

Senate Policy/Academic Affairs Approved By: Richard R. Rush

President

Policy Number: AA.11.007/SP.15.022

Effective Date: 05/10/16

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



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Financial Conflict of Interest Resolution Committee

Applicability:

All eligible CI faculty staff, and administrators.

Definition(s):

Principal Investigator identifies the individual (whether referred to in the Contract or Grant as a Principal Investigator, Project Director or other similar term) designated by the Sponsored Program Administrator to be responsible for ensuring compliance with the academic, scientific, technical, financial and administrative aspects and for day-to-day management of the Sponsored Program.

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 five percent 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.

Policy 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, for funders with this requirement
- 3. Upon funding renewal, if required by the sponsor.
- 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.
- Governmental Entities: Whether or not FCOI disclosure is required varies by entity. Disclosures are only required for those entities that require such disclosure.
- PIs may not be required to complete a disclosure form if their project is funded by internal University funds.



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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 the University. Some CI faculty and administrators 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 sub-recipients 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 sub-recipient'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 sub-recipient 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.



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- 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.
- 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 & Financial Affairs (or designee). 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 & Sponsored Programs, and when appropriate, the CI 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.



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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.
- 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.

EXHIBIT(S):

- FPPC Forms (Use 700 U for Principal Investigators)
- CI HR Conflict of Interest Page
- NIH Financial Conflict of Interest Page
- Institution of Higher Education Definition
- Exempt Organization List
- CSU Conflict of Interest Policies and Procedures

APPENDIX A



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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 Academy of Dermatology American Academy of Pediatrics

American Association for the Advancement of

Science

American Association for State & Local

History

American Association of Colleges of

Pharmacy

American Association of Obstetricians &

Gynecologists

American Association of Retired Persons

American Cancer Society
American Chemical Society

American College of Obstetricians &

Gynecologists

American College of Radiology

American Committee for the Weizmann

Institute of Science

American Council of Learned Societies

American Diabetes Association

American Foundation for Pharmaceutical

Education

American Fund for Dental Education, Inc. American Gastroenterologic Association American Health Assistance Foundation

American Heart Association American Kidney Fund American Library Association American Liver Foundation American Lung Association American Lupus Society, The American Nurses Foundation

American Parkinson Disease Association

American Philological Association American Philosophical Society

American Red Cross

Amyotrophic Lateral Sclerosis Society of

America

Arthritis Foundation

Asthma & Allergy Foundation of America

Bush Foundation, The

California Association for Neurologically

Handicapped Children

California Division of the American Cancer

Society

California Heart Association California Lung Association

Cargill Foundation

Carnegie Corporation of New York

Carnegie Foundation for the Advancement of

Teaching

Cerebral Palsy Foundation Chicago Community Trust, The

Childs Memorial Fund, The Jane Coffin

Christian Children's Fund

Clark Foundation, The Edna McConnell



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Columbia Foundation

Commonwealth Fund, The

Cooley's Anemia Foundation

Council on Library Resources

Culpeper Foundation, Inc., Charles E.

Cystic Fibrosis Foundation

Deafness Research Foundation, The

Donner Foundation, William H.

Dover Fund, Inc.

Dreyfus Foundation, Inc., The Camille &

Henry

Dreyfus Foundation, The Max & Victoria

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 Randolf & 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

Т

McKnight Foundation, The

March of Dimes

Markle Foundation, The John & Mary R.

Mellon Foundation, The Andrew W. Mott Foundation, Charles Stewart

Mott I oundation, Charles Stewar

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



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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 Tuberous 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

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