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October 23, 2018

CHANCELLORS
MEDICAL CENTER CHIEF EXECUTIVE OFFICERS
LAWRENCE BERKELEY NATIONAL LABORATORY DIRECTOR
VICE PRESIDENT – AGRICULTURE AND NATURAL RESOURCES

Dear Colleagues:

Enclosed is the new *Policy on Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research*.

This new policy went through the full systemwide review process on March 29, 2018, and all applicable comments received were incorporated into the attached final document. The policy applies to any research activity that is funded or supported by a non-governmental entity in whole or in part (a) through a contract or grant; (b) by a gift which is designated by the gift donor for a specific research project, or a specific Principal Investigator, or a laboratory or research program headed by a Principal Investigator; or (c) through in-kind support provided under a material transfer agreement (MTA). The Research Policy Analysis and Coordination's (RPAC) interim guidance and the APM-028 for the disclosure and review of Form 700-U will be replaced by this new Presidential Policy.

The new Policy is effective as of the date of this letter and will be published online at <http://policy.ucop.edu/>.

Yours very truly,

Janet Napolitano
President

Enclosure

cc: Division Leaders
Vice President for Research and Graduate Studies Ellis
Executive Director for Research Policy Analysis and Coordination Streitzi
Research Policy Analyst Miller
Ethics, Compliance and Audit Services Chief of Staff Levintov
Universitywide Policy Office



Disclosure of Financial Interests and Management of Conflicts of Interest in Private Sponsors of Research

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| Responsible Officer: | Provost & EVP - Academic Affairs |
| Responsible Office: | AA - Academic Affairs |
| Issuance Date: | 10/23/2018 |
| Effective Date: | 10/23/2018 |
| Last Review Date: | |
| Scope: | This Policy applies to any research activity that is funded or supported by a non-governmental entity in whole or in part (a) through a contract or grant, (b) by a gift which is designated by the gift donor for a specific research project, or a specific Principal Investigator, or a laboratory or research program headed by a Principal Investigator, or (c) through in-kind support provided under a material transfer agreement (MTA). |

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I. POLICY SUMMARY

This Policy describes the review process for disclosures of financial interests made on the State of California financial disclosure form entitled, *Statement of Economic*

Interests for Principal Investigators (Form 700-U).¹ Unless otherwise excepted, the Form 700-U applies to any research activity that is funded or supported, in whole or in part, by a non-governmental entity (a) through a contract or grant, (b) by a gift which is designated by the gift donor for a specific research project, or a specific Principal Investigator, or a laboratory or research program headed by a Principal Investigator, or (c) through in-kind support provided under a material transfer agreement (MTA). The Policy sets forth the requirements for review of such disclosures by campuses, and other UC locations, and authorizes reviewers to make recommendations about how to manage, reduce, or eliminate conflicts of interest.

II. DEFINITIONS

A. Designated Campus Reviewer (DCR)

A Designated Campus Reviewer (DCR), or the DCR's designee, is responsible for conducting preliminary reviews of financial interests disclosed on Forms 700-U. Consistent with this Policy, a DCR may either perform a substantive review and make a recommendation about how possible conflicts of interest can be managed, reduced, or eliminated before the acceptance of the grant(s), contract(s), gift(s), or Material Transfer Agreement(s) (MTA) or refer the matter to the location's Independent Substantive Review Committee (ISRC) for substantive review. A DCR is designated by the Chancellor of each UC campus, or in the case of the Lawrence Berkeley National Laboratory, the Director, or, in the case of the Division of Agriculture and Natural Resources, the Vice President.

B. Filing Officer

A person or persons designated by the Chancellor of each UC campus, or in the case of the Lawrence Berkeley National Laboratory, the Director, or, in the case of the Division of Agriculture and Natural Resources, the Vice President, to retain Forms 700-U submitted by Principal Investigators. The Filing Officer may be the DCR.

C. Financial Interest

As defined under the Fair Political Practices Regulations,² a Financial Interest includes one or more of the following for the Principal Investigator, Principal Investigator's spouse/registered domestic partner, and dependent children:

1. A business position with the sponsor or donor, such as a director, officer, partner, trustee, consultant, employee, or any other position of management.
2. Investment or equity (ownership) interest in the sponsor or donor worth \$2,000 or more.

¹ The Fair Political Practices Commission publishes and periodically updates the Statement of Economic Interests for Principal Investigators, also known as the Form 700-U.

² Cal. Code Regs., tit. 2, § 18755.

3. Income or loan from the sponsor or donor aggregating \$500 or more.
4. A gift from the sponsor or donor with a value of \$50 or more. A gift is anything of value for which you have not provided equal or greater consideration to the donor.
5. Payment for travel from the sponsor or donor with a value of (a) \$50 or more if a gift or (b) \$500 or more if income. Payments either in advance, as reimbursement, or in-kind are reportable. Travel payments are gifts if you did not provide services which were equal to or greater in value than the payments received. Travel payments are income if you provided services which were equal to or greater in value than the payments received.

D. Statement of Economic Interests for Principal Investigators (or Form 700-U)

A State of California financial disclosure form entitled, *Statement of Economic Interests for Principal Investigators*, is used to comply with the Fair Political Practices Regulations as it relates to the University of California and its Principal Investigators. The Form 700-U is a public record under Gov. Code Section 81008(a).

E. Independent Substantive Review Committee (ISRC)

A committee that performs a substantive review of research projects and makes recommendations to the Chancellor, Director, or Vice President of the UC Location or their designees regarding disclosed Financial Interests. The ISRC shall make recommendations as to whether Financial Interests disclosed on Form 700-U present a conflict of interest and, if so, about how possible conflicts of interest can be managed, reduced, or eliminated.

F. Principal Investigator (PI)

An employee of a UC Location who is principally responsible for the conduct of the research (a Principal Investigator, Co-PI, or Multiple PI).

G. UC Location

UC campus, the Office of the President, the Lawrence Berkeley National Laboratory, and the Division of Agriculture and Natural Resources.

III. POLICY TEXT

A. Purpose, Scope and Application

The purpose of this Policy is to describe the process of receiving and reviewing disclosures of financial interests made on the State of California financial disclosure form entitled, *Statement of Economic Interests for Principal Investigators* (Form 700-U). This Policy applies to all UC Locations. It requires that PIs use the Form 700-U to disclose whether they have a Financial Interest in the research sponsor, if that research is funded or supported, in whole or in part, by a non-governmental entity (a) through a contract or grant, (b) by a gift which is designated by the gift donor for a specific research project, or a specific Principal Investigator, or a laboratory or

research program headed by a Principal Investigator, or (c) through in-kind support provided under a material transfer agreement (MTA). A PI does not need to submit a Form 700-U if the project is funded or supported by (1) a governmental entity, (2) a non-profit, tax-exempt educational institution, e.g. Stanford University, or (3) an entity listed in California Code of Regulations, Title 2, Section 18755(d)(1).

This Policy also authorizes reviewers to make recommendations on how to manage, reduce, or eliminate a conflict of interest.

Forms 700-U and supplemental materials associated with Forms 700-U are open to public inspection.

B. Disclosure Requirement

1. Initial Disclosure

The initial Form 700-U must be submitted by PIs in accordance with the rules and procedures of the respective UC Location before final acceptance of a contract, grant, gift, or MTA. Each Form 700-U shall include any and all reportable business positions with and investments in the sponsor or donor as of the date of the offer of funding.³ Furthermore, each Form 700-U shall include reportable income, gifts, and travel payments received from the sponsor or donor within the 12 months prior to the date of the offer of funding.⁴

2. Interim Disclosure

A Form 700-U must be filed within 30 days after funding is renewed and shall disclose any and all reportable business positions, investments, income, gifts, and travel payments held or received during the period between the date the initial statement was filed and the date the funding for the project was renewed.

C. Supplemental Forms and Information

UC Locations may require PIs to complete supplementary campus forms to gather additional information to aid informed decisions. Forms on which supplemental information is gathered must bear appropriate privacy notices.

D. Disclosure Retention

Submitted Forms 700-U shall be retained at the UC Location by the locally designated Filing Officer in accordance with applicable UC document retention and disposition schedules. See [UC Records Retention Schedule](#).

E. Disclosure Review

When a Form 700-U indicates the PI has no Financial Interests (a “negative disclosure”), no further review is required.

³ Reportable investments and business positions are described above in § II.C.1 & 2.

⁴ Reportable income, gifts, and travel payments are described above in § II.C.3-5.

When a Form 700-U indicates that a Financial Interest exists (a “positive disclosure”), a substantive review must be performed either by the ISRC or a DCR. Pursuant to this Policy, a DCR should conduct an initial assessment of each positive Form 700-U. Positive disclosures that meet the criteria in paragraph 1 below must be reviewed by the ISRC. For other positive disclosures, UC Locations have the discretion to develop and implement local procedures and practices to assign the substantive review responsibilities to either the ISRC or the DCR.

1. Criteria for Required ISRC Reviews

If the DCR determines that any of the following circumstances exists, the ISRC shall perform a substantive review of the Form 700-U and related supplemental forms or information:

- The PI has received income, gifts, loans, or travel reimbursement from the sponsor or donor that, alone or when aggregated, equals or exceeds \$10,000 during the previous twelve months.
- The PI holds an equity interest in the sponsor or donor that equals or exceeds \$10,000.
- The PI holds a position as director, officer, partner, trustee, employee, or other position of management with the sponsor or donor.

In circumstances where the ISRC has previously substantively reviewed and made a recommendation and receives a subsequent 700-U where (1) the disclosing Principal Investigator is the same, (2) the non-governmental sponsor with whom the PI has a financial interest is the same, and (3) the circumstances of the financial interest are substantially similar, then additional ISRC substantive review is not required. Instead, substantive review may be performed pursuant to local procedures and practices as described in paragraph 2 below.

2. ISRC Review Pursuant to Local Procedures and Practices

For positive disclosures that do not meet the thresholds listed above in Section E.1, each UC Location may adopt local procedures and practices designating whether the substantive review of the research project should be conducted by the DCR or ISRC. Each UC location’s procedures and practices may provide the DCR the flexibility to seek substantive review by the ISRC even if the disclosed financial interests do not meet the criteria outlined in Section E.1.

3. Conduct of Reviews

The DCR and/or ISRC may seek additional information or expertise from, and/or consult with, administrators, faculty, and others involved in the research and review process, as well as the Principal Investigators and department chairs to provide additional or supplemental information to make a fully informed recommendation. Individuals with competence in special areas may assist in the review process when expertise beyond, or in addition to, that available to the DCR or ISRC is needed.

DCRs or ISRCs should recommend to the Chancellor, Director, or Vice President of the UC Location as appropriate or their designees whether there are any conflicts of interest that must be managed, reduced, or eliminated before support for the research project can be accepted by the campus. The recommendation should include any special conditions or restrictions, if necessary, to manage, reduce, or eliminate identified conflicts of interest.

4. Timeline of Reviews

Reviews must be completed and any identified conflicts of interest must be managed, reduced, or eliminated prior to the institution's expenditure of contract, grant, or gift funds, or acceptance of MTAs associated with the financial disclosure.

IV. COMPLIANCE/RESPONSIBILITIES

A. Chancellors and the Chief Executive or Head of each UC Location

Each UC Location is responsible for implementing this Policy locally and developing procedures for conducting independent substantive review consistent with this policy. Each Chancellor, the LBNL Director and the ANR Vice President (or a designee) is responsible for establishing the ISRC, and for designating a Filing Officer(s) and/or DCR to receive Forms 700-U, and store them for record keeping.⁵ Filing Officers and DCRs need not be the same person.

Subject to the requirements of this Policy, each UC Location has the authority to determine how reviews shall be conducted including whether such reviews should be conducted by a DCR or by an ISRC.

B. Designated Campus Reviewers (DCRs) and Independent Substantive Review Committees (ISRCs)

DCRs and ISRCs, per local campus policies and procedures, are responsible for reviewing substantively the subject matter of the proposed research and assessing the Principal Investigator's disclosed Financial Interest(s). In addition, they are responsible for communicating their assessment to the Chancellor, LBNL Director, or Vice President of ANR (or designee) along with a recommendation of whether support for research in the form of a contract, grant, gift, or MTA should be accepted and, if so, whether any modifications or conditions are required to manage identified conflicts of interest.

DCRs, their designees, and ISRC members should possess the academic, professional, and administrative competence and expertise necessary to review the subject matter of the proposed research and to assess the University and other public interests involved.

⁵ Cal. Gov't Code § 81009(e)(f).

C. Principal Investigators

Principal Investigators are responsible for complying with this Policy, including the California Fair Political Practices Commission's (FPPC) requirement to file Forms 700-U for research supported by non-governmental entities, APM-028, and the policies and/or procedures adopted by their UC Location to implement this Policy.

V. PROCEDURES

UC Locations should develop local procedures to implement this policy.

VI. RELATED INFORMATION

- Cal. Code Regs., tit. 2, § 18755.
- Fair Political Practices Commission, California Form 700-U and Instructions on Filing a Form 700-U, available at <http://www.fppc.ca.gov/search.html?q=Form+700U¤tTab=1> (last visited Mar. 26, 2018).
- University of California, Guidelines for Disclosure and Review of Principal Investigator's Financial Interest in Private Sponsors of Research, APM-028.

VII. FREQUENTLY ASKED QUESTIONS

Not applicable

VIII. REVISION HISTORY

October 23, 2018: This policy supersedes RPAC Guidance Memo 17-03 and is intended to establish the terms of that Guidance Memo as policy. This policy is replacing Policy on Disclosure of Financial Interest in Private Sponsors of Research (APM-028). Still in effect are the Guidelines for Disclosure and Review of Principal Investigator's Financial Interest in Private Sponsors of Research (APM-028-10), which can be found in the [Academic Personnel Manual](#).

This Policy was also remediated to meet Web Content Accessibility Guidelines (WCAG) 2.0.