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OFFICE OF THE VICE PRESIDENT — RESEARCH & INNOVATION

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Submitted electronically through: ampcomments@cirm.ca.gov

October 20, 2025

Subject: UC Comments on the Notice of Proposed Regulation Adoption: Addition of Section 100505 (CIRM Award Management Policy) to Chapter 5 of Title 17 of the California Code of Regulations

Dear Mr. Tocher,

The University of California ("UC") appreciates the opportunity to respond to the September 5, 2025 Notice of Proposed Regulation Adoption ("Proposed Regulation") that adds Section 100505 to Chapter 5 of Title 17 of the California Code of Regulations, and incorporates by reference the CIRM Award Management Policy ("AMP").

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 650 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. Given declining federal funding of cutting-edge research, it is more important than ever that State agencies such as CIRM support the California research environment.

As CIRM's research partner, UC seeks efficient award management that prioritizes accuracy, compliance, accountability, and fairness. To that end, we take this opportunity to provide feedback on certain points of the AMP and how the AMP would affect UC's ability to perform and comply with award requirements.

<u>Allowable Facilities Costs</u>

UC appreciates CIRM's effort to simplify its cost-recovery policy. As a leading public research institution, UC must advocate for the full recovery of both direct and indirect costs associated with research activities to ensure continued excellence and innovation over time. To ensure fairness and transparency, UC requests that the AMP include a clear and detailed description of the methodology and data sources the ICOC will use when determining allowable Facilities cost rates. This determination should be grounded in actual cost data and reflect the true financial burden borne by CIRM-funded institutions. At a minimum, the description should incorporate:

- **Published F&A rate agreements** for California public universities;
  - Absent a federally negotiated rate agreement, institutions should be permitted to provide equivalent supporting documentation
- **Historical Facilities cost data** from CIRM-funded projects at UC and CSU campuses;
- **Relevant inflationary or cost escalation factors** affecting research facility operations and maintenance.

Incorporating actual campus data ensures that CIRM's cost-recovery rates reflect the real costs of maintaining California's research infrastructure. Reliance on comparators, particularly those that do not reflect the unique scale, scope, and regulatory environment of California's public universities, risk undervaluing the true cost of research and undermining the long-term viability of the research ecosystem.

UC stands ready to collaborate with CIRM to develop a policy framework that is equitable, data-driven, and responsive to the evolving financial realities of academic research.

<u>Indirect Costs</u>

While indirect cost rates are normally defined by each funding program, the 10% maximum for training awards and frequently 0% or 10% for infrastructure awards does not reflect the administrative effort expended. Training and infrastructure awards take far more administrative time than individual research awards paying the full 20% indirect cost. For example, a training program includes monthly seminar series, annual retreats, symposiums, and other activities requiring administrative effort for planning and execution. Because the benefit of training and infrastructure awards is dispersed, the responsibility falls on central staff to carry out the programs. Funding these staff through either indirect costs or direct costs is necessary. Either the indirect cost rate needs to increase, or the administrative costs for programming should be allowed as a direct cost. While some training and infrastructure awards allow for administrative staff salaries, others such as CIRM SCHOLAR have very limited budget for non-trainee expenses.

<u>Effective Date</u>

UC agrees that active awards should transition to the new regulation and policy, as described in the Proposed Regulation. However, transitioning "on the start date of the next Budget or Operational Milestone Period" is an administratively complex and resource-draining way to achieve the transition. Each active award has its own Budget or Operational Milestone Period, so the transition would need to take place on a case-by-case timeline for each active award.

Federal agencies use a more streamlined method to transition to new regulations – the effective date of the regulation for all active and new awards is often one year after the regulation is amended. The one-year period gives grantees time to inform faculty and staff and implement new processes, if needed. Most importantly, all awards transition to the new regulations on the same day, so that neither CIRM nor UC need to look up the Budget or Milestone Period dates to know which regulations apply at what point in time.

Based on the explanation above, UC recommends that CIRM revise the Proposed Regulations to state the following:

> (b) Amendments to this regulation and the policy incorporated herein will be applied to already active awards, grants, loans or guarantees ~~on the start date of the next Budget or Operational Milestone Period~~ one year after the effective date of this regulation's amendment (except as provided in the applicable CIRM Intellectual Property Regulations).

Limitation of CIRM Liability

Regarding clause C.1. Limitation of CIRM Liability in the AMP, UC acknowledges CIRM's limited liability for Awardee's actions and research as CIRM is only serving as a funding agency. UC understands that CIRM is not participating in the performance of the research being conducted by UC. Additionally, UC agrees with the emphasis that UC must comply with all applicable federal, state, and local laws, regulations, institutional requirements, and recognized ethical standards. However, the terms in the AMP include a few changes that UC is unable to accept. Outlined below are explanations for minor edits that will enable UC to accept the revised language via an exception process under the UC Office of the President's delegation of authority.

Third paragraph of the proposed Limitation of CIRM Liability clause:

> To the fullest extent permitted by law, Awardee agrees to indemnify, defend, and hold harmless CIRM and its officers, employees, agents, and representatives from and against any and all claims, demands, damages, losses, liabilities, costs, and expenses (including reasonable attorneys' fees and costs of investigation) arising out of ~~or~~ and relating to: (a) Awardee's research activities under this Agreement; (b) the Awardee's use or application of any data, results, materials, or inventions resulting therefrom; or (c) any breach by Awardee of its obligations under this Agreement.

Explanation for the requested edits to the third paragraph:

The Standing Orders of The Regents of the University of California prohibit UC from entering into agreements where UC is required to assume liability for the conduct of persons other than UC officers, agents, employees, students, invitees, and guests. UC cannot control the actions of third parties, and as a public institution (taxpayer supported, non-profit), UC must limit our liability to that resulting from UC's acts.

UC Legal has opined that "or relating to" is too broad, so we request that the language be amended to "and relating to." Additionally, subpart (b) in paragraph three should include the clarification that the claims arise and relate to Awardee's use or application of any data, results, materials, or inventions resulting therefrom. If an award issued by CIRM to UC includes any subcontractors selected by UC, UC will flow down the liability clause to the subcontractor to require that they indemnify both UC and CIRM for their actions.

Fifth paragraph of the proposed Limitation of CIRM Liability clause:

> Awardees shall indemnify, defend, and hold CIRM harmless against any and all losses, claims, damages, expenses, or liabilities, including attorneys' fees, arising from ~~or~~ and related to any research conducted by the Awardee pursuant to the Award, and/or, in the alternative, Awardees shall name CIRM as an additional insured, or if self-insured, include CIRM as an additional covered party pursuant to the CIRM Award terms, and submit proof of such insurance. (Health and Safety Code section 125290.45, subd. (a)(2).). If the Awardee chooses only to insure, such insurance must provide coverage in amounts appropriate and proportional to cover the risks described in the previous sentence.

Explanation for the requested edits to the fifth paragraph:

The justification for the change from "or relating to" to "and relating to" is the same as above.

The reason for the addition of "or if self-insured include CIRM as an additional covered party pursuant to the CIRM Award terms" is because UC is self-insured through its wholly owned captive insurance company. This means that instead of transferring the risk of losses to an external commercial insurer, the UC system maintains a program of self-insurance to cover potential claims, damage or legal liabilities. UC cannot add, name, or endorse additional insureds to its insurance policies; however, UC can include additional covered parties pursuant to contract to fulfill its contractual indemnification obligations. The requested edits maintain CIRM's goal of ensuring appropriate coverage of an Awardee's indemnification obligations.

Unobligated Funds

UC understands the importance of returning unobligated funds to CIRM and CIRM's need to account for all research dollars. UC requests two timing-related changes to clause V.B to give UC's accounting offices enough time to process the return of funds:

> Upon Award Close-Out, including termination by CIRM, the Awardee shall return all Unobligated Funds to CIRM no later than 30 days after the final financial report deadline or 120 days after the Project Period end date, whichever is later.

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We believe these changes to the AMP will provide a strong foundation to support many years of scientific advancement. Thank you for the opportunity to provide our comments and we welcome any further discussion. For questions or further discussion, please contact Senior Research Policy Manager Felice Lu at Felice.Lu@ucop.edu.

Sincerely,

Agnes Balla

Agnes Balla
Director
Research Policy Analysis & Coordination
University of California Office of the President