



CALIFORNIA STATE UNIVERSITY CHANNEL ISLANDS POLICY MANUAL

Division of Academic Affairs

Policy Number: SP 14-05

Drafted By: Tina Knight
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Approval Date: November 25, 2014

Policy on Principal Investigator Financial Conflict of Interest

PURPOSE:

To outline the institutional requirements for reporting and managing financial conflicts of interest related to research and sponsored programs.

BACKGROUND:

In order to serve as an effective steward of public and private funds and to advance objectivity and integrity in research, CSU Channel Islands (CI) will take steps to identify and manage conflicts of interest related to research and sponsored programs. Some sponsoring agencies, such as the National Science Foundation (NSF), the National Institutes of Health (NIH), and the California Institute for Regenerative Medicine (CIRM), require grantee institutions to have policies on financial conflict of interest. The level of financial interest disclosure and the definition of what constitutes a “significant” financial interest varies by sponsor. CI will take steps to ensure that reporting, review and management protocols followed for each grant or contract meet the standards of the sponsor.

The process for insuring this may include (see Appendix B for sponsor specific provisions):

- a) Disclosures of significant financial interests (SFI).
- b) Institutional review of those significant financial interests to determine whether or not they constitute a financial conflict of interest (FCOI).
- c) Where a financial conflict of interest does exist, the creation of a Conflict of Interest Resolution Plan designed to manage the FCOI.
- d) Reporting of FCOIs and Conflict of Interest Resolution Plan to sponsors.
- e) Institutional review by a Conflict of Interest Resolution Committee of any failure to abide by implemented Conflict of Interest Resolution Plans.
- f) Making FCOI documentation available to the public, upon request.

While this policy aims to create safeguards against the perception of misuse of funds, it aims to do so in a way that should not create undue burdens for awardees.

POLICY:

Accountability:

Principal Investigators (PI)



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Policy on Principal Investigator Financial Conflict of Interest

Senior Research Officer, Research & Sponsored Programs (SRO, RSP)
Financial Conflict of Interest Resolution Committee

Applicability:

All eligible CI faculty staff, and administrators.

Definition(s):

For the purposes of this policy,

Principal Investigator(s) (PI): Defined as those listed in a proposal as Principal Investigator (PI)/Project Director, Co- Investigator (Co-PI)/Co-Director, and any other person who is responsible for the design, conduct or reporting of the sponsored project or of any related agreement. Depending on the nature of the grant/contract and the funding agency, the Principal Investigator may carry a different title in the contract or grant.

Significant Financial Interest (SFI): The term "significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests) in publicly traded or non-publicly traded entities; and intellectual property rights (e.g., patents, copyrights and royalties from such rights). Levels of disclosure and the definition of "significant" vary by sponsor. CI will review sponsor definitions to ensure at least the minimum requirements are met for each sponsor.

Generally, the term "significant financial interest" *does not* include:

1. Salary, royalties or other remuneration from the applicant institution.
2. Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program.
3. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
4. Income from service on advisory committees or review panels for public or nonprofit entities.
5. An equity interest that, when aggregated for the PI and the PI's spouse and dependent children, meets both of the following tests: does not exceed the sponsor-specific threshold, and does not represent more than a 5% ownership interest in any single entity.
6. Salary, royalties or other payments that when aggregated for the PI and the PI's spouse and dependent children, are not expected to exceed sponsor-specified thresholds.
7. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the PI does not directly control the investment decisions made in these vehicles.



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Financial Conflict of Interest (FCOI): A Financial Conflict of Interest occurs when an employee's Financial Interest (including an Investigator's Significant Financial Interest) compromises, or appears to compromise, his or her judgment or ability to carry out the professional responsibilities associated with his or her role as a Principal Investigator, Co-Principal Investigator, or other key personnel on a research project or other sponsored program. In general, a Financial Conflict of Interest arises when an employee is in a position to influence the University's business, research or decisions in ways that could lead directly or indirectly to financial gain for the employee or the employee's dependents, or could give an improper advantage to others to the detriment of the University.

Text:

CI requires Principal Investigators (PIs), Co-Principal Investigators (Co-PIs) and Key Personnel on a sponsored project to disclose a listing of significant financial interests (and those of their spouse and dependent children) that could be reasonably expected to bias the design, conduct, or reporting of the project. All PIs, Co-PIs and Key Personnel listed in a proposal for external funding must complete a disclosure form before expenses can be charged to an award.

Disclosure forms used by CI vary by sponsor. By the time of proposal submission, PIs are required to have signed a Proposal Administrative Review form, which includes a preliminary disclosure of potential conflicts of interest. PIs are also required to complete and submit pertinent FCOI forms at the following times:

1. At the time of proposal submission, for funders with this requirement.
2. Prior to project set-up for newly funded awards.
3. Annually, during the period of the award.
4. Within 30 days of discovering or acquiring a new FCOI.

A. Financial Conflict of Interest (FCOI) Exemption Policy

- Non-governmental Entities Exempt from Disclosure requirements: PIs are not required to complete a disclosure form if their project is sponsored by a non-governmental agency listed in Appendix A.
- PIs may not be required to complete a disclosure form if their project is funded by internal University funds.

B. California State University Conflict of Interest Policy

In addition, CI requires the annual completion of a Statement of Economic Interests Form 700 for all University positions whose decisions “may foreseeably have a material effect on financial interests” of



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the University. Some faculty and MPP directors at CI may be required to complete both a project-specific disclosure form for RSP and a Statement of Economic Interests Form for Human Resources. Further information on the annual CI requirement can be found on the CI Human Resources website: <http://www.csuci.edu/hr/ConflictofInterest.htm>.

C. Subrecipients

- CI requires subrecipients to identify whether they will follow CI's FCOI policy, or if their administrative institution will use its FCOI policy. The latter is allowable if the SRO determines the subrecipient's existing FCOI policy complies with all appropriate regulations at a level and in a manner analogous to this CI policy.
- CI requires that the subrecipient report identified FCOIs for its PIs within a timeframe that in turn allows CI to report FCOIs to the appropriate funding agency.

D. Institutional Certification and Review

- Certification will be performed by the SRO, RSP and will be based on information provided by the PI on the FCOI Disclosure form for each entity that may be involved. The SRO, RSP will review disclosures, assess their potential for a FCOI, and develop resolution strategies with the PI to manage, reduce or eliminate such conflicts.
- Prior to the expenditure of funds, CI will notify the sponsor of any FCOI and provide a Resolution Plan to address the conflict. If a FCOI is identified after an award has started, CI will notify the sponsor within 30 days of discovering the FCOI.

E. Resolution Plan

- If the designated official(s) determines that a FCOI exists, a Resolution Plan must be developed with the PI and implemented prior to the award being activated. The Resolution Plan must be in writing and approved by the Senior Research Officer, RSP, the AVP of the appropriate academic unit, and the Provost or his/her designee.
- Resolution options may include but are not limited to:
 - a) Public disclosure of significant financial interests.
 - b) Monitoring of research by independent reviewers.
 - c) Modification of the research plan.
 - d) Disqualification from participation in the portion of the project that is affected by the significant financial interest.
 - e) Divestiture of significant financial interests.



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- f) Severance of relationships that create actual or potential conflicts.

F. Enforcement Mechanisms and Sanctions

Potential violations of the Financial Conflict of Interest Resolution Plan shall be handled by the Conflict of Interest Resolution Committee made up of the Senior Research Officer, the AVP of the relevant academic unit, and the Vice President for Business and Financial Affairs (or delegate). This committee will establish and enforce appropriate sanctions based on the specific conduct of a PI failing to follow the agreed upon Resolution Plan. The faculty member may appeal the decision of the committee to the Provost.

G. Reporting

Conflicts of Interest and/or FCOI Resolution Plans will be reported to sponsors per the sponsor-specific guidelines.

H. Documentation and Records Maintenance

CI Research and Sponsored Programs, and when appropriate, the CSU Channel Islands Foundation, will maintain records of all financial disclosures and of all actions taken to resolve financial conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any federal action involving those records, whichever is longer.

ROLES AND RESPONSIBILITIES

Senior Research Officer, Research & Sponsored Programs (SRO, RSP)

- Has primary responsibility for ensuring FCOI policy and procedures are being followed, reviewing and certifying all FCOI forms, developing and implementing FCOI Resolution Plans, managing the Conflict of Interest Resolution Committee, overseeing FCOI training activities, and serving as FCOI liaison with sponsors and, when necessary, CSU legal counsel. SRO also has responsibility for ensuring appropriate Ethics training and/or Responsible Conduct of Research Training as required by sponsor type.

Principal Investigator (PI)

- Has primary responsibility for disclosing significant financial interests and/or financial conflicts of interest, notifying RSP of any change in disclosures, and assists in obtaining disclosures from Co-PIs and other key personnel.



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- Works with the SRO, RSP to develop a plan of action to address the conflict of interest if one exists.

Co-Investigator or other Key Personnel on the Project

- Is/are responsible for disclosing significant financial interests and/or financial conflicts of interest, for notifying RSP of any change in disclosure and for working with the SRO, RSP to develop a plan of action to address the conflict of interest if one exists.

Associate Vice President(s) of PI Academic Unit

- Are responsible for reviewing and approving any FCOI Resolution Plans related to projects in their academic unit and for participating as a member of the Conflict of Interest Resolution Committee.

RELATED DOCUMENTS

- Financial Interest Disclosure Documents (by sponsor or disclosure type).
- [California Form 700 U-Statement of Economic Interest for Principal Investigators](#)
- [CI HR Conflict of Interest Page](#)
- [NIH Financial Conflict of Interest Page](#)
- [Title 42 Code of Federal Regulations \(CFR\) Part 50 Subpart F](#)
- [Title 45 CFR Part 94 \(Research Contracts\)](#)
- [Institution of Higher Education Definition](#)
- [Exempt Organization List](#)
- [CSU System-wide Policy on Financial Conflict of Interest](#) (Policy # 11000.010.002)



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APPENDIX A

SPONSORS OF RESEARCH EXEMPTED FROM THE NONGOVERNMENTAL ENTITY FINANCIAL DISCLOSURE REQUIREMENT

These research sponsors are approved by the Fair Political Practices Commission for exemption from the nongovernmental entity financial disclosure requirement. Principal investigators are not required to complete Form 700-U financial disclosure statements for research that is sponsored by these organizations.

Alzheimer's Disease & Related Disorders Association	American Philosophical Society
American Academy of Dermatology	American Red Cross
American Academy of Pediatrics	Amyotrophic Lateral Sclerosis Society of America
American Association for the Advancement of Science	Arthritis Foundation
American Association for State & Local History	Asthma & Allergy Foundation of America
American Association of Colleges of Pharmacy	Bush Foundation, The
American Association of Obstetricians & Gynecologists	California Association for Neurologically Handicapped Children
American Association of Retired Persons	California Division of the American Cancer Society
American Cancer Society	California Heart Association
American Chemical Society	California Lung Association
American College of Obstetricians & Gynecologists	Cargill Foundation
American College of Radiology	Carnegie Corporation of New York
American Committee for the Weizmann Institute of Science	Carnegie Foundation for the Advancement of Teaching
American Council of Learned Societies	Cerebral Palsy Foundation
American Diabetes Association	Chicago Community Trust, The
American Foundation for Pharmaceutical Education	Childs Memorial Fund, The Jane Coffin
American Fund for Dental Education, Inc.	Christian Children's Fund
American Gastroenterologic Association	Clark Foundation, The Edna McConnell
American Health Assistance Foundation	Columbia Foundation
American Heart Association	Commonwealth Fund, The
American Kidney Fund	Cooley's Anemia Foundation
American Library Association	Council on Library Resources
American Liver Foundation	Culpeper Foundation, Inc., Charles E.
American Lung Association	Cystic Fibrosis Foundation
American Lupus Society, The	Deafness Research Foundation, The
American Nurses Foundation	Donner Foundation, William H.
American Parkinson Disease Association	Dover Fund, Inc.
American Philological Association	Dreyfus Foundation, Inc., The Camille & Henry
	Dreyfus Foundation, The Max & Victoria



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Dysautonomia Foundation
Earhart Foundation
Easter Seal Research Foundation
Epilepsy Foundation of America
Eye Research Institute of Retina Foundation
Fight for Sight
Ford Foundation, The
Foundation for Child Development
Fuller Fund, The Anna
German Marshall Fund of the U.S.
Giannini Foundation
Grant Foundation, The William T.
Guggenheim Foundation, H.F.
Guggenheim Memorial Foundation, John Simon
Haas Fund, The Walter & Elise
Hartford Foundation, John A.
Haynes Foundation, The John Randolph & Dora
Hearst Foundation, William R.
Hewlett Foundation, The William & Flora
Institute for Educational Affairs
International Research & Exchanges Board
Japan Foundation
Johnson Foundation, The Robert Wood
Juvenile Diabetes Foundation
Kade Foundation, Inc., The Max
Kaiser Family Foundation, The Henry J.
Keck Foundation, William M.
Kellogg Foundation, W.K.
Klingenstein Fund, The Esther & Joseph
Knights Templar Eye Foundation
Kresge Foundation, The
Kunstadter Family Foundation, The Albert
Leakey Foundation, The L.S.B.
Leukemia Society
Levi Strauss Foundation
Lilly Endowment, Inc.
Luce Foundation, Inc., The Henry
Lupus Foundation of America
MacArthur Foundation, John D. & Catherine T.
McKnight Foundation, The
March of Dimes
Markle Foundation, The John & Mary R.
Mellon Foundation, The Andrew W.
Mott Foundation, Charles Stewart
Muscular Dystrophy Association
Myasthenia Gravis Foundation
National Academy of Sciences
National Collegiate Athletic Association
National Council of Teachers of English
National Foundation for Ileitis & Colitis
National Foundation for Infectious Diseases
National Fund for Medical Education
National Geographic Society
National Head Injury Foundation
National Hemophilia Foundation
National Kidney Foundation
National Leukemia Association
National Migraine Foundation
National Multiple Sclerosis Society
National Research Council
National Retinitis Pigmentosa Foundation
National Society to Prevent Blindness
National Sudden Infant Death Syndrome Foundation
National Tuberos Sclerosis Association
Northern California Society to Prevent Blindness
Noyes Foundation, Inc., Jessie Smith
Organization for Tropical Studies
Packard Foundation, The David & Lucille
Paralyzed Veterans of America
Pardee Foundation, Elsa U.
Peierls Foundation, Inc., The
Picker Foundation, James
Population Council
Presiding Bishop's Fund for World Relief
Project HOPE
Research Corporation
Research to Prevent Blindness
Resources for the Future, Inc.
Retirement Research Foundation
Richardson Foundation, Smith
Rippel Foundation, Fannie E.
Rockefeller Brothers Fund



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Rockefeller Foundation
Rosenberg Foundation
Rubin Foundation, Inc., Samuel
Runyon-Walter Winchell Cancer Fund, Damon
Sage Foundation, Russell
San Francisco Foundation
Scaife Foundation, Inc., Sara
Schiff Foundation
Scottish Rite Schizophrenia Research Program
Sherman Foundation, Nate H.
Skaggs Foundation, L.J. & Mary C.
Skin Cancer Foundation
Sloan Foundation, Alfred P.
Social Science Research Council
Spencer Foundation, The

Teagle Foundation
Tinker Foundation, Inc., The
Treadwell Foundation, Nora Eccles
United Cerebral Palsy
United Scleroderma Research Foundation
U.S. Olympic Committee
Webb Foundation, Del E.
Weingart Foundation
Wenner-Gren Foundation for Anthropological
Research, Inc.
Whitehall Foundation
Whitney Foundation, the Helen Hay
Wood Charitable Trust, W.P.
Woods Hole Oceanographic Institution
Zellerbach Family Fund