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OFFICE OF THE PRESIDENT

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February 5, 2008

CHANCELLORS

Dear Colleagues:

As you know, at its September, 2007 meeting, the Board of Regents adopted RE-89, a Regental resolution requiring adoption of special review, approval, and reporting procedures for proposals to obtain research funding from the tobacco industry. I am writing to request that each of you ensure that your respective campus has in place policies and procedures for implementing RE-89, and to provide you with materials to facilitate implementation.

The full text of RE-89 as adopted is available online at: http://www.universityofcalifornia.edu/regents/aar/sepf.pdf, and additional background information is available in the item that was provided to The Regents before the September Regents' meeting. This item is available online at: http://www.universityofcalifornia.edu/regents/regmeet/sept07/re89.pdf.

As adopted by The Regents, RE-89 includes three elements:

- 1. A Regental statement to researchers: The resolution exhorts University researchers to consider carefully whether to accept research funding from the tobacco industry, and to exercise the utmost care to ensure that their research adheres to the highest scientific and ethical standards, including vigilance in not allowing any funder to direct or control the outcome of their research or the dissemination of its results.
- 2. A requirement that the Chancellors establish policies requiring scientific peer review and Chancellorial approval of proposals prior to submission to tobacco industry funders, and timely reporting to Regents on the proposals that are reviewed.

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3. A requirement for an Annual Report to The Regents. The President is directed to provide The Regents with an annual report summarizing the number of proposals submitted to the scientific review committees for review before submission to tobacco industry sponsors, the number approved, and the number funded, along with abstracts of the proposals. Campuses will need to submit this information to the Office of the President so that it can prepare the required reports.

It is worth noting that Philip Morris, the only known current tobacco industry sponsor of University of California research, recently discontinued its external research program, the program through which it has funded university researchers since 2000. Therefore, Chancellors may elect not to adopt a detailed peer review process at this time, choosing instead to initiate a review process on an "as-needed" basis should a researcher indicate the intent to submit a funding proposal to a tobacco industry sponsor in the event future funding opportunities become available.

Nonetheless, Chancellors should put in place a process to ensure that no new research proposals are submitted to tobacco industry sponsors unless/until they have undergone internal review as required by RE-89. This could be accomplished via a combination of one or more mechanisms, such as:

- Adding a "check a box" to appropriate contracts and grants routing forms requiring researchers to indicate whether they are requesting that their proposal be submitted to a tobacco industry funder, and indicating that such proposals must undergo special review.
- Advising researchers intending to seek funding from a tobacco industry sponsor to consult as far in advance as possible with a designated campus official (such as the campus Vice Chancellor for Research) to discuss the required review/approval process.
- Issuing campuswide guidance outlining the review/approval process that will be used for research proposals that are to be submitted to tobacco industry sponsors.

To facilitate your implementation of RE-89, the Office of Research has prepared the enclosed background materials and model policy, which were developed with input from campus Vice Chancellors for Research. While each campus may adopt individual implementation procedures that fit with local administrative processes, it is our hope that the enclosed materials will help promote consistency across campuses in general approach.

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I hope you find the enclosed information useful as you move forward in implementing this important policy, and I encourage you to get in touch with me or Ellen Auriti, Executive Director of Research Policy and Legislation, with any questions you may have. Executive Director Auriti can be reached by telephone at (510) 987-9429 or by e-mail at ellen.auriti@ucop.edu.

Enclosed are the following:

- 1. Model Policy on Tobacco Industry Funding of Research. This may be used as a model for campus policies/guidance. However, campuses are free to craft their own guidance consistent with RE-89.
- 2. Flowchart: Model Review Process. This flowchart depicts a suggested review process for implementing RE-89.

Thank you for your assistance in ensuring implementation of RE-89.

Sincerely,

Robert C. Dynes

Enclosures

cc: Provost Hume
Academic Council Chair Brown
Vice President Beckwith
Vice Chancellors for Research
Executive Director Auriti
Secretary and Chief of Staff Griffiths

Model Policy on Tobacco Industry Funding of Research at the University of California

I. General Policy: In accordance with University of California Regents Resolution RE-89, the University of California [insert name of campus] will not submit any new research proposals to tobacco industry sponsors unless/until the proposals have undergone internal review and have been approved by the Chancellor, as required by RE-89.

Researchers intending to seek funding from a sponsor that may be considered to be part of the tobacco industry should contact the Office of the Vice Chancellor for Research for guidance regarding the process for review and approval, and should do so well in advance of any submission deadline.

II. Background and Implementation: On September 20, 2007, The Regents of the University of California approved RE-89, a resolution that requires special review, approval and reporting procedures related to University submission of research proposals seeking funding from tobacco industry sponsors. The full text of RE-89 is available online at:

http://www.universityofcalifornia.edu/regents/aar/sepf.pdf¹ [See Page 3].

- A. Exhortation to Researchers: RE-89 exhorts University researchers to:
 - 1. Consider carefully whether to accept research funding from the tobacco industry (and whether their research might be better served by seeking funding from alternate sources).
- 2. Exercise the utmost case in assuring that their research (including research carried out with tobacco industry funding) adheres to the highest scientific and ethical standards. This includes being particularly vigilant about not allowing any funder to direct or control the outcome of the research or the dissemination of its results.
- B. Definition of tobacco industry/Scope of policy: RE-89 defines "tobacco industry" as "entities whose principal business is the manufacture and sale of tobacco products, and agencies that are substantially controlled by or acting on behalf of such entities." The special review and approval requirements apply only to tobacco industry sponsors of research, and only to proposals submitted after September 2007 (new proposals and/or competitive renewals of current grants). The campus Office of Research (working with the UCOP Office of Research) can provide guidance as needed in interpreting/applying this definition.
- C. Review/Approval Requirements: As required by RE-89, the review and approval process for submissions of proposals for research funding from the tobacco industry will include the following elements:

¹ Additional information can be found in the background item that was provided to The Regents prior to the September 20, 2007 Regents meeting, available online at: http://www.universityofcalifornia.edu/regents/regmeet/sept07/re89.pdf

- 1. Review of all such proposals by a scientific peer review committee designated by the Chancellor for that purpose.
 - a. The scientific review committee will be composed of at least three faculty members with expertise in areas of science relevant to the proposal being submitted, and will advise the Chancellor regarding whether the proposed study uses sound methodology and whether it appears designed to allow the researcher to reach objective and scientifically valid conclusions.
 - b. For each proposal it reviews, the scientific review committee will produce a written report including a recommendation as to whether the proposal should be approved for submission, and/or whether any changes should be made to the proposal prior to submission, along with the rationale for the committee's recommendation.
- 2. Chancellorial approval prior to submission of any proposal to seek funding from the tobacco industry. In deciding whether to approve submission of a proposal, the Chancellor will take into account the written review of the scientific peer review committee and any advice issued by the campus conflict of interest committee, in cases where, under existing policy requirements, the researcher has disclosed a financial interest in the research sponsor.
- 3. Issuance of a written Chancellorial determination approving or disapproving submission of a proposal to seek funding from a tobacco industry sponsor including a rationale of the determination with a copy to be provided to the researcher, the President, and The Regents.
- 4. An annual report from the President of the University to The Regents summarizing the number of proposals submitted to a scientific review committee under RE-89, the number approved, and the number funded, along with a description or abstract of each proposal.

Proposals for Tobacco Industry Funding: Model Review Process (Flowchart)

The following flowchart outlines how the review process might look at each campus.

Determination that sponsor is a "tobacco industry" entity

(Researcher in consultation with the Contracts & Grants Office; OP ready to offer assistance as needed)

Chancellor designates a scientific review committee composed of faculty with appropriate scientific expertise

(Note that Chancellor may designate a review committee in advance or may convene committee on an "as needed" basis)

Researcher submits draft proposal to peer review committee

(Accompanied by a description/abstract of the proposal)

Peer review committee reviews proposal

(Committee assesses whether proposed study uses sound methodology and appears designed to allow the researcher to reach objective and scientifically valid conclusions)

Peer review committee completes written review of proposal

(Committee recommends either a. Chancellorial approval; b. revisions to proposal prior to approval; or c. denial of Chancellorial approval. The Committee provides the written report to both the Chancellor and the researcher.)

(If required, researcher revises proposal based on recommendations of the committee and then submits revised proposal to the Chancellor for approval)

Chancellor Approves / Declines to Approve Submission of Proposal to Tobacco Industry Sponsor

(And conveys written decision to researcher with copy to the President and the Secretary and Chief of Staff to The Regents along with a copy of the Committee's written report and proposal description/abstract)

If approved by Chancellor

Campus submits proposal to tobacco industry sponsor

Campuses report funding outcomes to Office of the President

(Campuses report to UCOP on which proposals are funded)

President submits annual report to Regents

(Annual report summarizes the number of proposals submitted to the scientific review committee, the number approved, and the number funded, along with a description or abstract of each proposal)