

1 Amend 17 Cal. Code of Regs. section 100003 to read:

2 **§ 100003. Conflicts of Interest – Non-ICOC Members of the Scientific and Medical Research**
3 **Funding Working Group (the “Grants Working Group”).**

4 (a) Prohibition: Except as provided otherwise in this regulation, a non-ICOC Grants Working
5 Group member may not participate in a decision of the working group in which the individual has a
6 conflict of interest. A conflict of interest exists when a non-ICOC Grants Working Group member has
7 a real or apparent interest in the outcome of an application such that the member is in a position to gain
8 financially, professionally or personally from either a positive or negative evaluation of the grant
9 proposal.

10 (b) “Financial: Conflict of Interest - Defined: A non-ICOC member has a financial conflict of
11 interest if:

12 (1) The member or a member of his or her Immediate Family is an employee of either the
13 applicant organization, a Subcontractor, or a Partner, or has received, or has been promised, income or
14 anything else of value, of \$5,000 or more, or gifts worth \$500 or more, in the past year from the
15 applicant institution, a Subcontractor, a Partner, or a person listed in the application as Key Personnel.

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17 (2) The member or a member of his or her Immediate Family is under active consideration for
18 employment at the applicant organization, a Subcontractor, or a Partner.

19 (3) A member or a member of his or her Immediate Family stands to receive a financial benefit
20 of any amount from the application under review.

1 (4) A member or a member of his or her Immediate Family has a financial interest in the
2 organization, a Subcontractor, or a Partner of \$5,000 or more. A “financial interest” includes current
3 stock holdings, equity interest, intellectual property or real property interest, but does not include an
4 interest held through a diversified mutual fund.

5 (c) “Professional” Conflict of Interest - Defined: A non-ICOC member has a professional
6 conflict of interest if:

7 (1) A person listed in the application as Key Personnel has been a Research Collaborator, a
8 former trainee, or mentor of the member within the last three years.

9 (2) The member and a person listed in the application as Key Personnel are currently engaged
10 in, or are planning to be engaged in, a Research Collaboration.

11 (3) The member is also a member of the Clinical Advisory Panel advising the project that is the
12 subject of an application.

13 (d) “Personal” Conflict of Interest - Defined: A non-ICOC member has a personal conflict of
14 interest if:

15 (1) An Immediate Family member or close personal friend is a person listed in the application as
16 Key Personnel.

17 (2) The member and a person listed in the application as Key Personnel have been on opposing
18 sides in a lawsuit, arbitration or mediation.

19 (e) Disclosure: A non-ICOC working group member shall disclose confidentially and under
20 penalty of perjury the following financial interests:

1 (1) Income of \$5,000 or more, or gifts worth \$500 or more, received by the member of
2 a member of his or her Immediate Family from a California-based academic or non- profit research
3 organization in the past year.

4 (2) Income of \$5,000 or more received by the member or a member of his or her
5 Immediate Family from a publicly-held biotechnology or pharmaceutical company.

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7 (3) An investment worth \$5,000 or more held by the member or a member of his or her
8 Immediate Family in a publicly-held biotechnology or pharmaceutical company, not including an
9 investment held through a diversified mutual fund.

10 (4) Income received by the member or a member of his or Immediate Family from a
11 privately held biotechnology company.

12 (5) An interest worth \$2,000 or more held by the member or a member of his or her
13 Immediate Family in real property in California.

14 (f) Disqualification: A non-ICOC member is required to report to the CIRM staff any conflict of
15 interest of which he or she is aware, including, but not limited to, those described in subdivisions (b)
16 through (d) of this regulation, and any application as to which the Member believes his or her objectivity
17 could be compromised. A non-ICOC member of the Grants Working Group who has a conflict of
18 interest, as described in subdivisions (b) through (d) of this regulation, or who believes that his or her
19 objectivity could be compromised with respect to an application may not review or vote on the
20 application and must leave the room when that application is discussed. In exceptional cases, the
21 President of the CIRM may decide that the need for special expertise of the reviewer outweighs any

1 possible bias posed by a real or apparent conflict of interest. Under these circumstances, the CIRM
2 staff shall publicly disclose the working group member's interest before the meeting and the working
3 group member shall be permitted to participate in the discussion but will not be permitted to vote on the
4 application or participate in the scientific scoring.

5 (g) All non-ICOC members must indicate any possible conflicts of interest that they have in
6 advance of a review and must certify that they did not participate in the discussion or review of any
7 application for which they have a conflict of interest, or indicate permission to participate was granted
8 by the President pursuant to subdivision (e) of this regulation.

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

16 (i) For purposes of this section, the following terms have the following meanings:

17 (1) "Immediate Family" member means a non-ICOC member's spouse, domestic
18 partner, and dependent children.

19 (2) "Key Personnel" means (i) the principal investigator or program director; or (ii) any
20 other person, including an independent consultant or an employee of a Subcontractor or Partner, who is
21 expected to contribute to the scientific development or execution of the project in a substantive,

1 measurable way and who is expected to: (a) receive or has been promised income, or anything else of
2 value, of \$10,000 or more per year through the proposed project or (b) contribute one percent (1%) or
3 more effort to the proposed project. “Key Personnel” does not include a person who is expected to be
4 involved in the proposed project but who does not satisfy paragraphs (i) or (ii).

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6 (3) “Partner” means an organization that, in exchange for the right to the opportunity for
7 a future financial return, has agreed to provide matching funds for the proposed project or entered into
8 an agreement with the applicant organization relating to the commercialization of the proposed project.
9 Partner does not include an organization that, like the National Institutes of Health, provides research
10 funding to a proposed project but that does not have the right to a future financial return.

11 (4) “Research Collaborator” or “Research Collaboration” means participation as Key
12 Personnel on the same research project or effort to advance or publish research results or the
13 commercial development of a product. The terms do not include passive associations such as belonging
14 to the same scientific society or contributing to the same review article or textbook.

15 (5) “Subcontractor” means an organization (other than the applicant organization) that is
16 expected to: (a) contribute to the scientific development or execution of the project in a substantive,
17 measurable way and (b) receive \$25,000 or more through the proposed project. “Subcontractor” does
18 not include suppliers of widely available goods.

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20 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and
21 Safety Code.

1 Reference: Sections 125290.50, subd. (e), 125290.60, Health and Safety Code.