

1 Adopt 17 Cal. Code of Regs. section 100006 to read:

2 **§ 100006. Conflicts of Interest – Non-ICOC Members of the Treatments and Cures**
3 **Accessibility and Affordability Working Group.**

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

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

13 (1) The member or a member of his or her Immediate Family is an
14 employee of either the applicant organization, a Subcontractor, or a Partner, or has
15 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 Immediate Family is under
19 active consideration for employment at the applicant organization, a
20 Subcontractor, or a Partner.

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

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

28 (c) “Professional” Conflict of Interest - Defined: A non-ICOC member has a
29 professional conflict of interest if the member and a Key Personnel of an application are engaged
30 in, or are planning to be engaged in, a joint project.

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

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

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

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

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

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

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

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

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

53 (f) Disqualification: A non-ICOC member is required to report to CIRM staff
54 any conflict of interest of which he or she is aware, including, but not limited to, those
55 described in subdivisions (b) through (d) of this regulation, and any application as to
56 which the Member believes his or her objectivity could be compromised. A non-ICOC
57 member of the Working Group who has a conflict of interest, as described in subdivisions
58 (b) through (d) of this regulation, or who believes that his or her objectivity could be
59 compromised with respect to an application may not review or vote on the application. In
60 exceptional cases, the President/CEO of CIRM may decide that the need for special
61 expertise of the reviewer outweighs any possible bias posed by a real or apparent conflict
62 of interest. Under these circumstances, the working group member shall be permitted to

63 participate in the discussion but will not be permitted to vote on the application or
64 participate in the scoring.

65 (g) All non-ICOC members must indicate any possible conflicts of interest
66 that they have in advance of a review and must certify that they did not participate in the
67 discussion or review of any application for which they have a conflict of interest, or
68 indicate permission to participate was granted by the President/CEO pursuant to
69 subdivision (f) of this regulation.

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

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

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

81 (2) “Key Personnel” means (i) the principal investigator or program
82 director; or (ii) any other person, including an independent consultant or an
83 employee of a Subcontractor or Partner, who is expected to contribute to the

84 development or execution of the project in a substantive, measurable way and
85 who is expected to: receive or has been promised income, or anything else of
86 value, of \$10,000 or more per year through the proposed.

87 (3) “Partner” means an organization that, in exchange for the right to
88 the opportunity for a future financial return, has agreed to provide funds for the
89 proposed project or entered into an agreement with the applicant organization
90 relating to the proposed project. Partner does not include an organization that,
91 like the National Institutes of Health, provides research funding to a proposed
92 project but that does not have the right to a future financial return.

93 (4) “Subcontractor” means an organization (other than the applicant
94 organization) that is expected to: (a) contribute to the development or execution of
95 the project in a substantive, measurable way and (b) receive \$25,000 or more
96 through the proposed project. “Subcontractor” does not include suppliers of widely
97 available goods.

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99 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),

100 Health and Safety Code

1 Reference: Sections 125290.50, subd. (e), 125290.60, 125290.75, Health and Safety Code.