



To: Members, Governing Board
From: Kevin Marks, General Counsel
Date: January 27, 2022
Re: Final Approval of Conflict of Interest Policy for Members of Advisory Task Forces

The California Stem Cell Research, Treatments, and Cures Act of 2020 (Proposition 14) authorizes the Chair and the President to establish Advisory Task Forces to provide expert guidance regarding specific issues within CIRM's jurisdiction, such as scientific, policy, ethical, financial, and technical matters. Cal. Health & Saf. Code, § 125290.76. For purposes of conflict of interest rules, these Advisory Task Forces are treated like CIRM's working groups because they do not exercise decision-making authority. *Id.* § 125290.76(c). However, unlike members of the working groups, Advisory Task Forces members are barred from reviewing, commenting upon, or exercising any jurisdiction over any individual grant or loan approval. *Id.* § 125290.76(c)(2).

Health and Safety Code section 125290.50(e) requires the Board to adopt conflict of interest rules to govern members of working groups; this requirement also applies to members of advisory task forces established by CIRM.

On January 21, 2021, the Board adopted an Interim Conflict of Interest Policy for Members of Advisory Task Forces regulation to be in effect for 270 days and directed CIRM staff to promulgate this regulation under the procedures established by the California Administrative Procedures Act. *Id.* § 125290.40(m).

This regulation is modeled on the policies of the working groups but tailored to task forces, which do not consider individual applications but will instead provide high-level advice to the CIRM. The regulation prohibits Advisory Task Forces members from receiving a benefit from CIRM funding and requires disclosure and disqualification. Under the regulation, Advisory Task Forces members must disclose: (1) income received from nonprofit research institutions located in California and (2) investments in public biotechnology and pharmaceutical companies that are focused primarily on stem cell or

genetic research and therapy development. Finally, the Advisory Task Forces members are required to disqualify themselves if one of their financial interests is involved in a decision before the task force, unless the CIRM President/CEO determines that the need for the member's expertise outweighs any possible bias.

On April 22, 2021, CIRM staff began the first formal rulemaking process by submitting a notice of proposed regulation to the Office of Administrative Law, published in the California Regulatory Notice Register on April 30, 2021. CIRM did not receive any public comments during that comment period.

Upon further review of the draft regulation, CIRM staff made minor edits to the language of the regulation to clarify the authority of the Advisory Task Forces to make only recommendations to the ICOC. On November 23, 2021, CIRM staff began the second formal rulemaking process by submitting a notice of proposed regulation to the Office of Administrative Law, published in the California Regulatory Notice Register. CIRM did not receive any public comment during the comment period.

As a result, CIRM has not modified the interim regulation. CIRM staff now requests final approval of the Advisory Task Forces conflict regulation so that we may submit the regulation for review and approval by the Office of Administrative Law.

RECOMMENDATION: Approve the proposed regulation in its current form and authorize CIRM staff to submit the final rulemaking package to the Office of Administrative Law.



**Proposed Interim Regulation for Conflict of Interest Standards
for Members of Advisory Task Forces**

**(Adopted Pursuant to Health & Saf. Code, §§ 129290.76(c),
125290.50(e) and 125290.40(m))**

(a) Prohibitions: Members of Advisory Task Forces are precluded from deriving direct financial benefit from CIRM through research grants or loans and from acting as a Principal Investigator on any CIRM-funded award.

(b) Disclosure: Before a meeting of an Advisory Task Force, members of the Advisory Task Force shall disclose:

(1) All California-based academic or non-profit research institutions from which the member or the member's spouse has received income of \$5,000 or more in the preceding 12 months;

(2) All public biotechnology and pharmaceutical companies that are primarily focused on stem cell or genetic research and therapy development in which the member or the member's spouse has an investment of \$5,000 or more. A public biotechnology company or a public pharmaceutical company is considered to be primary focused on stem cell or genetic research and therapy development if it devotes more than 50 percent of its annual research and development budget to stem cell or genetic research and therapy development.

(c) Disqualification: A conflict of interest exists when a member has any financial interest identified in subdivision (b) of this regulation that is the subject of a proposed recommendation before the Advisory Task Force. A member who has a conflict of interest with respect to a proposed recommendation may not participate in the discussion related to the proposed recommendation and must leave the room when that proposed recommendation is discussed. In exceptional cases, the President/CEO of CIRM may decide that the need for special expertise of a member outweighs any possible bias posed by a conflict of interest. Under these circumstances, the member shall be permitted to participate in the discussion but will not be permitted to vote on the matter.



(d) Record-Keeping: All financial disclosures shall be kept confidential by CIRM staff and preserved for purposes of review by the State Auditor or another independent auditor and any other audit as required by law. Records of the Advisory Task Force indicating those members who participated in or voted on particular recommendations shall be maintained by CIRM staff. If CIRM or an auditor discovers a violation of these conflict of interest provisions, a report will be made to the Legislature along with a review of corrective actions taken by the CIRM to prevent future occurrences.