and unjustly triggered, may make it cost-prohibitive for UC to accept CIRM funding.

To illustrate this point, consider UC's expansive clinical activities. UC medical centers and clinics see 4.5 million outpatient visits each year. Inpatient admissions to UC hospitals top 160,000 per year and UC Emergency Room staff triage more than 350,000 patients with urgent needs annually. It is unclear how clinicians throughout the UC system could possibly identify a product or service that "resulted in whole or in part" from CIRM-Funded Research.[3] The Proposed Policy attempts to mandate a "CIRM-related freedom to operate" assessment be conducted in advance of clinicians' use of Drugs, products or services to investigate whether or not the Drug, at some point, arose from CIRM funding. It is not feasible for a non-CIRM project clinician to identify products or services that are encumbered by the

[1] The definition of "Drug" includes articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals.
[2] Net Commercial Revenue are gross amounts invoiced for the sale in any country or transfer of a Drug, product(s) or service(s) resulting in whole or in part from CIRM-Funded Research.
[3] As defined in "Net Commercial Revenue"

broad reaching CIRM provisions or to track the Net Commercial Revenue UC would end up obligated to pay to the State. Imposing such administrative burdens on clinical care would contribute to rising healthcare costs and negatively affect populations UC is dedicated to serve.

Broad obligation to report unlicensed "Regulatory Use"

At Article II., the Proposed Policy obligates Awardees to immediately notify CIRM upon learning of an unlicensed Regulatory Use by a third party. With over 230,000 employees and 260,000 enrolled students within the UC system, it would be difficult to obligate all staff and researchers throughout the system to be aware of, identify, and report a Regulatory Use.

"Collaborators" cannot be proactively identified

The Proposed Policy expands "Collaborators" to include any non-Awardee person or entity who obtains *any* ownership rights to a CIRM-Funded Invention or CIRM-Funded Technology (data, materials, research results or know-how that arises from CIRM-Funded Research). The determination of a Collaborator is not bounded by the receipt of CIRM funding, by direct participation in a CIRM project, or even knowledge that an area of research is supported by CIRM. Implementing the new definitions of Collaborator and CIRM-Funded Technology would have a significant chilling effect on Awardees' collaborations that are essential to accelerating research in regenerative medicine.

To illustrate by example, should an individual read a publicly available publication that describes or references CIRM-Funded Research and subsequently gains know-how, conducts research or gathers data, the Proposed Policy suggests that such individual would automatically become a "Collaborator" under an existing CIRM Award because they have an ownership interest in a CIRM-Funded Technology or CIRM-Funded Invention. Therefore, that Collaborator would assume the obligations of a CIRM Awardee[4] even if they never accepted CIRM funding, and even if they were completely unaware of the obligation, which is likely to be the case. There would be little or no incentive for such individual (or their institution) to retroactively agree to CIRM award terms and the CIRM awardee will have no means of compelling them to do so.

The Proposed Policy's over-reach will dissuade research scientists from industry and non-profit institutions alike from engaging with CIRM-funded institutions. One foreseeable example of this would affect CIRM-funded projects that rely on third party materials shared with the Awardee. CIRM may recognize that some industry partners find CIRM's *existing* IP regulations so alarming as to preclude their involvement (significantly, their provision of materials for use) in critical research projects. The threat of retroactive Collaborator status will amplify this chilling effect on the willingness of providers to share proprietary materials with CIRM awardees. Further, Awardees will be unable to consistently comply with other CIRM award terms.[5]

[4] Such obligations would include disclosing inventions and technologies to CIRM, reporting on the utilization and licensing of same, remaining subject to audit by CIRM, licensing the invention as required by CIRM Policy, and having their invention, data, materials, results or know-how licensed by CIRM under CIRM march-in rights.

[5] The following award terms would be impossible to satisfy for retroactively-identified Collaborators: §100602(a) - requiring Awardees to, prior to a Notice of Award and continuing 12 months after the close of an Award, have written agreements with Collaborators (whether funded by CIRM or not) requiring prompt disclosure to the Awardee of any CIRM-Funded Invention, and §100602(d)(7) - Awardee's requirement to have written agreements requiring Collaborators to report to Awardee information such as key progress toward commercialization, all patent applications filed, issuance or abandonment of patents, execution of all MTAs or collaborative agreements conveying rights in CIRM-Funded Inventions or CIRM-Funded Technologies and licensing revenue received.)

UC strongly recommends that Collaborators be limited to subrecipients of CIRM funding and unfunded collaborators who *knowingly* participate in a CIRM-Funded Project and have an advance opportunity to understand and accept the obligations of such participation.

Licensees will object to the requirement to provide a full copy of license agreements to CIRM

The Policy expands the license documentation required to be submitted by Awardee from excerpts of financial provisions to the entire license agreement. Potential licensees dislike the existing requirement as the financial and business development terms are considered proprietary by companies. The expansion of this requirement will likely be a further deterrent to licensing and commercialization. UC encourages CIRM to eliminate, to the extent possible under legal requirements, administrative hurdles that will delay or diminish licensing activity of CIRM-Funded Inventions.

UC objects to the partial retroactivity of the Proposed Policy

As written, the Proposed Policy would apply to all *prior* CIRM Awards made to an Awardee in the event that a new CIRM award utilizes a CIRM-Funded Technology or CIRM-Funded Invention arising out of a prior CIRM Award. Given the unbounded definitions of CIRM-Funded Technology and the incremental nature of scientific discovery, it is highly likely that some data, results or know-how of past work will prompt or be utilized in new investigations. UC strongly disagrees with any application of the Proposed Policy to prior CIRM Awards. UC accepted such prior awards with full understanding of the applicable terms and, in light of those terms, set a baseline level of expectations on the part of faculty and staff as to their rights, benefits, and obligations associated with their participation in CIRM-Funded activities. It is inappropriate to change those terms after the fact, especially given that prior CIRM-funded researchers may not be directly participating in or benefiting from the future CIRM Award which drives the retroactive application of the Proposed Policy. We cannot emphasize enough the importance of making the Proposed Policy effective only for awards issued after the effective date of the revised regulations so that at the time of award acceptance universities can be fully informed of the accompanying terms and conditions and adjust any associated known collaboration agreements accordingly.

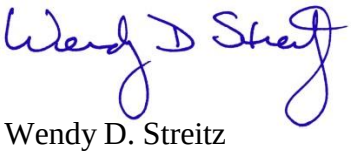
Finally, it is unclear whether existing Regulations §100601 - §100612 remain applicable, even in instances whereby they conflict with the Proposed Policy, as these existing Regulations are not specifically retracted or modified by the addition of §100650.

Conclusion

Like CIRM, UC strives to accelerate advancements in medical technologies that will help drive the next wave of California economic growth while realizing cost savings for Californians in healthcare. We look forward to advancing these goals in partnership with CIRM under policies that promote research transparency, collaborations and knowledge sharing leading to long term health and economic benefits for California and beyond. We acknowledge CIRM's goals to reduce administrative enforcement efforts as well as CIRM's responsibility to ensure the State share in CIRM-funded commercial successes. However, the Proposed Policy will generate such ambiguity and impossibility of compliance that neither aim will be accomplished. Viable solutions could be found through engagement with grantees and other stakeholders in the field, especially including industry. We urge CIRM to not institute these proposed regulations as it would have a serious deleterious effect on stem cell research at UC and our partnership with CIRM.

Thank you for the opportunity to provide our comments and we would welcome any further discussion regarding our concerns. Please do not hesitate to reach out if we can assist in crafting terms that are more conducive to collaborative research in the academic setting.

Sincerely,



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