



July-23-2024

To the Application Review Subcommittee of CIRM's ICOC Board,

We write this letter to highlight the key strengths of the INFR6.1-15366 proposal, "Shared Research and Training Facility for Bio-Fabrication of Organs for Regenerative Medicine (Bio-FORM) in Underserved Areas."

In the original review, released in January 2024, the Scientific and Medical Research Funding Working Group ("Grants Working Group or GWG") rated Bio-FORM's Scientific Proposal as a Tier 1 (with 13 of 15 members/reviewers awarding the best score). The Facilities Working Group (FWG) rated the Facilities Proposal as a Tier 2 (from 8 out of 9 reviewers): they also encouraged our team to resubmit.

With such promising scores and evaluation, our team engaged architects and facility contractors who have a strong track record in completing previous construction and renovation projects at UCR. This team substantively addressed the comments from the FWG. However, despite the strong support of UCR's leadership (as expressed in the attached letter from January 2024) and despite UCR's efforts at revision, the second Bio-FORM Facilities Proposal received an even worse score, which relegated it to a tier 3 ranking, effectively disqualifying UCR's INFR6.1 funding aspiration.

We hope that the Subcommittee will reconsider their decision. To that end, we would like to highlight the extent to which the GWG valued aspects of our scientific proposal. Bio-FORM received a perfect score on 2 of the 5 categories assessed (Plan and Design, and DEI principles), while the other 3 categories received 13 out of 14 positive votes (Significance, Feasibility, and Techniques and Course Design):

- Does the proposed SRL offer a significant value proposition? 13 out of 14 votes (13/14)
- Is the project well planned and designed? 14/14
- Is the project feasible? 13/14
- Does the project effectively uphold the principles of diversity, equity and inclusion? 14/14
- Is the Stem Cell Techniques Course well designed? 13/14

The Scientific Review notes expressed strong appreciation for the proposal, including these key elements quoted below:

- "The proposed Bio-FORM program will extend stem cell expertise to (1) work with organoid models, (2) create stem cell-based 3D models of organoids, tissues and organs, and (3) produce complex, 3D tissue structures and organs for regenerative therapies. These approaches represent the forefront of stem cell research and a nice blend of basic stem cell biology and bioengineering."
- "The course offerings will provide training in organoid culture and development of advanced 3D organoids using bioprinting and biofabrication. The facility will share resources with the Inland Empire Stem Cell Consortium and continue to work with companies."
- "This project will expand an existing, successful stem cell research center (previously funded by CIRM) to include techniques in organoid, tissue, and organ production."
- "The plan is very well designed and all the information needed to assess the program is provided. The project will be located in a geographic region of California with underserved healthcare and health care research."


In addition to our Scientific Proposal's merits, our revised Facilities Proposal substantively addressed the concerns raised by the FWG's initial review, including more detailed space design diagrams, information on mechanical/electrical/plumbing (MEP) configurations, shipping/receiving, airflow, biosafety cabinets, fume hoods, chemical storage, vibration, hazardous waste discharge, sterile construction, timelines, bid system, timeline and budget rationale that support the work flow. It also detailed the extent to which recent building renovations updated services and requirements beyond code. Unfortunately, despite these major improvements with the facility details that are responsive to the first round of review, FWG raised different sets of questions in the second review.

It seems that this result will trigger an unfortunate lose-lose situation for California: UCR and the underserved Inland Empire region will miss out on opportunities to innovate in stem cell research; at the same time, the lack of a CIRM Core presence in the Inland Empire will weaken CIRM's DEI mission.


UCR has been an exemplary representative of CIRM's values and has served its regional research community for 15 years. The value of the funds originally entrusted to UCR by CIRM have been amplified by the talent and dedication of many hard-working scientists committed to expanding the reach of state-of-the-art scientific knowledge and research potential to a region often neglected by our society. Our team, through the Stem Cell Core, has engaged 8 other research institutions in the area and provided key resources for training and research innovation. The proposed "Shared Research and Training Facility for Bio-Fabrication of Organs for Regenerative Medicine (Bio-FORM) in Underserved Areas" offers a unique opportunity to advance CIRMs and California's agenda to innovate at the forefront of scientific and technological progress. This initiative would improve the lives of diverse California residents while simultaneously embracing equity and inclusion in a region with significant needs.

**Given the excellent scientific merit, our disposition to address any facility issue, the need and service of our Bio-FORM, we respectfully ask a member of this committee to elevate our application and facilitate its funding.**

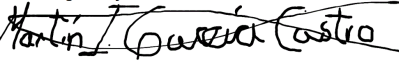
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1-22-2024

To the CIRM Application Review Subcommittee of the ICOC Board,

We submit this letter to provide written comments on the INFR6.1-15366 proposal, "Shared Research and Training Facility for Bio-Fabrication of Organs for Regenerative Medicine (Bio-FORM) in Underserved Areas."

The Bio-FORM facility is essential for equity in access to stem cell resources in the Inland Empire region of Southern California. The facility has been designed to balance training in stem cell biology and bioengineering that is at the forefront of stem cell research. As the only stem-cell research infrastructure located in the socioeconomically, educationally, and medically underserved Inland Empire region, Bio-FORM is a critical resource for an area with limited access to stem-cell-based models, facilities, and therapies, as demonstrated by the wide range of stakeholders represented in our 63 letters of support. Building on UC Riverside's current Stem Cell Core, Bio-FORM will be the first stem-cell modeling facility for the underserved communities in the Inland Empire and adjacent regions.

The Grants Working Group (GWG) understands the scientific value of our proposal and ranked it in Tier 1.

The Facilities Working Group (FWG) raised several concerns with the facilities portion of our proposal which was ranked in Tier 2. We understand the issues raised by the FWG to be: (1) concerns about Bio-FORM's sustainability, (2) the seeming disjointedness of Bio-FORM's space allocations, (3) concerns with construction planning and timelines, (4) concerns about how the physical characteristics of the spaces will impact implementation, and (5) construction cost/budgeting/procurement issues. We address these five issues below:

- (1) **Bio-FORM's Sustainability:** Bio-FORM will be established on the success of UCR's original Stem Cell Core, which we have maintained operational since its completion in 2009 and even after the end of initial CIRM funding. The CIRM team that performed the building inspection of our original Core stated that its construction was among the best they had seen in the state. Our original Core has remained in continual operation, even after CIRM funding ended in 2015, with funds provided by the UCR administration and private donations. Its longevity attests to the vital function this foundational Core has served and the long-term interest UCR administrators have in sustaining this facility. UCR's prior investment in the existing Core plus its generous commitment of matching funds for the Bio-FORM proposal should mitigate any concerns about the Bio-FORM's longevity. The robust, interdisciplinary collaborations between our stem cell labs are a vital part of UCR's research culture, and as indicated in the support letter of Vice Chancellor Torres and Provost Watkins originally submitted with this INFR6.1-15366 proposal, "UCR will continue to provide support to the center after CIRM funding ceases." In short, UCR's administration commits to supporting Bio-FORM beyond the period of CIRM funding. Like CIRM, UCR has a major financial investment in Bio-FORM and would not withdraw support or space in the future.
- (2) **Spatial Integration:** About 3,700 sq ft of space in the first floor of Batchelor-Keen and Boyce Halls has been committed to the Bio-FORM facility. Keen Hall, where the current Stem Cell Core is located, is simply a wing of Batchelor Hall. Part of Bio-FORM would occupy renovated rooms in Batchelor that are adjacent to Keen on the same floor and, in effect, an extension of the current Core. Boyce Hall is an adjacent building, just a few steps away from Batchelor-Keen. Boyce's first floor space was chosen because it does not require renovation and is high-quality biosafety level 2 (BSL-2) lab space. We do not foresee issues emerging from Boyce Hall's separation from the other space. Work done in the Batchelor-Keen spaces is focused on cell and organoid culture and bioprinting. Work in Boyce will mainly involve instrumentation, such as flow cytometry and microscopy. Separating these functions from organoid culture and bioprinting will not impact research workflows.
- (3) **Planning and Timelines for Construction in Batchelor Hall:** The Bio-FORM team includes the key members who designed and built the original Stem Cell Core lab that opened in 2009 and involved converting office space to functional BSL-2 labs. That facility has been in full operation ever since, with continuous support from the campus administration. Although the construction schedule is ambitious, it is not out of line with other fast-tracked projects of similar size, scope, and complexity that have been

completed at UCR. The construction duration was confirmed by a consulting contractor who has been working on Batchelor Hall renovation and is familiar with the building and type of work.

- (4) **Physical Characteristics of Allocated Spaces (impacts on implementation):** Batchelor-Keen Hall was constructed in 1965 with a loading dock on the east side and has been renovated significantly in the past 10-15 years with on-going major upgrades to mechanical, electrical and plumbing that will be completed in March 2024. The proposed Bio-FORM lab in Batchelor Hall does require renovation and conversion of existing office-type spaces to BSL-2 labs, with a HEPA filter system. The space being proposed for renovation is adjacent to a main mechanical chase and in an area of other active labs. As such, providing the single pass air needed for a BSL-2 will be easily accommodated by this fortunate adjacency. HEPA-filtered air will be provided in Batchelor by in-duct filters. Our team are already experienced in building the original Core and successful in converting adjacent office-type spaces to BSL-2 labs. There should not be any problem accessing culture rooms in the current Stem Cell Core or in Boyce during construction of the culture rooms in Batchelor. The analysis for the submission of the Bio-FORM proposal included input from the construction team currently renovating Batchelor Hall; nevertheless, we would bid the additional contract-funded work under existing procurement policies. We have met and consulted with the architects, the existing contractor team, and the environmental health & safety (EHS) team on the feasibility of the work required. Indeed, our lab design diagrams were only conceptual, lacking construction-level details, but we can provide the procurement documents and more extensive details if needed as we did a similar type of construction when building the original Core in 2009.

Culture rooms in Keen Hall already receive HEPA-filtered air which is further filtered in the biosafety cabinets. Extensive protocols are already in place for maintaining sterility, storing and handling chemicals, disposing of wastes, access during and after hours, signing up for equipment training and use, gaining key/FOB access, and billing for recharges. We plan to extend these same protocols to the new lab spaces in Batchelor and Boyce.

Boyce Hall was constructed in 1974 with a loading dock at its southeast corner. Boyce had recent renovations on its mechanical system and underwent a seismic retrofit to extend the life of this valuable building. The space in Boyce is high-quality finished lab space suitable for the planned instrumentation, and it is also a BSL-2 space suitable for sterile cultures.


Batchelor-Keen and Boyce Hall all have backup power. Both Batchelor-Keen Hall and Boyce Hall are designed as lab buildings and are reinforced concrete, which is not as susceptible to vibration as other types of construction. Vibration management techniques, such as base isolation of equipment, have been routinely employed on projects in these buildings.


- (5) **Construction Costs/Budgeting/Procurement:** The FWG had concerns about high percentage of design and management costs. That perception of high soft costs stems from construction expenditures (from matching funds) that are not visible in the budget we submitted to CIRM. The project's total facilities costs are substantially higher than the \$2.75M that we requested from CIRM: UCR has committed an additional \$523,103, which brings our total facilities expenditures to \$3.273M. This matching fund commitment affected the soft costs ratio and demonstrated UCR's firm commitment to the project.

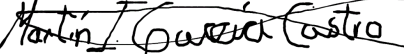
Procurement will follow the rigorous bidding process outlined by the California Contract Code for public projects. This includes publicly advertising for qualified bidders and awarding to the lowest responsive bidder. Further, outreach will be extended to Small Business and Disabled Veteran Enterprises in keeping with UCR's proven record, leadership, and commitment to Diversity, Equity, and Inclusion. As an example, the original Stem Cell Core was built by a construction company owned by a woman.

In summary, the Bio-FORM proposal demonstrates the critical need, exceptional scientific merits, and a strong collaborative leadership team capable of executing the proposed plan for establishing the shared Bio-FORM research and training facility in an underserved area. We have an excellent track record in building and sustaining our original Stem Cell Core, and our strong administrative track record has supported UCR researchers and trainees, as well as eight other institutions that serve disadvantaged students, patients, and communities. There is no other stem cell core in the Inland Empire region. It is important that our stem cell labs, trainees, students, and communities not be further disadvantaged. Bio-FORM will remain true to and build on this history. We therefore respectfully request that the Application Review Subcommittee and ICOC consider approving funding for INFR6.1-15366 without further revision based on the updated information provided in this letter.

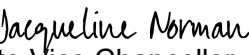
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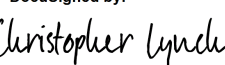
  
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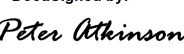
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