

Bylaws of the Treatments and Cures Accessibility and Affordability Working Group

Originally adopted by the ICOC on _____;

ARTICLE I. Authority.

The Treatments and Cures Accessibility and Affordability Working Group (“AAWG”) 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 125290.75 of the Health and Safety Code, also known as the California Stem Cell Research, Treatment and Cures Act of 2020, together, the “Act.”

ARTICLE II. Purpose.

The AAWG is created for the purpose of providing recommendations to the ICOC intended to examine, develop, and assist with the implementation of financial models to enhance the accessibility and affordability of treatments and cures arising from institute-funded research for Californians and to enhance access to clinical trials, including reimbursement alternatives for patient-qualified costs to help achieve the objective that reimbursement covers patient expenses. This purpose will be accomplished through standards and criteria adopted by the ICOC, in order to make recommendations to the ICOC. 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 AAWG shall have to following duties, functions, and responsibilities:

- A. Examine, develop, and assist with the implementation of financials models to enhance the accessibility and affordability of treatments and cures arising from CIRM funded research and to enhance access to clinical trials;
- B. Recommend to the ICOC policies and programs to help Californians obtain access to human clinical trials and to make treatments and cures arising from CIRM funded research available;
- C. Recommend to the ICOC policies and programs to help Californians afford to participate in human clinical trials and to make treatments and cures arising from CIRM funded research affordable to patients;
- D. Work with the CIRM team to develop model programs and coverage models to promote the access and affordability of treatments and cures arising from CIRM funded research for patients, including within Alpha Stem Cell Clinics and Community Care Centers of Excellence and other health care institutions. The AAWG will also work with CIRM’s internal

teams to engage with external stakeholders such as payors and policymakers.

- E. Advise the ICOC regarding the coverage criteria and process for reimbursement of therapies and cures arising from CIRM funded research and made available to patients.

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

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

Section 2 (Appointment). The AAWG shall be composed of: (1) five (5) 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; (2) an individual who has private sector experience in innovative therapy medical coverage terms, qualifications, and the process for reimbursement; (3) an expert or a highly knowledgeable individual with experience in federal therapy coverage, qualifications, and process for reimbursement; (4) an expert or a highly knowledgeable individual with experience in California's public insurance program (currently Covered California), coverage, qualifications, and the process for reimbursement of innovative therapies; (5) two (2) representatives from hospitals in California that are participating in stem cell clinical trials or that are treating patients with federal Food and Drug Administration (FDA) approved stem cell or genetic therapies; (6) a representative from a philanthropic organization who has experience assisting patients with clinical trial access and affordability or with access to, and the affordability of, innovative therapies; (7) two representatives from patient advocacy organizations who have technical expertise or experience in coverage, qualifications, and the process for reimbursement of innovative therapies; (8) a health care economist with experience in advising or negotiating with private insurers, government insurers, or corporate self-insurance programs on coverage for innovative therapies or human trials; (9) a patient navigator with training and experience helping patients obtain financial support from private insurers, public support, or nonprofit support, and helping patients obtain social science support to facilitate their participation in FDA approved human trials or qualification for access and financial assistance for innovative therapies; and; (10) the Chairperson and Vice Chairperson of the ICOC.

Section 3 (Term of Service). AAWG members shall normally serve for six (6) years. AAWG 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. AAWG members shall continue to serve until their replacements are appointed.

Section 5 - (Ad Hoc Members). 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 6 (Chair of the AAWG).

The ICOC shall appoint as Chair of the AAWG one of the five (5) ICOC members of the AAWG.

Section 7 (Compensation and Expenses of AAWG Members).

- A. ICOC Members – ICOC members of the AAWG, 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. Non-ICOC Members – Non-ICOC Members of the AAWG, including Specialists and AdHoc Members, shall be entitled to a daily consulting rate and reimbursement for expenses, as established by the ICOC.

Section 10. (Conflict of Interest). All Non-ICOC Members, including Specialists, and AdHoc 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 AAWG shall comply with CIRM's Confidentiality Policy, which is attached as Appendix A.

Section 12. (Grounds for Removal of Members). Any Non-ICOC Member of the AAWG maybe 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 AAWG 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. 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 Non-ICOC Member of the AAWG 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 AAWG, 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 Non-ICOC Member of the AAWG 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 Non-ICOC 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 AAWG Members and Role of CIRM President and Staff With Respect to Grant Applications and Contracts.

Section 1 (Concept Proposals, Requests for Applications (RFAs), and Applications).

The AAWG provide direction to the CIRM team to develop concept proposals, RFAs and conduct reviews for research that would be brought to the ICOC for final approval.

When topics are identified as area for concept and RFA development, the CIRM team would produce the materials that would be subject to AAWG input and final approval for delivering to the ICOC (including the appropriate subcommittee(s)) for consideration.

The AAWG Members are responsible for evaluating any grant applications related to the AAWG functions stated in Section 1 above for merit and for voting on grant recommendations to the Application Review Subcommittee of the ICOC.

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 any one expert review session. Ad Hoc Members shall have voting privileges and their presence is counted towards a quorum.

The review is led by the Chair. During the review, Members of the AAWG are responsible for assessing the merit of each application, according to the criteria stated by CIRM, based on their own expertise and the expert opinion of the other reviewers. In written critiques and during review meetings, they should be willing to explain their reasoning to assist other Members in fulfilling their responsibilities on the AAWG 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 evaluations of applications, Members may ask questions, probe the views expressed by other participants, and express their own views. Members are expected to consider the views expressed by other participants, but their confidential

scores should reflect their own independent scientific judgment.

After the evaluation of applications concludes, Members of the AAWG will vote on motions concerning the final funding recommendation to the Application Review Subcommittee of the ICOC.

Section 2 (Specialists). Specialists may be invited by the CIRM team to participate in meetings of the AAWG for the purpose of providing expertise on a particular issue(s), area, or field and/or for a specific grant application.

Section 3 (Role of CIRM President). CIRM's President serves on the AAWG as a non-member participant in all AAWG discussions but does not assign, make motions or vote. As the leader of CIRM's team members, the President may ask AAWG members to consider how an application will address issues that have come up in the field or in the execution of CIRM-funded research, respond to questions by AAWG members on CIRM-related matters, and provide information within his/her expertise.

The President should alert the AAWG 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 4 (Role of CIRM Team). Members of CIRM's team, under the leadership of the President, support the AAWG, by designing concept proposals, RFAs, 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. Once awards are made, the CIRM team would manage the awards utilizing its internal oversight and contracting mechanisms.

To this end, the 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 AAWG making informed evaluations. The team also ensures that review criteria, priorities and requirements are appropriately applied to the evaluations and discussions of applications and help the Chair ensure that all AAWG members contribute to the proper evaluation and scoring of applications. Team members should, on request of the Chair, provide information to the AAWG in their areas of expertise.

The team members are responsible for monitoring progress of CIRM-funded projects and may be called upon to report on that progress if it is relevant to the review of an application before the AAWG or for the AAWG to provide recommendations. They are responsible for summarizing, for the Application Review Subcommittee of the ICOC, applicants and the public, the reasoning behind the AAWG recommendations. Accordingly, team members may ask AAWG 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 AAWG recommendations, the President and team should consider whether there are applications which they believe warrant particularly close review, or whether specific modifications may be needed to execute successfully a particular proposal.

ARTICLE VI. Meetings.

Section 1 (Regular Meetings). The AAWG shall hold at least four meetings per year, one of which will be designated as its annual meeting. The AAWG may hold additional meetings as the AAWG determines are necessary or appropriate.

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

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

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

ARTICLE VII. Procedure for Recommending Grants and Contracts.

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

Section 2 (Taking Action). Actions of the AAWG 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 AAWG shall be present in-person or via teleconference during the meeting and may participate in all discussions.

B. Evaluation and Scoring

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

2. The Members of the AAWG shall evaluate each application for merit and base its recommendation on standards and criteria adopted by the ICOC. The criteria and standards for evaluation are hereby incorporated by reference into these Bylaws.

Section 6 (Oversight Reviews).

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

Section 7 (Recommendations and Minority Reports).

Recommendations of the AAWG to the Application Review Subcommittee of the ICOC shall be made by a majority vote of a quorum of the members of the AAWG. If thirty-five percent (35%) of the members of the AAWG panel award scores in the funding range, a minority recommendation report shall be submitted to the Application Review Subcommittee of the ICOC.

ARTICLE VIII. Rules of Order.

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

APPENDIX A



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CIRM CONFIDENTIALITY POLICY FOR ACCESSIBILITY AND AFFORDABILITY WORKING GROUP

The California Institute for Regenerative Medicine (CIRM) is committed to maintaining confidentiality during the grant review process to protect the interests of the applicants and to encourage candor on the part of the reviewers as to the scientific and medical value of the applications being reviewed. Applicants provide confidential information to the CIRM as part of their applications, and it is the obligation of those participating in the review to safeguard this information.

According to CIRM policy, Working Group (WG) members must not disclose the identity of applicants and institutions that they consider. The principal investigator's name and institution, the project title and abstract will be made public for funded grants, but the contents of the applications, even in funded grants, remain confidential for the protection of the applicants.

The applications and proposals and associated materials made available to WG members, as well as the discussions that take place during the closed session of the WG review meetings, are strictly confidential and must not be disclosed to or discussed with any individual who has not been officially appointed to participate in the review process. WG members are not to discuss the identity of the applicants, the contents of the applications or the WG discussions with anyone other than WG members or CIRM review personnel. If you wish to discuss a technical matter related to an application with a colleague who is not on the Working Group, please do not contact the person directly. Rather, notify the Grants Review Officer who will review the request and contact the person directly if appropriate.

All hard copy materials associated with the review that you receive or that you generate must not be shared with anyone and must be destroyed after the review is complete.

I understand the confidentiality policies of CIRM and will abide by them.

Signature: _____

(Print Name)