

April 20, 2017

To: Vice Chancellors for Research, Research Compliance Advisory Committee Members, and Conflict of Interest Coordinators

Subject: Guidance for Review of 700-U Forms

Purpose

This Memorandum provides guidance to the campuses for the review of 700-U forms in light of the California Fair Political Practices Commission's 2015 changes to its regulations. The Memorandum supersedes Guidance Memo 16-02.

Background

Effective July 22, 2015, the Fair Political Practices Commission (FPPC) made a number of changes to its regulations. The revised regulations still require those with primary responsibility for a research project (Principal Investigators, or "PIs") to complete a 700-U form (disclosing certain reportable financial interests) if their research is supported by non-governmental entities. However, the revised regulations do not expressly address review of 700-U forms. Nonetheless, since the regulatory change, the University has continued to review 700-U forms and the UC Provost, the Campus Vice Chancellors for Research, and the FPPC have re-affirmed their support of continued institutional review of the still-required 700-U forms and for management of identified conflicts of interest, as necessary, as part of the University's commitment to the ethical oversight of research.

This Guidance was developed in consultation with the Systemwide Conflict of Interest Coordinators Workgroup, which includes representatives from all ten campuses, the Lawrence Berkeley National Laboratory (LBNL), Agriculture and Natural Resources (ANR), and the Office of General Counsel (OGC).

This Guidance is intended for the review of 700-U disclosures for conflicts of interest pending revision of related University policies, including the University Policy on Disclosure of Financial Interest in Private Sponsors of Research, Disclosure of Financial Interests and Management of Conflicts of Interest, National Science Foundation Awards, Disclosure of Financial Interest in Private Sponsors of Research (Academic Personnel Manual Section 028, and other local campus policies and procedures).

Responsibilities and Authority

1. Chancellors, Lawrence Berkeley National Laboratory (LBNL) Director, and ANR Vice President

Each UC campus, LBNL, and ANR (“Campus”) is responsible for implementing this Guidance locally and developing procedures for conducting independent substantive review consistent with this Guidance. Each Chancellor, the LBNL Director and the ANR Vice President (or a designee to whom they delegate their authority in this area) is responsible for designating a campus official (Designated Campus Reviewer, or “DCR”) to receive 700-U forms. Subject to the requirements of this Guidance, each Campus may determine how independent substantive reviews of positive disclosures on 700-U forms shall be conducted.

2. Designated Campus Reviewers (DCRs) and Independent Substantive Review Committees (“ISRCs”)

DCRs and ISRCs are responsible, per local campus policies and procedures, 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, Material Transfer Agreement or gift should be accepted and, if so, whether any modifications or conditions are required to manage identified conflicts of interest. Per local campus policies and procedures, campus Conflict of interest staff may serve as DCRs so long as they have sufficient education, training, or experience to conduct the review.

3. Principal Investigators

Principal Investigators are responsible for complying with this Guidance, including [the FPPC requirement to file 700-U forms](#) for research supported by non-governmental entities, and the policies and/or procedures adopted by their Campus to implement this Guidance.

Systemwide Substantive Review Requirements

1. When a 700-U form indicates that a Principal Investigator (PI) has no reportable financial interests (negative disclosure), no further review is required.
2. When a 700-U form indicates that a reportable financial interest exists (positive disclosure), a DCR must perform a substantive review or assess whether further review by the campus ISRC is required in accordance with this Guidance and the Campus policies and/or procedures.

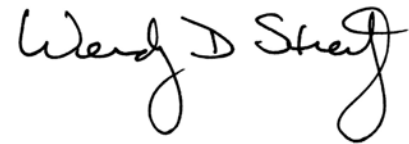
3. If, during the DCR's review, any of the following circumstances are determined to exist, the campus ISRCs *shall* perform a substantive review of a 700-U form to identify conflicts of interests that must be managed, reduced or eliminated before the acceptance of a contract, grant, material transfer agreement or gift:
 - The PI has received income, gifts, loans, or travel reimbursement from the sponsor that, alone or when aggregated, equals or exceeds \$10,000 during the previous twelve months.
 - The PI holds an equity interest in the sponsor that equals or exceeds \$10,000.
 - The PI holds a position as director, officer, partner, trustee, employee, or any position of management with the sponsor.
4. In addition to the above-described mandatory substantive review, each Campus *may* adopt local procedures and practices under which substantive review by the DCR and/or ISRC is mandatory or discretionary for positive disclosures that do not meet the criteria for mandatory substantive review listed above. For example, a campus may require ISRC review whenever a PI's financial interest meets the threshold for reporting on a 700-U form, or may require that PIs submit certain supplementary information, or may adopt other campus-determined criteria such as a lower threshold for review or require additional information if the research involves human subjects.
5. In accordance with local campus procedures, the DCR or the ISRC shall review the 700-U form and any supplementary materials submitted by a PI in connection with the 700-U form, and recommend to the Chancellor, LBNL Director, or Vice President of ANR (or designee) as applicable, 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 DCR and/or ISRC may consult with administrators, faculty, and others involved in the research and review process, and may also consult with or request 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 Designated Official or ISRC is needed.

Reviews must be completed and any identified conflicts of interest must be managed, reduced or eliminated in accordance with the determination of the Chancellor, LBNL Director, or Vice President of ANR prior to the institution's expenditure of contract, grant, or gift funds, or acceptance of Material Transfer Agreements associated with the financial disclosure.

Contact

Jeff Hall
Director, Research Policy Development
jeff.hall@ucop.edu
(510) 987-0688

A handwritten signature in black ink that reads "Wendy D Streit". The signature is written in a cursive style with a large, looped 'W' and 'S'.

Wendy D. Streit
Executive Director
Research Policy Analysis & Coordination