

Bylaws of the Scientific and Medical Research Funding Working Group

ARTICLE I. Authority.

The Scientific and Medical Research Funding Working Group (“SMRFGWG”) 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 SMRFGWG 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 SMRFGWG 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 SMRFGWG to audit a grantee and forward any recommendations for action to the ICOC.

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

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

Section 2 (Appointment). The SMRFGW 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 from institutions outside the State of California, and; (3) the Chairperson of the ICOC.

Section 3 (Term of Service). SMRFGW 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 SMRFGW 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. SMRFGW 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. SMRFGW members shall continue to serve until their replacements are appointed.

Section 5 (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 SMRFGW. Alternate Scientist Members may serve in place of a Scientist Member of the SMRFGW who is unavailable to attend a meeting. Alternate Scientist Members have voting privileges in the SMRFGW and their presence is counted towards a quorum. In the event that a Scientist Member resigns from the SMRFGW, an Alternate Scientist Member may be confirmed by the ICOC as a replacement.

Section 6 (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 SMRFGW and may occasionally attend meetings of the SMRFGW 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 7 (Specialists) Individuals with scientific expertise on a particular issue may occasionally be invited to attend meetings of the SMRFGW for the purpose of providing evaluation or expertise with respect to specific grant(s) or research fields. Specialist members do not have voting privileges and their presence is not counted towards a quorum.

Section 8 (Chair of SMRFG)

- (A) **(Appointment)** The ICOC shall appoint a Scientist Member of the SMRFG to serve as Chair of the SMRFG.
- (B) **(Duties)** The Chair of the SMRFG shall preside over the scientific evaluation of grants described herewith in Article VI, Section 2(A).

Section 9 (Vice-Chair of SMRFG)

- (A) **(Appointment)** The ICOC shall appoint as Vice-Chair of the SMRFG a Patient Advocate member of the ICOC.
- (B) **(Duties)** The Vice-Chair of the SMRFG shall preside over the grant and loan recommendation procedures described herewith in Article VI, Section 2(B).

Section 10 (Compensation and Expenses of SMRFG Members).

- (A) **ICOC Members** – Each member of the SMRFG who is also an ICOC member, except the chairperson, shall receive a per diem of one hundred dollars (\$100) per day (adjusted annually for cost of living) for each day the member attends a SMRFG 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 \$12.50 per hour shall be paid to ICOC members of the SMRFG for time spent in preparation for a meeting of the SMRFG.
- (B) **Non-ICOC Members** – Non-ICOC members of the SMRFG shall be entitled to a daily consulting rate and reimbursement for expenses, as established by the ICOC.

Section 11 (Conflict of Interest). All non-ICOC members of the SMRFG 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.

ARTICLE V. Duties of SMRFG Members.

Section 1 (Scientist Members). The fifteen (15) Scientist Members of the SMRFG are responsible for evaluating and scoring grant and loan applications for scientific merit, and for recommending, along with the other members of the SMRFG, grant and loan funding awards to the ICOC.

Section 2 (Patient Advocate Members). The seven (7) Patient Advocate members of the SMRFG, together with the Scientist Members, are responsible for recommending grant and loan funding awards to the ICOC.

Section 3 (Alternate Scientist Members). At the discretion of staff, Alternate Scientist Members may serve as substitutes for SMRFGW Scientist Members when a Scientist Member cannot attend a SMRFGW 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 SMRFGW 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 SMRFGW Scientist Member when a Scientist Member cannot attend a SMRFGW 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 SMRFGW for the purpose of providing scientific expertise on a particular issue(s), area, or field and/or for a specific grant application.

ARTICLE VI. Meetings.

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

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

Section 3 (Open Meetings). The SMRFGW 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 of SMRFGW 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 SMRFGW may recommend additional exceptions to the ICOC as necessary to carry out the mission of the SMRFGW.

Section 4 (Special and Emergency Meetings). Special and emergency meetings may be called by the Chair of the SMRFGW if necessary.

ARTICLE VII. SMRFGW Procedure for Recommending Grant and Loan Applications.

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

Section 2 (SMRFGW Recommendation Procedures).

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

(B) Scientific Evaluation and Scoring

1. The Chair of the SMRFGW shall preside over the scientific evaluation and scoring process.
2. The fifteen (15) Scientist Members of the SMRFGW 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 will be calculated and recorded as its scientific score.

(C) Funding Recommendations

1. Once grant and loan applications have been assigned a scientific score, all voting members of the SMRFGW shall place each grant and loan application into one of three categories by separate or by *en bloc* vote as appropriate:
 - a. **Recommended for Funding (Tier 1)** – Highly meritorious grant and loan applications that are recommended for funding to the ICOC.
 - b. **Recommended for Funding Pending Available Funds (Tier 2)** – Meritorious grant and loan applications that are recommended for funding to the ICOC pending available funds.
 - c. **Not Recommended for Funding (Tier 3)** – Grant and loan applications that are not sufficiently meritorious to be recommended for funding to the ICOC.
2. The SMRFGW may recommend partial funding of an application, if it determines that parts of an application are not sufficiently meritorious to be recommended for funding to the ICOC.

Section 3 (Recommendations and Minority Reports). Recommendations of the SMRFGW to the ICOC shall be made by a majority vote of a quorum of the members of the SMRFGW, except for recommendations involving “vital research opportunities,” which require a two-thirds vote of a quorum of the members of the SMRFGW pursuant to Health & Safety Code

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

Section 4 (Priority for Funding).

- (A) The SMRFWG 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 SMRFWG 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 SMRFWG. Human reproductive cloning shall not be considered a vital research opportunity.

ARTICLE VIII. Rules of Order.

Debate and proceedings in the SMRFWG shall be conducted in accordance with Robert’s Rules of Order (Newly Revised) when not in conflict with rules of the SMRFWG 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 SMRFWG may recommend amendments to these bylaws to the ICOC for its consideration.