

Bylaws of the Scientific and Medical Accountability Standards Working Group

ARTICLE I. Authority.

The Scientific and Medical Accountability Standards Working Group (“SWG”) of the Independent Citizens’ Oversight Committee (“ICOC”) to the California Institute for Regenerative Medicine (“Institute”) is established by Chapter 3, Article 1, section 125290.50 and section 125290.55 of the Health & Safety Code, also known as the California Stem Cell Research and Cures Act (“Act”).

ARTICLE II. Purpose.

The SWG is created for the purpose of recommending scientific, medical, and ethical standards to the ICOC. This purpose will be accomplished by: (1) recommending standards for all medical, socioeconomic, diversity, and financial aspects of clinical trials and therapy development and delivery to patients, including equitable access to therapies; (2) recommending standards for the oversight of funded research; and (3) advising the ICOC on relevant ethical and regulatory issues.

ARTICLE III. Functions.

The duties of the SWG shall include the following:

- (A) Recommend to the ICOC scientific, medical and ethical standards;
- (B) Recommend to the ICOC standards for all medical, socioeconomic, diversity, and financial aspects of clinical trials and therapy development and delivery to patients, including among others, standards for equitable access to therapies and safe and ethical procedures for obtaining materials and cells for research and clinical efforts for the appropriate treatment of human subjects in medical research consistent with paragraph (2) of subdivision (b) of Section 125290.35, and to ensure compliance with patient privacy laws.
- (C) Recommend to the ICOC modifications of the standards described in paragraphs (A) and (B) above, as needed;
- (D) Make recommendations to the ICOC on the oversight of funded research to ensure compliance with the standards described in paragraphs (A) and (B) above;
- (E) Regularly advise the ICOC, the Scientific and Medical Research Funding Working Group, and the Scientific and Medical Research Facilities Working Group on relevant ethical and regulatory issues.

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

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

Section 2 (Appointment). The SWG shall have 19 members, as follows: (1) five 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 or from the members appointed pursuant to paragraph (6) of subdivision (a) of Section 125290.20 of the Act; (2) nine scientists and clinicians (“Scientist/Clinician Members”) nationally recognized in the field of pluripotent and progenitor cell research; (3) four medical ethicists; and (4) the Chair of the ICOC.

Section 3 (Term of Service). SWG members shall 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 an SWG 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. SWG 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 60 days. SWG members shall continue to serve until their replacements are appointed.

Section 5 (Co-Chairs of SWG).

- (A) **(Appointment)** The ICOC shall appoint a Patient Advocate Member of the SWG to serve as Co-Chair of the SWG. In addition, the ICOC shall appoint a Scientist/Clinician Member or an Ethicist Member of the SWG to serve as Co-Chair.
- (B) **(Duties)** The Co-Chairs of the SWG shall preside over meetings of the SWG and shall work with CIRM staff to coordinate the work of the SWG.
- (C) **(Substitute Co-Chairs)** In the event that the Patient Advocate Co-Chair must be absent from a meeting of the SWG, he or she may ask another Patient Advocate member of the SWG to serve as co-chair at that meeting. In the event that the Scientist/Clinician/Ethicist Co-Chair must be absent from a meeting of the SWG, he or she may ask another Scientist/Clinician/Ethicist member of the SWG to serve as co-chair at that meeting.

Section 6 (Compensation and Expenses of SWG Members).

- (A) **ICOC Members** – Each member of the SWG who is also an ICOC member, except the chairperson, shall receive a daily consulting rate as established by the ICOC bylaws.
- (B) **Non-ICOC Members** – Non-ICOC members of the SWG shall be entitled to a daily consulting rate and reimbursement for expenses, as established by the ICOC.

Section 7 (Conflict of Interest). Non-ICOC members of the SWG members shall be governed by conflict of interest rules and economic disclosure requirements adopted by the ICOC. ICOC members of the SWG 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. Meetings.

Section 1 (Regular Meetings). The SWG shall hold at least four meetings per year, one of which will be designated as its annual meeting, except as otherwise determined by CIRM.

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

Section 3 (Open Meetings). As provided in its Meeting Procedures, which are incorporated herein by this reference, the SWG shall meet in public session except for discussions related to matters involving patient privacy or the review of a complaint regarding an investigator's or institution's compliance with medical or ethical standards adopted by the ICOC, 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 SWG may recommend additional exceptions to the ICOC as necessary to carry out the mission of the SWG.

Section 4 (Special and Emergency Meetings). Special and emergency meetings may be called by the Co-Chairs if necessary.

ARTICLE VI. SWG Procedure for Recommending Scientific, Medical, and Ethical Standards.

Section 1 (Quorum). Sixty-five percent of the SWG members who are eligible to vote shall constitute a quorum of the SWG. All actions of the SWG shall be taken by a majority vote of a quorum of members.

Section 2 (Voting Procedures).

- (A) Unless excused due to conflicts, both ICOC and non-ICOC members of the SWG shall be present in-person or via teleconference during the entire SWG meeting.
- (B) The Co-Chairs of the SWG shall preside over the discussion and recommendation process, and all members of the SWG, except for those who are excused due to conflicts, shall participate in the discussion and vote on standards.
- (C) All motions, including motions to recommend standards to the ICOC, shall be made by a majority vote of a quorum of the members of the SWG. Amendments to pending motions may be made with the concurrence of the maker of the motion and the second, unless a member of the ICOC requests a vote on the proposed amendment, in which case, action on the proposed amendment shall be taken by a majority vote of a quorum, before the vote on the pending motion.

Section 3 (Minority Reports). If thirty-five percent (35%) of the members of the SWG 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 ICOC.

ARTICLE VII. Rules of Order.

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

ARTICLE VIII. 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.