CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Memorandum

To: Members of the ICOC
From: Gil Sambrano, Vice President, Portfolio Development and Review
Re: Adoption of Ammended Bylaws for the Grants Working Group
Date: March 27, 2025

The purpose of the GWG is to provide recommendations to the ICOC regarding standards, criteria, requirements, funding, and oversight of grant and loan applications and awards. The GWG, like other CIRM working groups, is subject to bylaws that govern the activities of the GWG.

The ICOC adopted the GWG Bylaws at its September 9, 2005, meeting, and the Bylaws have been amended multiple times, the last on September 28, 2023.

Summary of Proposed Changes

CIRM is proposing changes to Sections 3, 4, and 5 of ARTICLE VII – *Procedure for Recommending Grant and Loan Applications* to better align newly proposed funding opportunities with appropriate scoring methodology. Briefly, CIRM is adding a new subsection to Section 3 – *Recommendation Procedures*. The new subsection (C) – *Funding Recommendations* addresses the scoring methodology to be used by the GWG in making recommendations to the ICOC. The new section states that the scoring methodology used by the GWG will be that determined by CIRM to be the most appropriate for the specific funding opportunity and that such methodology will be described within the relevant RFA or PA. This addition aligns the GWG Bylaws with the comparable section in the AAWG Bylaws addressing funding recommendations to the ICOC and provides additional flexibility for the Board and CIRM to apply scoring methodology to new funding opportunities.

With the addition described above, CIRM is removing Sections 4 and 5 that describe specific scoring methodology to be used by the GWG for making funding recommendations in non-clinical and clinical programs.

Requested Action: CIRM requests ICOC approval of the proposed changes to the GWG Bylaws.

Bylaws of the Scientific and Medical Research Funding Working Group

Originally adopted by the ICOC on 09/09/05; amended on 3/15/07, 06/27/08, 12/09/09,10/25/12, 03/19/13, 03/26/15, 5/21/15, 12/17/15, 5/19/16, 9/21/16, 2/25/21, 10/27/22, ~~and~~ 09/28/23 and 03/27/25

ARTICLE 1. Authority.

The Scientific and Medical Research Funding Working Group ("Grants Working Group" or "GWG") of the Independent Citizen's Oversight Committee ("ICOC") to the California Institute for Regenerative Medicine ("Institute") is established by Part 5, Division 106, Chapter 3, section 125290.50 and section 125290.60 of the Health and Safety Code, also known as the California Stem Cell Research and Cures Bond Act, as amended by the California Stem Cell Research, Treatment and Cures Act of 2020, together, the "Act."

ARTICLE II. Purpose.

The GWG is created for the purpose of providing recommendations to the ICOC regarding standards, criteria, requirements, funding, and oversight of grant and loan applications and awards. This purpose will be accomplished through the review of grants and loan applications, based on standards and criteria adopted by the ICOC, in order to make recommendations to the ICOC for the awarding and continued funding of training, research, therapy development, clinical trial, and therapy delivery grants and loans. Finally, this purpose will be accomplished through oversight reviews of grantees to ensure compliance with the terms and conditions of the award in order to fulfill the mission of the Act, and to report and make recommendations for subsequent actions to the ICOC or the CIRM President, as appropriate.

ARTICLE III. Functions.

The duties of the GWG shall include the following:

(A) Recommend to the ICOC interim and final criteria, standards and requirements for considering funding applications and for awarding grants and loans;

(B) Recommend to the ICOC standards for the scientific and medical oversight of awards;

(C) Recommend to the ICOC any modifications of the criteria, standards and requirements described in sections (A) and (B) above as needed;

(D) Review grant and loan applications based on the criteria, requirements and standards adopted by the ICOC and make recommendations to the Application Review

Subcommittee of the ICOC for the award of grants and loans to promote training, research, therapy development, clinical trials, and therapy delivery;

(E) Oversee expert peer-group reviews of grantees to ensure compliance with the terms of the award, and report to the ICOC or the President of CIRM, as appropriate, any recommendations for subsequent action;

(F) Recommend to the ICOC standards for the evaluation of grantees to ensure that they comply with all applicable requirements. Such standards shall mandate periodic reporting by grantees and shall authorize the GWG to audit a grantee and forward any recommendations for action to the ICOC.

ARTICLE IV. Membership, Selection, and Terms of Service.

Section 1 (Method of Appointment). Members of the GWG shall be appointed by the ICOC.

Section 2 (Appointment). The GWG shall be composed of: (1) seven ICOC members drawn from members who qualify for appointment pursuant to paragraphs (3), (4), and (5) of subdivision (a) of Section 125290.20 of the Act; or from the Nurse members described in paragraph (6) ("Patient Advocate Members"), (2) scientists nationally recognized in the field of stem cell research, genetic research, and other vital research opportunities who are not California residents and who are not employed in the State of California ("Scientist Members"), 15 of whom shall be invited to participate in each expert peer review, and; (3) the Chairperson of the ICOC.

Section 3 (Term of Service). GWG members shall normally serve for six (6) years except that after the first six-year term the Scientist Members' terms will be staggered so that one-third of the members shall be appointed for a term that expires two years later, one-third of the members shall be appointed for a term that expires four years later, and one-third of the members shall be appointed for a term that expires six years later. Subsequent terms are for six years. In the event that a Scientist Member resigns prior to completing his or her term of service, incoming members appointed by the ICOC shall be invited to serve for a term of two (2), four (4), or six (6) years. GWG members may serve a maximum of two consecutive terms, provided that the ICOC may, by a two-thirds vote of a quorum, reappoint non-ICOC working group members to serve more than two consecutive terms.

Section 4 (Expiration of Term). When a member's term expires, the ICOC shall appoint a new member within 90 days. GWG members shall continue to serve until their replacements are appointed.

Section 5 (Alternate Patient Advocate Members). In the event that a Patient Advocate Member of the GWG cannot attend all or a portion of a meeting of the GWG, that Patient Advocate Member may designate an alternate from among any of the Patient Advocates who are members of the ICOC to serve as an Alternate Patient Advocate Member in the absence of the appointed Patient Advocate Member.

Section 6 (Specialists and Ad Hoc Members). Individuals with scientific expertise on a particular issue may occasionally be invited to attend meetings of the GWG for the purpose of providing evaluation or expertise with respect to specific applications or research fields. Specialists do not have voting privileges and their presence is not counted towards a quorum. In addition, the ICOC may appoint Ad Hoc Members as necessary to obtain expertise for a particular expert review session, not to exceed three members for any one expert review session. Ad Hoc Members shall have voting privileges and their presence is counted towards a quorum.

Section 7 (Review Chairs of the GWG).

(A) (Appointment) For each peer review, the President shall appoint a Scientist Member to serve as Review Chair of the GWG for all matters that are specific to that review. The President shall select a Review Chair with the knowledge and background necessary to lead that review.

(B) (Duties) A Review Chair of the GWG shall preside over the scientific evaluation of applications accepted for review, as described herewith in Article VII, Section 2, and other GWG business associated with that review meeting. The duties of a Review Chair shall commence upon appointment by the President and shall conclude when final action has been taken on all applications considered under that review.

(C) (Alternate Review Chair) In the event that a Review Chair of the GWG cannot attend all or a portion of a scientific review meeting pertaining to the designated RFA or PA, the President may designate another Scientist Member to serve as an alternate Review Chair in the absence of the Review Chair.

Section 8 (Vice-Chair of the GWG).

(A) (Appointment) The ICOC shall appoint as co-Vice-Chairs of the GWG two Patient Advocate Members of the ICOC.

(B) (Duties) The Vice-Chairs of the GWG shall moderate the Application Review Subcommittee's consideration of programmatic issues pursuant to Article VI, Section 6 of the Board Bylaws.

Section 9 (Compensation and Expenses of GWG Members).

(A) ICOC Members – ICOC members of the GWG, except the Chair and Vice Chair of the ICOC, shall be entitled to a daily consulting rate and reimbursement for expenses, as established by the ICOC.

(B) Scientist Members – Scientist Members of the GWG, including Specialists and Ad Hoc Members, shall be entitled to a daily consulting rate and reimbursement for expenses, as established by the ICOC.

Section 10. (Conflict of Interest). All Scientist Members, including Specialists, and Ad Hoc members, shall be governed by conflict of interest rules and economic disclosure requirements adopted by the ICOC. ICOC members shall be governed by California conflict of interest laws, as set forth in Health and Safety Code section 125290.30(g) and the conflict of interest policy for ICOC members adopted by the ICOC.

Section 11. (Confidentiality). Members of the GWG shall comply with CIRM's Confidentiality Policy, which is attached as Appendix A.

Section 12. (Grounds for Removal of Members). Any Scientist Member of the GWG may be removed by the ICOC for cause. The grounds for removal are as follows:

(A) An intentional violation or violations of the conflict of interest policy applicable to the member;

(B) Two or more grossly negligent violations of the conflict of interest policy applicable to the member;

(C) Consistent failure to perform the assigned duties of the member or unexcused absence from three consecutive GWG meetings;

(D) Violation of medical or ethical standards by the member in his or her professional capacity as determined by the appropriate research institution or the appropriate professional group;

(E) Residency or employment by an institution located in the State of California;

(F) The conviction of a felony or act involving serious moral turpitude.

Section 13. (Procedure for Suspension of Members). The President of the CIRM may suspend a Scientist Member of the GWG based on any of the grounds enumerated above by giving the member written notice of his or her suspension, including the grounds for the suspension. The suspension shall remain in effect until it is terminated by the President, the member resigns from the GWG, or the ICOC has considered the permanent removal of the member pursuant to Section 15.

Section 14. (Procedure for Removal of Members). The President of CIRM may recommend to the ICOC the removal of a Scientist Member of the GWG based on any of the grounds enumerated above. The President must inform the member in writing that he has requested that the ICOC consider removal of the member at least 10 days prior to the ICOC's consideration of the matter. The notice must include the grounds for the recommendation. The member may address the ICOC in writing or in person during the meeting of the ICOC at which the removal of the member is considered.

Section 15. (Procedure for Temporary Leave of Absence). The President of CIRM shall consider and may, at his or her discretion, grant requests, from Scientist Members for

temporary leaves of absence, not to exceed six months, due to family or personal illness, death of a loved one, or other extenuating circumstances.

ARTICLE V. Duties of GWG Members and Role of CIRM President and Scientific Officers.

Section 1 (Scientist and Ad Hoc Members). The Scientist Members of the GWG are responsible for evaluating and scoring grant and loan applications for scientific merit, and for voting, along with the other members of the GWG, on grant and loan funding recommendations to the Application Review Subcommittee of the ICOC. Scientist Members, along with the other members of the GWG, will also vote on recommendations regarding active awards in the CIRM portfolio.

Ad Hoc Members may be designated to serve on an expert review panel as necessary to obtain expertise for a particular expert review session, provided that no more than three Ad Hoc Members participate in any one expert review session. Ad Hoc Members shall have voting privileges and their presence is counted towards a quorum.

Scientist and Ad Hoc Members of the GWG participate in all aspects of the GWG's review of applications. They provide the essential scientific expertise to inform the recommendations of the full GWG and the decisions made by the ICOC.

The review is led by the Review Chair, a Scientist Member. During the review, Scientist and Ad Hoc Members of the GWG are responsible for assessing the scientific merit of each application, according to the criteria stated by CIRM, based on their own scientific expertise and the expert opinion of the other scientific reviewers. In written critiques and during review meetings, they should be willing to explain their reasoning to assist Patient Advocate Members in fulfilling their responsibilities on the GWG and the ICOC, to allow CIRM scientific team members to prepare summaries for the ICOC, applicants and the public, and to provide guidance or recommendations that will be useful in the management of approved awards. During the scoring of applications, Scientist and Ad Hoc Members may ask questions, probe the views expressed by other participants, and express their own views. Scientist and Ad Hoc Members are expected to consider the views expressed by other participants, but their confidential scores should reflect their own independent scientific judgment.

After the scoring of applications concludes, Scientist and Ad Hoc Members of the GWG join the Patient Advocate Members to make and vote on motions concerning the final funding recommendation to the Application Review Subcommittee of the ICOC. If thirty-five percent (35%) of the members of the GWG panel award scores in the funding range, a minority recommendation report, including a summary of the strengths and weaknesses of the application and a rebuttal to the majority recommendation, shall be submitted to the Application Review Subcommittee of the ICOC.

Section 2 (Patient Advocate Members). The seven (7) Patient Advocate Members of the GWG, together with the Scientist and Ad Hoc Members, are responsible for voting on grant and loan recommendations to the Application Review Subcommittee of the ICOC.

Patient Advocate Members of the GWG are full members and participate in all aspects of the GWG's review of applications, except for assigning scientific scores. They represent the patients whose needs drive all CIRM-funded research. As members of the ICOC, they provide a continuum for the flow of information and insights between the two bodies.

A Patient Advocate Member of the GWG will be invited to participate as a reviewer for each application accepted for review. During the review of applications, the Patient Advocate reviewer will be invited to offer his or her views of the merits of the application but will not record a final scientific score for the application. In addition, all Patient Advocate Members may ask questions, probe the views expressed by other participants, and express their own views.

Patient Advocate Members may also participate in the evaluation and scoring of application components addressing diversity, equity, and inclusion (DEI) when such components are part of an application. A DEI score assigned by the Patient Advocate Members will be included with the GWG recommendations, but the DEI score shall be distinct from the scientific score assigned by the scientific members.

After the scoring of applications concludes, the Patient Advocate Members join the Scientist Members and Ad Hoc Members of the GWG to make and vote on motions concerning the final recommendation to the Application Review Subcommittee of the ICOC. In addition, the Patient Advocate Members shall participate in a motion after the completion of the review to provide the Application Review Subcommittee with their assessment as to whether or not, based on their participation in the review, the review was fair and free from undue bias.

Section 3 (Specialists). Specialists may be invited by the CIRM team to participate in meetings of the GWG for the purpose of providing scientific expertise on a particular issue(s), area, or field and/or for a specific grant application.

Section 4 (Role of CIRM President). CIRM's President serves on the GWG as a non-member participant in all GWG discussions, but does not assign scientific scores, make motions, or vote. As the leader of CIRM's scientific and professional team members, the President may ask GWG members to consider how an application will address scientific issues that have come up in the field or in the execution of CIRM-funded research, respond to questions by GWG members on science matters, and provide information within his/her expertise.

The President should alert the GWG and the Application Review Subcommittee of the ICOC to matters that have been found to be inconsistent or incorrect in the review of a grant application.

Section 5 (Role of CIRM Scientific Review Team). Members of CIRM's scientific review team, under the leadership of the President, support the GWG, by managing and coordinating the review process, including but not limited to tracking conflicts of interest, ensuring observance of confidentiality rules, setting the schedule of review, and ensuring that applications are appropriately evaluated and scored. To this end, the scientific review team

members provide guidance and information regarding CIRM's programs, portfolio and procedures, including explaining the scope and requirements of the RFA or PA and the review criteria and responding to requests for information regarding awards or applications that aid the GWG in making informed evaluations. The scientific review team also ensures that review criteria, priorities and requirements are appropriately applied to the evaluations and discussions of applications and help the Review Chair ensure that all GWG members contribute to the proper evaluation and scoring of applications.

The CIRM team is responsible for reporting on progress of existing CIRM funded research projects if it is relevant to the review of an application before the GWG or for the GWG to provide recommendations on progress of an existing award. The scientific review team is responsible for summarizing, for the Application Review Subcommittee of the ICOC, applicants and the public, the reasoning behind the scientific scores and GWG recommendations. Accordingly, scientific review team members may ask GWG members to clarify their views or address specific issues in order to present a complete and useful report.

Prior to Application Review Subcommittee's consideration of GWG recommendations, the President and leaders of the CIRM scientific teams should consider whether there are applications which they believe warrant particularly close review, or whether specific modifications may be needed to successfully execute a particular proposal.

ARTICLE VI. Meetings.

Section 1 (Regular Meetings). The GWG shall hold at least four meetings per year, one of which will be designated as its annual meeting. The GWG may hold additional meetings as the CIRM determines are necessary or appropriate. The annual meeting shall be attended **in person** by GWG members.

Section 2 (Teleconference Meetings). At the discretion of the CIRM team, members of the GWG may participate in meetings of the GWG, with the exception of the annual meeting, by teleconference, provided that the public has the opportunity to participate in public sessions of the GWG that are conducted by teleconference. Significant medical needs of members of the GWG will be given a high priority in arranging teleconference meetings.

Section 3 (Open Meetings). The GWG shall meet in public session except for discussions related to evaluation of grant applications and recommendation of applications to the Application Review Subcommittee of the ICOC, discussions related to appeals or requests for reconsideration of GWG recommendations, discussions related to the review of a grantee's progress and compliance with the terms of the award, and discussions of other matters that may be considered in closed session under the Bagley-Keene Open Meeting Act or under Health and Safety Code section 125290.30. The GWG may recommend additional exceptions to the ICOC as necessary to carry out the mission of the GWG.

Section 4 (Special and Emergency Meetings). Special and emergency meetings may be called by the CIRM President if necessary.

ARTICLE VII. Procedure for Recommending Grant and Loan Applications.

Section 1 (Quorum). Sixty-five percent of the GWG members who are eligible to vote shall constitute a quorum of the GWG.

Section 2 (Taking Action). Actions of the GWG may be taken only by a majority of those members present and voting.

Section 3 (Recommendation Procedures).

(A) Unless excused due to conflicts, both ICOC and non-ICOC members of the GWG shall be present in-person or via video/teleconference during the meeting and may participate in all discussions.

(B) Scientific Evaluation and Scoring

1. The Review Chair of the GWG shall preside over the scientific evaluation and scoring process, and the process to arrive at the final recommendations to the Application Review Subcommittee of the ICOC.

2. The fifteen (15) Scientist and Ad Hoc Members of the GWG shall evaluate each application for scientific merit and assign a numerical value to each application based on standards and criteria adopted by the ICOC. The criteria and standards for evaluation are hereby incorporated by reference into these Bylaws.

(C) Funding Recommendations

For purposes of making funding recommendations to the ICOC, the GWG members will score applications based on the methodology determined by CIRM to be the most appropriate for a given funding opportunity. The scoring method to be used will be described within the RFA or PA for the opportunity.

~~**Section 4 (Applications for Non-Clinical Programs).** Unless otherwise provided for in a program concept plan reviewed and approved by the ICOC, the following shall apply:~~

~~**(A)** For purposes of making funding recommendations to the Application Review Subcommittee of the ICOC for applications for non-Clinical Program awards, each application shall be assigned to one of two categories based on the median score and shall be ranked within that category based on the median score as follows:~~

~~1. Recommended for Funding = median score 85 and above, representing applications that have exceptional merit and that warrant funding, if funds are available; or~~

2. Not Recommended for Funding = median score below 85, representing applications that are not recommended for funding.

(B) The grants review office will inform reviewers of these tiers in advance of the GWG meeting so that this guidance may be incorporated into their reviews and scores.

(C) At the conclusion of the consideration of all applications, the Scientist and Ad Hoc Members will have a final opportunity to review their individual scores and make any changes they wish as to any application in which they are able to participate (not in conflict). After an appropriate amount of time, the Scientist and Ad Hoc Members will then submit final scores. After final submission, the scores may not be changed.

(D) For applications for Infrastructure Awards,
Scientist and Ad Hoc Members shall assign a score of 1, 2, or 3, as described below:

A score of "1" means that the application has exceptional merit and warrants funding, if funds are available;

A score of "2" means that the application needs improvement and does not warrant funding but, at the applicant's option, may be resubmitted to address areas for improvement if the Application Review Subcommittee has not approved an application for funding following the Grants Working Group's review;

A score of "3" means that the application is sufficiently flawed that it does not warrant funding.

The CIRM team will tally the numbers of Scientist and Ad Hoc Members who assigned a score of 1, 2 and 3, respectively, and will present that information for each application to the entire GWG. If a majority of Scientist and Ad Hoc Members score the application a 1, 2 or 3, then that score shall constitute the recommendation of the GWG. If no majority exists for a score of 1, 2, or 3, then the application shall automatically be assigned a score of 2.

Section 5 (Applications for Clinical Program). Unless otherwise provided for in a program concept plan reviewed and approved by the ICOC, the following shall apply:

(A) For applications for Clinical Program awards (CLIN1, CLIN2, and CLIN3, and any subsequent amended versions or new Clinical Program PAs), Scientific and Ad Hoc Members shall assign a score of 1, 2, or 3, as signified below:

1. A score of "1" means that the application has exceptional merit and warrants funding, if funds are available;

2. A score of "2" means that the application needs improvement and does not warrant funding at this time but, at the applicant's option, may be resubmitted to address areas for improvement;

~~3. A score of "3" means that the application is sufficiently flawed that it does not warrant funding, and the same project cannot be resubmitted for review for at least six months after the date of the GWG's recommendation.~~

~~**(B) Funding Recommendations for Clinical Program Awards**~~

~~The CIRM team will tally the numbers of Scientist and Ad Hoc Members who assigned a score of 1, 2 and 3, respectively, and will present that information for each application to the entire GWG. If a majority of Scientist and Ad Hoc Members score the application a 1, 2 or 3, then that score shall constitute the recommendation of the GWG. If no majority exists for a score of 1, 2, or 3, then the application shall automatically be assigned a score of 2. A score of "2" shall be considered a provisional score until the GWG reviews a resubmission of the application and makes a recommendation to fund (score of "1") or not to fund (score of "3") the application.~~

Section 46 (Oversight Reviews).

When reviewing progress on existing awards, any member of the GWG may make and second a motion to make a recommendation to the ICOC or the President, as appropriate, for subsequent actions.

Section 57 (Recommendations and Minority Reports).

(A) Recommendations of the GWG to the Application Review Subcommittee of the ICOC shall be made by a majority vote of a quorum of the members of the GWG, except for recommendations involving "vital research opportunities," which require a two-thirds vote of a quorum of the members of the GWG pursuant to Health and Safety Code section 125290.60(c)(1)(D), unless the ICOC has designated a research category as a "vital research opportunity," in which case a majority vote is required. If thirty-five percent (35%) of the members of the GWG panel award scores in the funding range, a minority recommendation report shall be submitted to the Application Review Subcommittee of the ICOC.

(B) Upon completion of the review, the members shall consider a two-part motion with respect to the review. All members shall vote as to part (1); only the Patient Advocate members shall vote as to part (2):

1. The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores accurately reflect the recommendations of the GWG.
2. The review was carried out in a fair manner and was free from undue bias. (PAs only).

(C) The outcome of the vote on both parts of the motion shall be made available to the Application Review Subcommittee, along with the GWG's recommendations.

Section 68 (Vital Research Opportunity).

(A) Through the eligibility criteria specified in RFAs and PAs, CIRM gives priority to applications involving pluripotent stem cell and progenitor cell research and genetic research that cannot, or is unlikely to receive timely or sufficient federal funding, unencumbered by limitations that would impede the research. However, the GWG may recommend funding for vital research opportunities. A "vital research opportunity" means scientific and medical research and technologies, including, but not limited to, genetics, personalized medicine, and aging as pathology, and/or any stem cell research not actually funded by the institute under paragraph (3) of subdivision (c) of Section 125290.60 which provides a substantially superior research opportunity, vital to advance medical science as determined by at least a two-thirds vote of a quorum of the members of the GWG, provided, however, that if the ICOC has already designated a research category as a "vital research opportunity," a majority vote is required. Human reproductive cloning shall not be considered a vital research opportunity.

ARTICLE VIII. Rules of Order.

Debate and proceedings in the GWG shall be conducted in accordance with Robert's Rules of Order (Newly Revised) when not in conflict with rules of the GWG or other statutory requirements.

ARTICLE IX. Amendments.

These Bylaws may be amended or repealed by the ICOC at any regular or special meeting by a majority vote of a quorum of the ICOC. The GWG may recommend amendments to these bylaws to the ICOC for its consideration.