

Bylaws of the Scientific and Medical Research Funding Working Group

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06/27/08, 12/09/09,10/25/12 and
03//19/13.

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 & Safety Code, also known as the California Stem Cell Research and Cures Bond Act (“Act”).

ARTICLE II. Purpose.

The GWG is created for the purpose of recommending standards, criteria and grant and loan awards to the ICOC. 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 award of training, research, therapy development, and clinical trial 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 make recommendations for subsequent actions to the ICOC.

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 ICOC for the award of grants and loans to promote training, research, therapy development, and clinical trials;
- (E) Oversee peer-group reviews of grantees to ensure compliance with the terms of the award, and report to the ICOC 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 have 23 members composed of: (1) seven ICOC members from the ten (10) disease advocacy group members (“Patient Advocate Members”) described in paragraphs (3), (4), and (5) of subdivision (a) of Section 125290.20 of the Act; (2) fifteen (15) scientists (“Scientist Members”) nationally recognized in the field of stem cell research who are not California residents and who are not employed in the State of California, 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 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 GWG 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.

Section 4 (Expiration of Term) When a member’s term expires, the ICOC shall appoint a new member within 30 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 (Alternate Scientist Members) Individuals with strong scientific expertise in stem cell research may be appointed by the ICOC to serve as Alternate Scientist Members of the GWG. Alternate Scientist Members may serve in place of a Scientist Member of the GWG who is unavailable to attend a meeting. Alternate Scientist Members have voting privileges in the GWG and their presence is counted towards a quorum. In the event that a Scientist Member resigns from the GWG, an Alternate Scientist Member may be confirmed by the ICOC as a replacement.

Section 7 (Ad Hoc Members) Individuals with strong scientific expertise in stem cell research or on a particular issue may be appointed by the ICOC to serve as Ad Hoc Members of the GWG and may occasionally attend meetings of the GWG when a Scientist Member is

unavailable to attend a meeting. Ad Hoc Members have voting privileges and their presence is counted towards a quorum.

Section 8 (Specialists) 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 grant(s) or research fields. Specialists do not have voting privileges and their presence is not counted towards a quorum.

Section 9 (Administrative Chair of the GWG)

- (A) **(Appointment)** The ICOC shall appoint a Scientist Member of the GWG to serve as Administrative Chair of the GWG.
- (B) **(Duties)** The Administrative Chair of the GWG shall preside over public meetings of the GWG and all other GWG business that has not been assigned to an Acting Chair pursuant to Section 9.5 of this Article. The Administrative Chair shall also work collaboratively with the Vice Chairs and the Review Chair to support and enhance the relationship between the Scientist Members and the Patient Advocate Members of the GWG.
- (C) **(Alternate Administrative Chair)** In the event that the Administrative Chair of the GWG cannot attend all or a portion of a scientific review meeting, the Administrative Chair may designate a Scientist Member or an Alternate Scientist Member to serve as the alternate Administrative Chair in the absence of the Administrative Chair.

Section 9.5 (Review Chairs of the GWG)

- (A) **(Appointment)** For each Request for Applications (“RFA”) that CIRM issues, the President shall appoint a Scientist Member or Alternate Scientist Member of the GWG to serve as Review Chair of the GWG for all matters that are specific to that RFA. The President shall select a Review Chair with the knowledge and background necessary to lead the review of proposals under that RFA.
- (B) **(Duties)** A Review Chair of the GWG shall preside over the scientific evaluation of applications submitted in response to the designated RFA, as described herewith in Article VI, Section 2(A), and other GWG business associated with that RFA. 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 submitted in response to the designated RFA.
- (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, the Chair may designate a Scientist Member or an Alternate Scientist Member to serve as an alternate Review Chair in the absence of the Review Chair.

Section 10 (Vice-Chair of the GWG)

- (A) **(Appointment)** The ICOC shall appoint as co-Vice-Chairs of the GWG two Patient Advocate member 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 11 (Compensation and Expenses of GWG Members).

- (A) **ICOC Members** – Each member of the GWG who is also an ICOC member, except the chairperson, shall receive a per diem of one hundred dollars (\$116) per day (adjusted annually for cost of living) for each day the member attends a GWG meeting, plus reasonable and necessary travel and other expenses incurred in the performance of the member's duties. In addition, compensation in the amount of \$14.00 per hour shall be paid to ICOC members of the GWG for time spent in preparation for a meeting of the GWG.
- (B) **Non-ICOC Members** – Non-ICOC members of the GWG shall be entitled to a daily consulting rate and reimbursement for expenses, as established by the ICOC.

Section 12 (Conflict of Interest). All non-ICOC members of the GWG (including Scientist Members, Alternate Scientist Members, Ad Hoc Members and Specialists) 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 13. (Grounds for Removal of Members) Any non-ICOC 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 14. (Procedure for Suspension of Members) The President of the CIRM may suspend a non-ICOC 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 15. (Procedure for Removal of Members) The President of CIRM may recommend to the ICOC the removal of a non-ICOC 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 16. (Procedure for Temporary Leave of Absence) The President of CIRM or the Administrative Chair shall consider and may, at his or her discretion, grant requests, from non-ICOC GWG 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 Members). The fifteen (15) 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 ICOC.

Scientist Members of the GWG are full members and 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 funding decisions made by the ICOC.

The review is led by the Review Chair, a Scientist Member. During the review, Scientist Members of the GWG are responsible for assessing the scientific merit of each application, according to the criteria stated in the RFA, 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 Advocates in fulfilling their responsibilities on the GWG and the ICOC, to allow CIRM scientific staff to prepare summaries for the ICOC, applicants and the public, and to provide guidance that will be useful in the management of approved awards. During the scoring of applications, Scientist Members may ask questions, probe the views expressed by other participants, and express their own views. Scientist 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 Members of the GWG join the Patient Advocate Members to make and vote on motions concerning the final funding recommendation to the ICOC. Discussion for this closing phase of the review is led by the Review Chair, and allows for the entire GWG to adjust funding recommendations based on the review criteria specified in the RFA by making and considering motions to move applications from one tier to another. Recommendations may include specific conditions, such as removal of an element of the proposal or a reduction in the budget. If thirty-five percent (35%) of the members of the GWG join together in a minority position, a minority report may be submitted to the ICOC.

Section 2 (Patient Advocate Members). The seven (7) Patient Advocate members of the GWG, together with the Scientist Members, are responsible for voting on grant and loan funding recommendations to 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 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.

During the review of applications, Patient Advocate Members may ask questions, probe the views expressed by other participants, and express their own views.

After the scoring of applications concludes, the Patient Advocate Members join the Scientist Members of the GWG to make and vote on motions and minority reports concerning the final funding recommendation to the ICOC.

Section 3 (Alternate Scientist Members). At the discretion of staff, Alternate Scientist Members may serve as substitutes for GWG Scientist Members when a Scientist Member cannot attend a GWG meeting. Alternate Scientist Members shall perform the same duties as Scientist Members.

Section 4 (Ad Hoc Members) Ad Hoc members are responsible for attending meetings of the GWG for the purpose of providing scientific expertise on a particular issue(s), area or field and, at the discretion of the staff, may serve as a substitute for a GWG Scientist Member when a Scientist Member cannot attend a GWG meeting. Ad Hoc members shall perform the same duties as Scientist Members.

Section 5 (Specialists). Specialists may be invited by the staff 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 6 (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 staff, the President may ask 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 ICOC to matters that have been found to be inconsistent or incorrect in the review of a grant application.

Section 7 (Role of CIRM Scientific Staff). Members of CIRM's scientific staff, 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 staff provides guidance and information regarding CIRM's programs, portfolio and procedures, including explaining the scope and requirements of the request for applications and the review criteria and responding to requests for information regarding awards or applications that aid the GWG in making informed evaluations. The scientific staff 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. Scientific staff should, on request of the Review Chair, provide information to the GWG in their areas of expertise.

The scientific staff are responsible for monitoring scientific progress of CIRM-funded research projects, and may be called upon to report on that progress if it is relevant to the review of an application before the GWG. They are responsible for summarizing, for the ICOC, applicants and the public, the reasoning behind the scientific scores and GWG recommendations. Accordingly, scientific staff may ask members to clarify their views or address specific issues in order to present a complete and useful report.

Prior to ICOC consideration of GWG recommendations, the President and scientific staff 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, any Alternate Members, and any Specialist/Ad Hoc Members.

Section 2 (Teleconference Meetings). At the discretion of staff, 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 ICOC, discussions related to appeals or requests for reconsideration of GWG recommendations, discussions related to the review of a grantee's 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 & 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 Administrative Chair of the GWG 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 (Recommendation Procedures).

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

(B) Scientific Evaluation and Scoring

1. The Acting Chair of the GWG shall preside over the scientific evaluation and scoring process, and the process to arrive at the final recommendations to the ICOC.
2. The fifteen (15) Scientist Members of the GWG shall evaluate each grant and loan application for scientific merit and assign a numerical value to each grant based on standards and criteria adopted by the ICOC. The criteria and standards for evaluation are hereby incorporated by reference into these Bylaws.
3. The average numerical score for each grant and loan application will be calculated and recorded as its scientific score.
4. For purposes of making funding recommendations to the ICOC, each individual score and the average numerical score for each application shall be assigned to one of three tiers as follows:
 - a. Tier 1 = score 75 and above, representing applications that are recommended for funding;
 - b. Tier 2 = score 65-74, representing applications that are judged to be of moderate scientific quality or applications where consensus on scientific merit cannot be reached, and may be suitable for programmatic consideration; or
 - c. Tier 3 = 64 and below, representing grants that are not recommended for funding.

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.

5. At the conclusion of the consideration of all applications, the scientist 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 scientists will then submit final scores. After final submission, the scores may not be changed.

(C) Funding Recommendations

Staff will tally the scores after all applications have been reviewed, after which the entire slate in rank order will be presented to the entire GWG. During this phase of review, any member of the GWG, including Patient Advocate members, may make and second a motion to move an application from one tier to another, based on the review criteria identified in the RFA under consideration. This discussion will be moderated by the Review Chair.

Section 3 (Recommendations and Minority Reports).

Recommendations of the GWG to 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 & Safety Code section 125290.60(c)(1)(D). If thirty-five percent (35%) of the members of the GWG join together in a minority position, a minority report may be submitted to the ICOC.

Section 4 (Priority for Funding).

- (A) The GWG shall give priority to applications involving pluripotent stem cell and progenitor cell research that cannot, or is unlikely to receive timely or sufficient federal funding, unencumbered by limitations that would impede the research. Applications involving research categories funded by the National Institutes of Health shall not be recommended for funding pursuant to this subdivision.
- (B) Notwithstanding subdivision (A), the GWG may recommend funding for vital research opportunities. A “vital research opportunity” means scientific and medical research and technologies and/or any stem cell research that is not recommended for funding pursuant to (A) of this section but 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. 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.