



Financial Conflict of Interest for Public Health Service (PHS) and National Science Foundation (NSF) Sponsored Activities

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POLICY STATEMENT

Butler University promotes objectivity in Research and Sponsored Activities by establishing policies and procedures purposed to remove or manage conflicts that may bias the design, conduct and reporting of Public Health Service agency and National Science Foundation Sponsored Activities by Investigators.

REASON FOR POLICY

These guidelines define Butler University policy and procedures regarding potential Financial Conflicts of Interest in relationship to Public Health Service (PHS) and National Science Foundation (NSF) Sponsored Activities. In accordance with Federal regulations, Butler University has a responsibility to manage, reduce, or eliminate any actual or potential Financial Conflicts of Interest of an Investigator. To that end, the University will undertake efforts to identify Significant Financial Interests held by Investigators and determine whether or not those Significant Financial Interests constitute a Financial Conflict of Interest that could directly and significantly affect the design, conduct or reporting of Sponsored Activities funded by a Public Health Service agency or the National Science Foundation.

ENTITIES AFFECTED BY THIS POLICY

Institutional Wide

POLICY APPROVAL

Provost and Vice President for Academic Affairs

CONTACTS

Institutional Official
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TABLE OF CONTENTS

PAGE #

Policy Statement	1
Reason for Policy	1
Entities Affected by this Policy	1
Policy Approval	1
Contacts	1
Table of Contents	1
Definitions	2

Procedures	4
Disclosure	4
Annual Disclosure	4
Ad Hoc Disclosure	4
Travel	5
Review Process	5
Retrospective Review	5
Sub-recipients	5
Reporting to the Sponsor	6
Managing Financial Conflicts of Interest for PHS or NSF Sponsored Activities...	6
Appeal Process	7
Violations of the Financial Conflict of Interest for PHS or NSF Sponsored	
Activities Policy	7
Retention of Records	7
Confidentiality	7
Public Accessibility	8
Additional Requirements for PHS funded activities.....	8
Training	8
Regulatory Authority	8
Forms/Resources	8
Appendices	8
History/Revision Dates	8

DEFINITIONS

Entity	<i>Entity</i> means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator or Related Person/Covered Person receives remuneration or in which any person has an ownership or equity interest.
Financial Conflict of Interest	<i>Financial Conflict of Interest</i> means a Significant Financial Interest that the Institutional Official reasonably determines could directly and significantly affect the design, conduct or reporting of a PHS or NSF Sponsored Activity.
Financial Conflict of Interest Committee	<i>Financial Conflict of Interest Committee</i> means a University committee comprised of the Research Integrity Officer as an ex-officio non-voting member and following voting members: a) one faculty member from each college and library, 2) a member of the Institutional Review Board, 3) any other member as appointed by the Provost.
Financial Interest	<p><i>Financial Interest</i> means anything of monetary value received or held by an Investigator or Related Persons/Covered Persons, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.</p> <p><i>Financial Interest</i> does NOT include:</p> <ol style="list-style-type: none"> salary, royalties, or other remuneration from the Institution; income from the authorship of academic or scholarly works; income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated

with institutions of higher education, academic teaching hospitals, and medical centers; or

- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Institutional Official *Institutional Official* means the individual at Butler University that is responsible for the solicitation and review of disclosures of Significant Financial Interests including those of Investigators and Related Persons/Covered Persons to the Investigator’s Institutional Responsibilities. For the purposes of this policy, the Institutional Official is designated by the Provost.

Institutional Responsibilities *Institutional Responsibilities* means an Investigator’s professional responsibilities associated with his/her Institutional appointment, such as research, teaching, clinical activities, administration, and institutional, internal and external, professional committee service.

Investigator *Investigator* means the principal investigator/project director, co-principal investigators, and any other person regardless of title or position at the University who is responsible for the design, conduct, or reporting of research or educational activities funded, or proposed for funding, by a PHS or NSF sponsor.

PHS or NSF Sponsored Activity *PHS or NSF Sponsored Activity* means a Sponsored Activity funded by a Public Health Service (PHS) agency or the National Science Foundation (NSF) or any other Sponsor using PHS or NSF Financial Conflict of Interest Regulations.

Related Persons/Covered Persons *Related Persons/Covered Persons* means Investigator’s spouse/domestic partner and dependent children/step-children.

Research *Research* means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge.

Significant Financial Interest *Significant Financial Interest* means a Financial Interest that reasonably appears to be related to the Investigator’s Institutional Responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or

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- e) is reimbursed or sponsored travel related to their institutional responsibilities.

Sponsored Activity

A Sponsored Activity means all externally funded activities, (including but not limited to, Research, training, instruction and/or public service projects) involving funds, materials, or other compensation from Sponsors, under a grant, contract or other agreement between the University and the Sponsor that meets any of the following conditions:

- a) Butler University is committed to a line of scholarly or scientific inquiry specified in a sponsored agreement. Such scholarly or scientific inquiry may be indicated as a deliverable or by the stipulation of requirements for orderly testing or validation of particular approaches, or by the designation of performance targets
- b) The Sponsor requires, or the proposal submitted for consideration contains, a line-item budget or a Public Health Services modular budget. A line-item budget details expenses by activity, function, or project period. The designation of overhead (or indirect costs) qualifies a budget as "line item";
- c) The Sponsor requires financial and/or programmatic reports;
- d) The Sponsor requires that the services performed, the funds awarded or the materials supplied under the agreement are subject to external audit; or,
- e) The agreement provides for the disposition of either tangible (e.g., equipment, records, technical reports, theses, or dissertations) or intangible (e.g., rights in data, copyrights, or inventions) properties that may result from activities covered by the agreement.

Sub-recipient

Sub-recipient means an entity that receives a sub-award from the prime recipient under an award and is accountable to the prime recipient for the use of Sponsor funds provided by the award.

University

The term "University" will herein mean Butler University.

PROCEDURES

I. Disclosure

All investigators are required to disclose their Significant Financial Interests (including those of the Related Persons/Covered Persons) to the University on an annual and on an ad hoc basis.

A. Annual Disclosures

All Investigators must disclose their Significant Financial Interests to the Institution that are related to the Investigator's Institutional Responsibilities on an annual basis, via the University's Significant Financial Interests Disclosure Form for PHS and NSF Sponsored Activities. All forms should be submitted to the Institutional Official.

B. Ad hoc Disclosures

In addition to the annual disclosure, certain situations require ad hoc disclosure. When submitting a grant proposal for funding from a PHS agency, the NSF or any other Sponsor using PHS or NSF Financial Conflict of Interest regulations, the Investigator must complete a Significant Financial Interests Disclosure Form for PHS and NSF Sponsored Activities and submit it to the Institutional Official at or before the time the project proposal is submitted for institutional approval. If Significant Financial Interests are reported,

supporting documentation that identifies any business enterprise or entity involved and the nature and amount of the interest should be sealed in an envelope and attached to the form. Butler will not submit a proposal unless the Investigator has submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

C. Travel

Investigators must also disclose reimbursed or sponsored travel related to their Institutional Responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's PHS or NSF Sponsored Activity.

D. Review Process

If the Significant Financial Interests Disclosure Form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to eliminate, reduce, or manage the conflict, as appropriate. The Institutional Official may consult with the Financial Conflict of Interest Committee for guidance in specific cases or in the application of the policy to particular situations.

E. Retrospective Review

If the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Institutional Official or Financial Conflict of Interest Committee will complete a retrospective review of the Investigator's PHS or NSF Sponsored Activity to determine whether it was conducted during the period of non-compliance and if it was biased in its design, conduct or reporting.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to the Sponsor or the Prime Awardee relating to the activity, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established by the Sponsor's regulations. If bias is found, the institution will promptly notify the Sponsor and submit a mitigation report in accordance with the Sponsor's regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

F. Sub-recipients

The University is responsible for ensuring all sub-recipients' compliance with the applicable federal regulations regarding Financial Conflicts of Interest. To this end, the University shall enter a written

agreement with each sub-recipient that shall specify whether this policy, or the applicable policy of the sub-recipient's institution, will apply to sub-recipient Investigators. Said agreement will specify the timing for reporting of Financial Conflicts of Interest by sub-recipients to the University to enable the timely review and reporting of such Financial Conflicts of Interest in compliance with Sponsor's requirements.

G. Reporting to the Sponsor

Should any reported conflict or non-compliance require reporting to the sponsor, the Institutional Official will report in accordance with the Sponsor's regulations. If the funding for the project is made available via a subaward agreement, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the sponsor.

H. Managing Financial Conflicts of Interest for PHS or NSF Sponsored Activities

The Institutional Official's recommendations to manage any identified Financial Conflict of Interest shall be incorporated into a Memorandum of Understanding (MOU) between Butler University and the Investigator that details the conditions or restrictions imposed in the conduct of the project or in the relationship with the business enterprise or entity and will be signed by the Investigator and the Institutional Official. Actual or potential Financial Conflicts of Interest will be satisfactorily managed, reduced, or eliminated in accordance with these guidelines prior to Butler's expenditure of any PHS or NSF funds under the award, or they will be disclosed to the Sponsor for action.

The Institutional Official or Financial Conflict of Interest Committee may recommend that management of the Financial Conflict of Interest be implemented using, for example, but not limited to, one or more of the following:

1. *Disclosure:* Disclosure is typically required in every case including public disclosure of the financial interests of the Investigator if applicable, in all relevant publications and presentations (whether or not academic presentations), including presentations at the level of the Investigator's primary department or higher; disclosure to the appropriate co-Investigators, members of the laboratory or research group, and students or trainees; and disclosure on human subjects consent forms.
2. *Restriction on Equity:* placement of stock in escrow until a time specified by the Institutional Official or Financial Conflict of Interest Committee, or requirement that options, warrants and similar instruments not be exercised without the prior approval of the Financial Conflict of Interest Committee;
3. *Limiting the role of the Investigator with an identified Financial Conflict of Interest:* requiring that the role of the Investigator with the identified Financial Conflict of Interest be limited in some way (e.g., the Investigator may not be allowed to serve as Principal Investigator or Project Director, analyze data or results, or solicit consent from human research subjects);
4. *Modification of the Research plan;*
5. *Oversight:* appointment of a disinterested individual or group to monitor the relevant PHS or NSF Sponsored Activities. An oversight committee may be charged with ensuring that the Sponsored Activity is conducted and reported according to scientific and ethical standards and that Financial Conflict of Interest management measures are observed. In cases concerning a Dean or Associate Dean, the individual or group monitoring the activity shall be appointed by and report to the Provost;
6. *Divestiture:* the sale or disposal of specified Significant Financial Interests to eliminate or reduce the Financial Conflict of Interest by a certain date;

7. Severance of *Relationships that Heighten or Create Actual or Potential Conflicts*: for example, relinquishing a seat on a board of directors or terminating a consulting arrangement with an outside entity in order to reduce the Financial Conflict of Interest.
8. The Conflict of Interest Committee may recommend other conditions or limitations on the proposed arrangements if, in its view, such conditions or limitations will contribute to the elimination, reduction or management of the Financial Conflict of Interest.

I. Appeal Process

If the Investigator is dissatisfied with the recommendations on how to manage the Financial Conflict of Interest, s/he may appeal to the Institutional Official who will consult with the Investigator and/or the Conflict of Interest Committee as is necessary and appropriate to the particular circumstance.

J. Violations of the Financial Conflict of Interest for PHS or NSF Sponsored Activities Policy

The Investigator is expected to comply fully with the policy. Instances of deliberate breach of policy, including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms, violation of the guidelines, or failure to comply with prescribed monitoring procedures may result in sanctions being imposed upon the violating individual. Such sanctions may include for example, but are not limited, to the following actions:

1. Notification of Sponsor and termination of award;
2. Employment discipline up to and including termination;
3. Suspension of the privilege to apply for external funding;
4. For Investigators who are not Butler University employees, compliance with this policy is a condition of participating with Butler University in the capacity that qualifies them as an Investigator. Butler University may require the individual to execute a document certifying that they know compliance with this Policy is a condition of participation in the PHS or NSF Sponsored Activity; however, the failure to obtain or to provide such an executed document will not prevent or mitigate any enforcement action taken under this Policy.

K. Retention of Records

The Butler Institute for Research and Scholarship will maintain in a central repository all records received and created pursuant to this Policy as well as all records of actions taken with respect to each Significant Financial Interest for: (a) at least three (3) years beyond the termination or completion of the PHS or NSF Sponsored Activity, (b) for as long as is required under Federal or State law, (c) for as long as is required by any agreement covering a PHS or NSF Sponsored Activity or (d) until resolution of any investigation, audit, or other action by a Sponsor involving the records, whichever is longer.

L. Confidentiality

To the extent permitted by law, all disclosure forms, Financial Conflict of Interest management plans, and related information will be confidential. However, the University may make such information available to a Sponsor funding research of the faculty member, to a requestor of information concerning Financial Conflict of Interest related to a Sponsor funding or to the primary entity who made the funding available to Butler, if requested or required. If the University is requested to provide disclosure forms, Financial Conflict of Interest management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

M. Public Accessibility

Prior to the expenditure of funds, the University will publish on a publicly-accessible website or respond to any requestor within five (5) business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

1. The Significant Financial Interest was disclosed and is still held by the Investigator;
2. A determination has been made that the Significant Financial Interest is related to the PHS or NSF Sponsored Activity; and
3. A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the policies of the Sponsor.

II. Additional Requirements for PHS funded activities:

A. Training

An Investigator must complete training on this policy prior to engaging in activities funded by PHS, and at least every four (4) years thereafter. S/he must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to the PHS or NSF Sponsored Activity.

Please contact the Butler Institute for Research and Scholarship for more information about Financial Conflict of Interest trainings.

B. Regulatory Authority

This policy implements the requirements of 42 CFR 50 and 45 CFR 94 and NSF 15-1 (PAPPG); where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

FORMS/RESOURCES

Significant Financial Interest Disclosure Form for PHS and NSF Sponsored Activities
(Please visit the BIRS web page for this form.)

APPENDICES

HISTORY/REVISION DATES

Issue Date: March 9, 2015

Amended Date: N/A

Policy approved by the Policy Work Group on February 25, 2015.

Final approval of Policy by the Provost and Vice President for Academic Affairs on February 27, 2015