

## ***Policies and Procedures***

<i>SECTION:</i> <b>Financial</b>	<i>NO.</i> <b>3.1.10.</b>			
<i>CHAPTER:</i> <b>General</b>	<i>ISSUED:</i> 10/1/95	<i>REV. A</i> 10/12/05	<i>REV. B</i> 12/21/05	<i>REV. C</i> 1/28/09
<i>POLICY:</i> <b>Externally-Sponsored Projects Financial Conflict of Interest</b>	<i>PAGE 1 OF 9</i>			

### **POLICY SUMMARY**

This policy applies to Investigator/Support Personnel (as defined in the Policy) involved in externally funded research, educational projects or other activities, who have a Significant Financial Interest that may create a Conflict of Interest that could be perceived to influence the outcome of the project. A Significant Financial Interest includes, but is not limited to, an equity interest in the sponsor that exceeds \$10,000, or represents more than a 5% ownership interest, receipt of more than \$10,000 from a sponsor that may include payment for speakers fees, consulting fees, honorariums, protocol design, finders fees, referral fees, recruitment bonuses, gifts and intellectual property rights including patents and royalties.

Investigator/Support Personnel involved in a project must indicate on the Proposal Routing Form (“Green Sheet”) whether or not they may have a Significant Financial Interest. Those who have a Significant Financial Interest must complete a Disclosure Form and submit it to the Associate Vice President for Research and Compliance at the time of project submission. This form must also be completed and submitted to the Associate Vice President for Research and Compliance any time an Investigator/Support Personnel obtains a new or additional significant financial interest during the course of a project. In all cases, this information must be updated annually, as determined by the Associate Vice President for Research and Compliance.

The Conflict of Interest Committee (CIRC) will review the disclosure and decide if a conflict of interest exists. The CIRC will prepare a resolution plan to manage, reduce or eliminate any identified Conflict of Interest before the project can proceed. If the project involves human subjects research, the Institutional Review Board (IRB) may impose additional requirements before granting IRB approval. There is a right to appeal the CIRC’s decision by requesting a reconsideration of their initial decision. Failure to comply with this policy will result in appropriate disciplinary action in accordance with applicable University policies.

### **PURPOSE**

The purpose of this policy is to assure objectivity in research and educational projects funded through Creighton University by external sources including grants, contracts or cooperative agreements (“projects”). These standards ensure there is no reasonable expectation that the design, conduct or reporting of externally funded research and educational projects will be biased by any conflicting interest of an Investigator/Support Personnel or their Family Member. This policy also supports Creighton University’s institutional compliance with the Public Health Service regulations (42 CFR Part 50, Subpart F) and the provisions of the National Science Foundation (Grant Policy Manual § 150).

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## **POLICY**

All Investigator/Support Personnel are required to disclose all known Significant Financial Interests of the Investigator/Support Personnel and his/her Family Member:

- a. That would reasonably appear to be affected by the project; and
- b. In entities whose financial interests would reasonably appear to be affected by the project.

In all cases, actual or potential Conflicts of Interest will be satisfactorily managed, reduced, or eliminated in accordance with this policy prior to expenditure of any external funding, or they will be disclosed to the external sponsor for action.

## **SCOPE**

This policy applies to all Investigator/Support Personnel who are responsible for the design, conduct, reporting or approval of any externally funded project at Creighton University.

This policy also applies to subgrantees, contractors, or collaborators of Creighton University involved in the project unless individuals provide written assurance to the Associate Vice President for Research and Compliance that they are subject to a similar financial conflict of interest policy.

This policy does not apply to Small Business Innovation Research (SBIR) Program Phase I applications.

## **DEFINITIONS**

**Conduct of Research or Educational Project** includes, but is not limited to, enrolling human subjects for human subjects research (including obtaining informed consent), making decisions related to eligibility to participate in the research and analyzing data.

**Conflict of Interest.** A Conflict of Interest exists when it is reasonably determined that a Significant Financial Interest could significantly affect the design, conduct, or reporting of the externally funded project. This includes situations where financial considerations may compromise (or have the appearance of compromising) an Investigator/Support Personnel's professional judgment in conducting or reporting research, impacting the collection, analysis, and interpretation of data, hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human subjects and statistical methods.

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**Family Member** means the Investigator/Support Personnel's spouse or dependent children.

**Investigator/Support Personnel** means the Principal Investigator, co-Investigator, and any other person involved in the design, conduct or reporting of a research or educational project.

**PHS Awarding Component(s)** means the organizational unit(s) of the PHS that funds the research that is subject to 42 CFR Part 50, Subpart F.

**Research** means a systematic investigation designed to develop or contribute to knowledge, including social sciences and behavioral research. The term encompasses basic and applied research and product development.

**Significant Financial Interest** means anything of monetary value received, obtained or held directly or indirectly, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria, protocol design); clinical research incentives (e.g., finders fees, referral fees, recruitment bonuses); equity interests (e.g. stocks, stock options or other ownership interests); gifts; and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term **does not** include the following:

- (1) salary (including payments from external funders based on percentage of effort), royalties, or other payments or benefits from Creighton University;
- (2) income from seminars, lectures, or teaching engagements that are sponsored by government agencies or nonprofit entities;
- (3) income from service on advisory committees or review panels for governmental agencies or nonprofit entities;
- (4) an equity interest that when aggregated for the Investigator/Support Personnel or his/her Family Member, meets both of the following test:
  - (a) does not exceed **\$10,000** in value as determined through reference to public prices or other reasonable measures of fair market value, and
  - (b) does not represent more than a five percent (5%) ownership interest in any single entity;
- (5) salary, royalties, gifts, in-kind compensation, or any other payments that when aggregated for the Investigator/Support Personnel or his/her Family Member during the prior 12 months did not exceed **\$10,000** in value and over the next 12 months, are not expected to exceed **\$10,000** in value;

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- (6) payments to Creighton University that are directly related to the reasonable costs incurred in the conduct of the research and educational project as specified in the agreement between the external sponsor and Creighton University. It **excludes** any bonus or milestone payments that are in excess of reasonable costs incurred; or
- (7) interests held directly through funds such as mutual funds, pension funds, or other institutional investment fund in which the Investigator/Support Personnel does not control the selection of investments.

Examples of payments, equity interests and property rights that constitute Significant Financial Interests can be found in Appendix “A” of this policy.

**Small Business Innovation Research (SBIR)** means the extramural research program for small business that is established by the PHS Awarding Components and certain other federal agencies under the Small Business Innovation Development Act, as amended. It also includes the Small Business Technology Transfer (STTR) Program.

## Procedure

### **A. Disclosure of Potential Conflicts of Interest**

The Office for Research and Compliance shall provide all Investigators/Support Personnel with a copy of this policy and advise them of their reporting obligations.

1. Initial Disclosure of Significant Financial Interest.
  - a. Investigators/Support Personnel on Current Projects. Investigators/Support Personnel participating in currently funded research or educational projects shall complete and submit a “Disclosure of Financial Relationship for Sponsored Projects” (Disclosure Form), Appendix “B” to the Associate Vice President for Research and Compliance .The Disclosure Form shall include significant financial interests obtained during the previous 12 months or that are expected to exceed \$10,000 during the next 12 month period.
  - b. New Research or Educational Projects. All Investigators/Support Personnel shall complete and submit a Disclosure Form to the Associate Vice President for Research and Compliance **prior to the time** the project is submitted to the external sponsor. The Disclosure Form shall include Significant Financial Interests obtained during the previous 12 months or that are expected to exceed \$10,000 during the next 12 month period. Grant application(s) will not be approved by the Office of Research and Compliance until a Disclosure Form for all Investigators/Support Personnel involved in the project has been submitted.

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- c. Investigator/Support Personnel Added to an Existing Project. Investigator/Support Personnel added to an existing research or educational project must complete and submit a Disclosure Form to the Associate Vice President for Research and Compliance before they can be added to the project. No one shall be added to the project until the Disclosure Form has been reviewed pursuant to this policy.
2. New or Additional Financial Interests. If any Investigator/Support Personnel or his/her Family Member obtains a new or additional Significant Financial Interest during the period of the project, the Investigator/Support Personnel must submit an updated Disclosure Form to the Associate Vice President for Research and Compliance within 30 days of acquiring the new or additional Significant Financial Interest.
3. Annual Disclosure. Investigator/Support Personnel shall annually submit an updated Disclosure Form to the Associate Vice President for Research and Compliance on or before the 31<sup>st</sup> day of January for each project in which they are involved. The annual Disclosure Form shall include Significant Financial Interests obtained during the previous calendar year (January 1 through December 31) or that are expected to exceed \$10,000 during the next 12 month period.

### **B. Review Process**

1. Initial Review by the Associate Vice President for Research and Compliance. The Associate Vice President for Research and Compliance, or his/her designee, will review each Disclosure Form to ensure that it has been properly filled out and signed by the Investigator/Support Personnel to determine the existence of any Significant Financial Interest.
  - a. Associate Vice President for Research and Compliance Determines there is No Significant Financial Interest. If the Associate Vice President for Research and Compliance determines that no Significant Financial Interest exists as outlined in this policy, the Associate Vice President for Research and Compliance shall notify the Investigator/Support Personnel in writing and include this correspondence in the project file. In addition, the Associate Vice President for Research and Compliance shall notify the external sponsor according to the sponsor's policies.



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- b. Role of the University's Institutional Review Board (IRB). The IRB may accept or decline the determination and resolution of the CIRC. The IRB is ultimately responsible for protecting the rights and welfare of human subjects and, if not satisfied that the CIRC's final determination will protect the rights and welfare of human subjects, shall independently review the financial interest and either refuse to approve the study or recommend to the CIRC its requirements to manage, reduce or eliminate the Conflict of Interest.

### **E. Appeal Rights**

If the Investigator/Support Personnel disagrees with the Resolution Plan, he/she may appeal the determination by submitting a written request to the CIRC for reconsideration along with any supporting materials. The CIRC shall review the request and supporting materials and issue its final determination which shall not be subject to further appeal. The Investigator/Support Personnel shall sign any Resolution Plan required by the CIRC before any funds will be expended under the project(s).

### **F. Records Retention**

The Associate Vice President for Research and Compliance shall retain records of all financial disclosures and all actions taken by Creighton University with respect to each conflicting interest as follows:

- PHS Funded Projects: Three years after the date of submission of the final expenditures report or, where applicable, from other dates specific in 45 CF 74.53 (b) for different situations;
- NSF Funded Projects: Three years beyond the termination or completion of the project, or until the resolution of any NSF action involving those records, whichever is longer;
- All Other Externally Funded Projects: Three years after the termination or completion of the project.

### **G. Enforcement, Sanctions and Noncompliance**

1. Generally. Investigator/Support Personnel are expected to fully comply with this policy. Examples of breaches of this policy include, but are not limited to, failure to submit the Disclosure Form, intentionally filing an incomplete, erroneous, or misleading Disclosure Form, or failing to provide any additional information requested by the Associate Vice President for Research and Compliance or CIRC. Failure to comply with this policy may result in disciplinary action ranging from a public letter of reprimand to dismissal and termination of employment or affiliation with the University. Disciplinary action will be consistent with and subject to Creighton University's progressive disciplinary policy or applicable sections of the Faculty Handbook.

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## 2. PHS Funded Projects.

- a. If an Investigator/Support Personnel's failure to comply with this policy has biased the design, conduct or reporting of the externally funded project, the Associate Vice President for Research and Compliance shall promptly notify the appropriate federal agency of the corrective action taken or to be taken.
- b. If the Department of Health and Human Services determines that a PHS-funded project of clinical research evaluating the safety or effectiveness of a drug, medical device or treatment, was designed, conducted or reported by an Investigator/Support Personnel with a conflicting interest that was not disclosed or managed, Creighton University shall require the Investigator/Support Personnel to disclose the conflicting interest in each public presentation of the results of the research.

## H. Other Requirements

1. PHS Certification. The appropriate Creighton University official shall certify on each PHS funded proposal that:
  - There is a written and enforced administrative process to identify, manage, reduce or eliminate conflicting interests;
  - Prior to the expenditure of any funds, a report will be made to the PHS Awarding Component of any Conflict of Interest (but not the nature of the interest or details) found by Creighton University and assure that the interest has been managed, reduced or eliminated. If any conflicting interest is identified subsequent to the initial report, a report will be made and the Conflict of Interest managed, reduced or eliminated at least on an interim basis, within 60 days of that identification; and
  - Upon request, make information available to the Department of Health and Human Services regarding all conflicting interests and how those interests have been managed, reduced or eliminated.
2. PHS Notification. Prior to the expenditure of any funds, the Associate Vice President for Research and Compliance shall submit a report to the PHS of any conflicting interest (but not the nature of the interest or other details) found by Creighton University and assure that the interest has been managed, reduced or eliminated. If any conflicting interest is identified subsequent to the initial report, a report will be made and the Conflict of Interest managed, reduced or eliminated at least on an interim basis, within 60 days of that identification.

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3. **NIH Notification.** Prior to the expenditure of any funds, the Associate Vice President for Research and Compliance shall submit a report to the NIH of any conflicting interest (but not the nature of the interest or other details) found by Creighton University and assure that the interest has been managed, reduced or eliminated. If any conflicting interest is identified subsequent to Creighton University's initial report, a report will be made and the Conflict of Interest managed, reduced or eliminated, at least on an interim basis, within 60 days of that identification.
  
4. **NSF Notification.** The Associate Vice President for Research and Compliance shall keep the NSF Office of the General Counsel appropriately informed if Creighton University finds that it is unable to satisfactorily manage a Conflict of Interest under an NSF funded project.

### **ADMINISTRATOR AND INTERPRETATION**

Questions regarding this policy may be directed to the Associate Vice President for Research and Compliance or General Counsel at Creighton University.

### **AMENDMENTS OR TERMINATION OF THIS POLICY**

Creighton University reserves the right to modify, amend or terminate this policy at any time. Nothing in this policy should be construed as a contract between Creighton University and its employees.

**EXAMPLES OF SIGNIFICANT FINANCIAL INTERESTS**

The following are examples of Significant Financial Interests as defined under Policy 3.1.10 that must be reported on the Statement of Significant Financial Interests Form. These examples are neither exclusive or exhaustive of the types of significant financial interests that may be reportable under Policy 3.1.10

- Payments (e.g., stipends, honoraria) from a sponsor, directly or indirectly, for speaking engagements when the Investigator/Support Personnel knows the source of the funding for the speaking fee. In those instances where the speaking fee is received indirectly from the sponsor, other than sponsor funded educational programs subject to ACCME requirements, you should disclose who determines the content, who selects the speakers and other factors that may assist in determining whether or not a conflict of interest exists.
- Income from service on the advisory board or scientific review panel for a for-profit pharmaceutical company that exceeds \$10,000 for the previous calendar year or is expected to exceed \$10,000 over the next 12 months from the date of completing the Conflict of Interest Form.
- Consulting fees from any sponsor (excluding service on an advisory board or scientific review panel of a government or non-profit company) that exceeds \$10,000 for the previous calendar year or is expected to exceed \$10,000 over the next 12 months from the date of completing the Conflict of Interest Form.
- A Family Member’s direct ownership of stock in a publicly traded company valued at over \$10,000 that may or may not be affected by the project.
- Any payment incentives (money, gifts, other items of value) above and beyond the actual costs of enrollment, conduct of the research and reporting of the results, such as finders fees, recruitment bonuses, enrollment bonus for reaching an accrual goal.
- Payments for protocol or study design that exceed \$10,000 in the previous calendar year or that are expected to exceed \$10,000 over the next 12 months.
- A right or expectation of obtaining a proprietary interest related to the project or related to any test article or device that will be used in the project, including any proprietary interests that you may assign to any entity, including Creighton University.
- Serving as an officer or director (whether or not paid for such service) with any entity providing funds or other support to the project or in any entity that may be affected (benefited or harmed) by the results of the project (i.e., competitor, customer, collaborator or affiliate of a commercial sponsor).
- Planning to use project funds to purchase items or services from an entity in which you or a Family Member have an interest (stock, stock options, employment, partnership)
- Holding a 10% partnership interest (valued at \$5,000) in an entity that may be impacted (detriment or benefit) by the proposed project.

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**DISCLOSURE OF FINANCIAL RELATIONSHIP  
FOR SPONSORED PROJECTS  
(01/01/2008—12/31/2008 or 2009 Update)**

Name (Print): \_\_\_\_\_ Date: \_\_\_\_\_

Department: \_\_\_\_\_ Phone: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

Please check appropriate boxes:

Initial Disclosure

Annual Disclosure

Update

Investigator

Co-Investigator

Support Personnel

This Form shall be completed by all Investigator/Support Personnel pursuant to University Policy 3.1.10, Externally Sponsored Project Financial Conflict of Interest Policy.

**Section A. Financial Interests/Relationships**

Report all financial interests/relationships currently held, or held within the past 12 months (or during the previous calendar year for annual disclosures), unless otherwise stated, indicating the amount of the financial interest/relationship and the entity or organization. This form must be updated with 30 days of acquiring any new or additional financial interests/relationships.

**1. Payment for Services.** Have you and/or your spouse or dependents received or will you and/or your spouse or dependents receive any salaries and/or other payments (e.g., consulting fees; honoraria, study design; management position, independent contractor, service on advisory committees or review panels of for-profit entities, board membership of for-profit entities; seminars, lectures or teaching engagements for for-profit entities) from any one entity or group of related entities that when totaled together for that entity or group of related entities exceeded \$10,000 during the previous 12 months or are expected to exceed \$10,000 over the next 12 months?

Yes  No

If Yes, note amount with explanation of source:

\_\_\_\_\_  
\_\_\_\_\_

**2. Equity (Ownership) Interests.** Do you and/or your spouse or dependents hold any equity interests or ownership interests (e.g., stock, stock options, partner) in entities related to the research activity that when totaled together for any entity or group of related entities exceed \$10,000 in value or represent more than 5% equity/ownership interest. EXCLUDES INTERESTS IN DIVERSIFIED MUTUAL FUNDS?

Yes  No

If Yes, note amount with explanation of source:

\_\_\_\_\_  
\_\_\_\_\_

**3. Other Financial Interests or Relationships.** Have you and/or your spouse or dependents received any loans, payments, gifts, in-kind contributions or similar financial interests or relationships with research related entities?

Yes  No

If Yes, note amount with explanation of source:

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**4. Incentives.** If involved in any research activity, will you receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, an enrollment bonus for reaching an accrual goal or similar types of payments?

Yes  No

If Yes, note amount with explanation of source:

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**5. Other.** Do you and/or your spouse or dependents have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

Yes  No

If Yes, note amount with explanation of source:

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**Section B. Declaration**

- I, my spouse and/or my dependents have** a significant financial interest with an entity (or its affiliate) that is providing funds or other support for any research and/or education project, or that may be affected by the research and/or education project as noted in Section A above.
- I, my spouse and/or my dependents do not have** a significant financial interest with an entity (or its affiliate) that is providing funds or other support for any research and/or education project, or that may be affected by the research and/or education project.

**Section C. Attestation**

I affirm that I:

Have read the University Policy 3.1.10, Externally Sponsored Project Financial Conflict of Interest Policy and agree to abide by its terms.

Will update this Disclosure Form on an annual basis or as any new reportable significant financial interest arises.

Will comply with any resolution plan proposed by the CIRC (and/or IRB, if the project involves human subjects) to manage, reduce or eliminate any actual or potential financial conflict of interest before conducting any research or educational activity where a conflict of interest has been identified by the CIRC.

Signed: \_\_\_\_\_

Dated: \_\_\_\_\_

➤ **Submit the completed and signed form in an envelope marked confidential to:**  
**Kathleen Taggart, Associate Vice President for Research and Compliance**  
**Research Compliance Office, CRISS I**