

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

2 **§ 100003. Conflicts of Interest – Non-ICOC Members of the Scientific and Medical**

3 **Research Funding Working Group (the “Grants Working Group”).**

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

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

12 (1) The member or a member of; his or her ~~spouse, or any other person with whom the~~
13 ~~member has a common financial interest~~ Immediate Family; is an employee of either the
14 ~~institution or the Principal Investigator on an applicant organization, a Subcontractor, or a~~
15 Partner, or has received, or has been promised, income or anything else of value, of \$5,000 or
16 more, or gifts worth \$500 or more, in the past year from the applicant institution, a
17 Subcontractor, a Partner, or a person listed in the application as Key Personnel.

18 (2) The member or a member of; his or her ~~spouse, or any other person with whom the~~
19 ~~member has a common financial interest~~ Immediate Family is under active consideration for a
20 ~~faculty or administrative position~~ employment at an the applicant institution organization, a
21 Subcontractor, or a Partner.

1 (3) A member, ~~or a member of~~ his or her spouse, ~~or any other person with whom the~~
2 ~~member has a common financial interest,~~ Immediate Family stands to receive a financial benefit
3 of any amount from ~~an~~ the application under review.

4 (4) A member, ~~or a member of~~ his or her ~~spouse, or any other person with whom the~~
5 ~~member~~ Immediate Family has a ~~common~~ financial interest, ~~has received or could receive a~~
6 ~~financial benefit of any type from an~~ in the applicant institution or organization, a
7 Subcontractor, or a Partner unrelated to the proposal, of ~~over~~ \$5,000 ~~per year. This total includes~~
8 ~~honoraria, fees, stock and other benefits. It also~~ more. A “financial interest” includes current
9 stock holdings, equity interest, intellectual property or real property interest, but does not include
10 an interest held through a diversified mutual funds.

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

13 (1) A person listed ~~on~~ in the grant application as ~~Principal Investigator or someone who~~
14 ~~receives salary from the grant is~~ Key Personnel has been a ~~professional associate, such~~
15 ~~as~~ Research Collaborator, a former ~~student trainee, or post-doctoral fellow, or someone with~~
16 ~~whom or mentor of~~ the member ~~has co-authored a publication~~ within the last three years.

17 (2) The member and a ~~primary member of the applicant’s research team~~ person listed in
18 the application as Key Personnel are currently engaged in, or are planning to be engaged in, a
19 Research Ceollaboration.

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

1 ~~(3) An applicant is someone with whom the member has had long-standing scientific~~
2 ~~differences or disagreements that are known to the professional community and could be~~
3 ~~perceived as affecting the member's objectivity.~~

4 (d) "Personal" Conflict of Interest - Defined: A non-ICOC member has a personal
5 conflict of interest if:

6 (1) ~~A~~ eløsen Immediate F family member or close personal friend is ~~an applicant.~~

7 ~~(2) An applicant is someone with whom a person listed in the member has had long-~~
8 ~~standing personal differences~~ application as Key Personnel.

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

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

13 (1) ~~All~~ Income of \$5,000 or more, or gifts worth \$500 or more, received by the
14 member of a member of his or her Immediate Family from a California-based academic or non-
15 profit research institutions from which members, their spouses, or others with whom the member
16 has a common financial interest, receives income or other benefit of \$5,000 or more organization
17 in the past year.

18 (2) ~~All~~ Income of \$5,000 or more received by the member or a member of his or
19 her Immediate Family from a publicly-held biotechnology ~~and or~~ pharmaceutical ~~companies~~

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21 (3) An investment worth \$5,000 or more held by the member or a member of his
22 or her Immediate Family in a publicly-held biotechnology or pharmaceutical company, not
23 including from which members, their spouses, or others with whom a member has a common

1 ~~financial interest, receives current income or other benefit, or holds an investment, of \$5,000 or~~
2 ~~more held through a diversified mutual fund.~~

3 (43) ~~All~~ Income received by the member or a member of his or Immediate Family
4 ~~from a~~ privately held biotechnology ~~companies in which reviewers, their spouses, or others with~~
5 ~~whom a member has a common financial interest, has an equity interest~~ company.

6 ~~——~~(54) ~~An interest worth \$2,000 or more held by the member or a member of his or~~
7 ~~her Immediate Family in r~~Real property ~~interests in California held by members, their spouses,~~
8 ~~or others with whom a member has a common financial interest.~~

9 (f) Disqualification: A non-ICOC member is required to report to the CIRM staff any
10 conflict of interest of which he or she is aware, including, but not limited to, those described in
11 subdivisions (b) through (d) of this regulation. ~~Any, and any application as to which the Member~~
12 ~~believes his or her objectivity could be compromised. A non-ICOC~~ member of the Grants
13 ~~Review~~ Working Group who has a ~~real or apparent~~ conflict of interest, ~~as described in~~
14 ~~subdivisions (b) through (d) of this regulation, or who believes that his or her objectivity could~~
15 ~~be compromised~~ with respect to an application may not review or vote on the application and
16 must leave the room when that application is discussed. In exceptional cases, the President of
17 the CIRM may decide that the need for special expertise of the reviewer outweighs any possible
18 bias posed by a real or apparent conflict of interest. Under these circumstances, the CIRM staff
19 shall publicly disclose the working group member's interest before the meeting and the working
20 group member shall be permitted to participate in the discussion but will not be permitted to vote
21 on the application or participate in the scientific scoring.

22 (g) All non-ICOC members must ~~sign a pre-review statement indicating~~ indicate any
23 possible conflicts of interest that they have ~~in advance of a review;~~ and must ~~also sign a post-~~

1 ~~review statement~~certify that they did not participate in the discussion or review of any
2 application for which they ~~might~~ have a conflict of interest, or ~~shall~~ indicate permission to
3 participate was granted by the President pursuant to subdivision (e) of this regulation.

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

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

12 (1) “Immediate Family” member means a non-ICOC member’s spouse, domestic
13 partner, and dependent children.

14 (2) “Key Personnel” means (i) the principal investigator or program director; or
15 (ii) any other person, including an independent consultant or an employee of a Subcontractor or
16 Partner, who is expected to contribute to the scientific development or execution of the project in
17 a substantive, measurable way and who is expected to: (a) receive or has been promised income,
18 or anything else of value, of \$10,000 or more per year through the proposed project or (b)
19 contribute one percent (1%) or more effort to the proposed project. “Key Personnel” does not
20 include a person who is expected to be involved in the proposed project but who does not satisfy
21 paragraphs (i) or (ii).
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1 (3) “Partner” means an organization that, in exchange for the right to the
2 opportunity for a future financial return, has agreed to provide matching funds for the proposed
3 project or entered into an agreement with the applicant organization relating to the
4 commercialization of the proposed project.

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

9 (5) “Subcontractor” means an organization (other than the applicant organization)
10 that is expected to: (a) contribute to the scientific development or execution of the project in a
11 substantive, measurable way and (b) receive ~~\$50,000~~ \$25,000 or more through the proposed
12 project. “Subcontractor” does not include suppliers of widely available goods.

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

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