

Policies and Procedures

SECTION: Financial	NO. 3.1.10.						
CHAPTER: General	ISSUED: 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>REV. D</i> 8/10/10	<i>REV. E</i> 8/24/12	<i>REV. F</i> 10/18/12
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POLICY SUMMARY

This Policy applies to Creighton University Investigators/Support Personnel (as defined in the Policy) involved in research who have a Significant Financial Interest (as defined in this Policy) that may create a Financial Conflict of Interest.

Investigators/Support Personnel involved in a research project must complete a disclosure form and submit it to the Office of Research and Compliance annually. This form must also be completed and submitted to the Office of Research and Compliance within 30 days after an Investigator/Support Personnel obtains a new or additional Significant Financial Interest during the course of a project that is not included in their annual disclosure.

The Conflict of Interest Review Committee (CIRC) reviews the disclosure forms and decides whether a Financial Conflict of Interest exists. The CIRC prepares a resolution plan to manage, reduce, or eliminate any identified Financial Conflict of Interest. If the project involves human subjects research, the Institutional Review Board (IRB) may impose additional requirements before granting IRB approval.

Investigators/Support Personnel have the right to appeal the CIRC's decision by requesting a reconsideration of their initial decision within 14 business days after notification of the decision. Failure to comply with this Policy will result in appropriate disciplinary action in accordance with applicable University policies.

PURPOSE

This Policy assures objectivity in research projects funded through Creighton University by all sources, including grants, contracts, or cooperative agreements. It ensures that the design, conduct, or reporting of research projects will not be biased by any conflicting interest of an Investigator/Support Personnel or his/her family members. This Policy also supports Creighton University's institutional compliance with the Public Health Service regulations (42 CFR Part 50, Subpart F, and, as applicable, 45 CFR Part 94) and the grant requirements of the National Science Foundation.

POLICY

All Investigators/Support Personnel shall disclose all known Significant Financial Interests of the Investigator/Support Personnel and his/her family members.

In all cases, Financial Conflicts of Interest will be satisfactorily managed, reduced, or eliminated in accordance with this Policy.

SCOPE

This Policy applies to all Investigators/Support Personnel.

This Policy also applies to subrecipients involved in research projects when the written agreement between Creighton University as the prime awardee and the subrecipient specifies that it will apply.

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DEFINITIONS

Disclosure: An Investigator/Support Personnel's statement to the University of any Significant Financial Interests.

Equity interest: Any stock, stock option, or other ownership interest.

Family member: Investigator's/Support Personnel's spouse or dependent children.

Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.

Institution of higher education: An educational institution in any state that:

- Admits as regular students only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such a certificate; or persons who have completed a secondary school education in a home school setting that is treated as a home school or private school under state law;
- Is legally authorized within such state to provide a program of education beyond secondary education;
- Provides an educational program for which the institution awards a bachelor's degree or provides not less than a two-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the Secretary of Health and Human Services;
- Is a public or other nonprofit institution; and
- Is accredited by a nationally recognized accrediting agency or association. If not so accredited, the institution must have been granted preaccreditation status by an agency or association recognized by the Secretary of Health and Human Services for the granting of preaccreditation status, and the Secretary has determined that the institution will meet the accreditation standards of the agency or association within a reasonable time.

Institutional (professional) responsibilities: An Investigator's/Support Personnel's responsibilities on behalf of the University, including:

- Research
- Research consultation
- Teaching
- Professional practice
- Consulting or other services to third parties related to Investigator's/Support Personnel's academic field and/or academic subject matter expertise
- Institutional committee memberships
- Service on panels, such as Institutional Review Boards or Data and Safety Monitoring Boards

Investigator/Support Personnel: The Principal Investigator, Project Director, co-Investigator, and any other person, regardless of title or position, involved in the design, conduct, or reporting of a research project.

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PHS awarding component(s): The organizational unit(s) of the Public Health Service of the United States Department of Health and Human Services that funds the research project.

Reimbursed travel: Travel and related expenses (transportation, lodging, meals, incidentals) that are reimbursed to the PHS-funded Investigator/Support Personnel and are related to the Investigator's/Support Personnel's institutional (professional) responsibilities. This does **NOT** include travel that is reimbursed by:

- A Federal, state, or local government agency;
- An institution of higher education;
- An academic teaching hospital;
- A medical center; or
- A research institution that is affiliated with an institution of higher education.

Related to the research: When the CIRC determines that the Significant Financial Interest could be affected by the research or is in an entity whose financial interest could be affected by the research.

Remuneration: Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Research: A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge, including, but not limited to, that relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). The term includes, but is not limited to, any such activity for which research funding is available from a PHS awarding component through a contract, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, infrastructure award, institutional training grant, program project, or research resources award.

Significant Financial Interest: Anything of monetary value (whether or not that value is readily ascertainable) that reasonably appears to be related to the Investigator's/Support Personnel's institutional (professional) responsibilities and is received, obtained, or held directly or indirectly by the Investigator/Support Personnel and/or a family member, including one or more of the following interests:

- With regard to any **publicly traded entity**, a Significant Financial Interest exists if the value of any **remuneration** received from the entity in the 12 months preceding the disclosure and the value of any **equity interest** in the entity as of the date of disclosure, when aggregated, exceeds \$5,000, as determined through reference to public prices or other reasonable measures of fair market value. (**Note:** \$5,000 threshold for both remuneration and equity interests.)
- With regard to any **non-publicly traded entity**, a Significant Financial Interest exists if the value of any **remuneration** received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator/Support Personnel and/or family member holds any **equity interest**. (**Note:** Remuneration has a \$5,000 threshold, equity interests have a \$0 threshold.)
- **Reimbursed or sponsored travel in any amount** (**Note:** \$5,000 threshold), only if received by a PHS-funded Investigator/Support Personnel and, when aggregated per entity, exceeds \$5,000

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The term *Significant Financial Interest* does **NOT** include the following types of financial interests:

- Salary, royalties, or other remuneration paid by the University to the Investigator/Support Personnel;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator/Support Personnel does not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures, or teaching engagements sponsored by a Federal, State, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- Income from service on advisory committees or review panels for a Federal, State, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Sponsored travel: Travel and related expenses (transportation, lodging, meals, incidentals, etc.) that are paid on behalf of the PHS-funded Investigator/Support Personnel and are not reimbursed to the Investigator/Support Personnel and are related to the Investigator's/Support Personnel's institutional (professional) responsibilities. This term does **NOT** include travel that is sponsored by:

- A Federal, state, or local government agency;
- An institution of higher education;
- An academic teaching hospital;
- A medical center; or
- A research institution that is affiliated with an institution of higher education.

Subrecipient: Subgrantees, contractors, collaborators, or subcontractors.

PROCEDURE

1. Disclosure of Significant Financial Interests

a. Initial Disclosure of Significant Financial Interests to the Office of Research and Compliance

- i. **Annual Disclosure:** Investigators/Support Personnel shall submit an updated disclosure form annually.
- ii. **New Research Projects.** If an annual disclosure form has not been submitted, all Investigators/Support Personnel shall complete and submit a disclosure form before any research project may be submitted to an external sponsor or for internal funding, as well as before all Institutional Review Board/Institutional Animal Care and Use Committee/Institutional Biosafety Committee applications are submitted.
- iii. **Investigator/Support Personnel Added to an Existing Project.** If an annual disclosure form has not been submitted, all Investigators/Support Personnel added to an existing research project shall complete and submit a disclosure form. No one shall be added to the project until the disclosure form has been reviewed pursuant to this Policy.

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- b. **New or Additional Financial Interests.** Any Investigator/Support Personnel or his/her family member who discovers or acquires (e.g., through purchase, marriage, or inheritance) a new or additional Significant Financial Interest during the period of a research project must submit an updated disclosure form to the Office of Research and Compliance within 30 days of discovering or acquiring the new or additional Significant Financial Interest.
- c. **Reimbursed Travel or Sponsored Travel.** If not disclosed on the annual disclosure form, PHS-funded Investigators/Support Personnel shall disclose reimbursed or sponsored travel *when aggregated per entity exceeds \$5,000*. When a disclosure includes a report of reimbursed travel or sponsored travel received by a PHS-funded Investigator/Support Personnel, the disclosure shall include:
- i. The purpose of the trip,
 - ii. The identity of the sponsor/organizer,
 - iii. The destination of the travel,
 - iv. The duration of the travel, and
 - v. The monetary value of the travel.

Sponsored travel does **NOT** include travel that is sponsored by:

- i. A Federal, state, or local government agency;
 - ii. An institution of higher education;
 - iii. An academic teaching hospital;
 - iv. A medical center; or
 - v. A research institution that is affiliated with an institution of higher education.
- d. **Additional Information.** Investigators/Support Personnel shall provide such additional information about disclosures as may be requested at any time by the Associate Vice President for Research and Compliance or his/her designee or the CIRC.

2. Review Process

- a. **Initial Review by the Office of 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.
- i. If **NO Significant Financial Interest** is disclosed, the disclosure form is filed and no further action is required.
 - ii. If a **Significant Financial Interest is disclosed**, the Office of Research and Compliance shall determine whether it is related to any grants or contracts, or to any open human, animal, or laboratory research. The nature of the study is reviewed relative to the

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Significant Financial Interest, and is then referred to the CIRC. The CIRC shall determine whether any Financial Conflict of Interest exists and, if so, how to manage, reduce, or eliminate the Financial Conflict of Interest before expenditure of project funds. No project funds shall be released until a final determination has been made.

- b. **Conflict of Interest Review Committee Review Process.** The CIRC shall review (and, where necessary, investigate) all information contained in the disclosure to determine whether an Investigator/Support Personnel's Significant Financial Interest is related to the research and, if so, whether it constitutes a Financial Conflict of Interest.

The following are possible determinations the CIRC may make regarding Financial Conflicts of Interest:

- i. If it is determined that there is no Significant Financial Interest, the CIRC shall notify the Investigator/Support Personnel in writing, and this correspondence shall be included in the project file.
- ii. If it is determined that there is a Significant Financial Interest, the CIRC shall determine whether any Financial Conflict of Interest exists and, if so, how to manage, reduce, or eliminate the Financial Conflict of Interest before expenditure of project funds, including developing and implementing a management plan and, if necessary a retrospective review and mitigation report.

Examples of conditions or restrictions that might be imposed in a management plan include, but are not limited to:

1. Public disclosure of Financial Conflicts of Interest (e.g., when presenting or publishing the research).
2. For research projects involving human subjects, disclosure of Financial Conflicts of Interest directly to participants.
3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest.
4. Modification of the research plan.
5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
6. Reduction or elimination of the Significant Financial Interest (e.g., sale of an equity interest).
7. Severance of relationships that create financial conflicts.

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c. Review of Projects Involving Human Subjects Research

- i. **Participation of an Investigator/Support Personnel with a Significant Financial Interest.** Any Significant Financial Interest(s) of Investigators/Support Personnel who are involved in human subjects research may present real or perceived risks to the welfare of human subjects and may require additional review. In most cases, an Investigator/Support Personnel may not participate in human subjects research while he/she has a Significant Financial Interest in the project or with the sponsor.

The CIRC may grant an exception on a case-by-case basis if the Investigator/Support Personnel provides compelling reasons to maintain the Significant Financial Interest and participate in human subjects research. These compelling circumstances or facts shall be consistent with the rights and welfare of human subjects. The CIRC shall establish written policies to require disclosure, monitoring, and implementation of any other measures it deems necessary in this circumstance.

- ii. **Role of the University's Institutional Review Board (IRB).** The IRB may accept or decline the CIRC's determination and resolution. The IRB is ultimately responsible for protecting the rights and welfare of human subjects and, if it is not satisfied that the CIRC's final determination will protect the rights and welfare of human subjects, it shall independently review the Significant Financial Interest and either refuse to approve the study or recommend to the CIRC its requirements to manage, reduce, or eliminate the Financial Conflict of Interest. The IRB has the final authority to determine whether any interest and its management allow the research to be approved.

- d. **Intellectual Property Rights.** An Investigator/Support Personnel is **NOT** required to disclose as a Significant Financial Interest income (including royalties, license fees, or other forms of revenue) paid by the University to the Investigator/Support Personnel due to intellectual property rights assigned to the institution by the Investigator/Support Personnel and agreements to share in revenue related to such rights. However, Creighton University's Intellectual Resource Management (IRM) Technology Transfer Office shall provide a report to the CIRC of any such intellectual property rights and agreements. The CIRC shall determine whether a Financial Conflict of Interest exists and whether a management plan is required. The involved Investigator/Support Personnel shall be required to comply with any such management plan, and the Financial Conflict of Interest identified shall be disclosed as required.

- e. **New or Undisclosed Significant Financial Interests.** Whenever:

- i. an Investigator/Support Personnel new to a research project discloses a Significant Financial Interest,
 - ii. an existing Investigator/Support Personnel discloses a new Significant Financial Interest,
- or

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- iii. the University identifies a Significant Financial Interest that was not previously disclosed by an Investigator/Support Personnel or, for whatever reason, was not previously reviewed by the University during an ongoing research project (e.g., was not reviewed or reported by a subrecipient),

the CIRC shall, within 60 days:

- i. Review the Significant Financial Interest,
- ii. Determine whether it is related to the research,
- iii. Determine whether a Financial Conflict of Interest exists, and, if so,
- iv. Implement, on at least an interim basis, a management plan specifying the actions that have been and will be taken to manage such Financial Conflict of Interest going forward.

Depending on the nature of the Financial Conflict of Interest, the University may determine that additional interim measures are necessary regarding the Investigator's/Support Personnel's participation in the research project between the date that the Financial Conflict of Interest or the Investigator's/Support Personnel's noncompliance is determined and the completion of the University's retrospective review.

3. **Appeal Rights:** If the Investigator/Support Personnel disagrees with a management plan developed by the CIRC, he/she may appeal the determination by submitting a written request and any supporting materials to the CIRC for reconsideration within 14 days after receiving notification of the management plan. 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 management plan required by the CIRC before any funds may be expended.
4. **Ongoing Monitoring:** Whenever the University implements a management plan, the University, through the Research Compliance Quality Assurance Program and CIRC, shall monitor Investigator/Support Personnel compliance with the management plan on an ongoing basis until the research is completed.
5. **Records Retention:** The Office of Research and Compliance shall retain records of all disclosures and the University's review of and response to each disclosure as follows:
 - a. **PHS-Funded Projects:** Three years after the date of submission of the final expenditures report or, where applicable, from other dates specific in 45 CFR 74.53 (b) for different situations.
 - b. **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.
 - c. **All Other Externally or Internally Funded Projects:** Three years after the termination or completion of the project.

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6. Enforcement, Sanctions, and Noncompliance

- a. **General.** Investigators/Support Personnel shall fully comply with this Policy. Examples of breaches of this Policy include, but are not limited to:
- i. Failure to submit the disclosure form
 - ii. Intentionally filing an incomplete, erroneous, or misleading disclosure form
 - iii. Failing to provide any additional information requested by the Office of 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 shall be consistent with and subject to the University's progressive disciplinary policy or applicable sections of the Faculty Handbook.

b. PHS-Funded Projects

- i. **Retrospective Review:** When a Financial Conflict of Interest is not identified or managed in a timely manner, the University shall, within 120 days of the University's determination of noncompliance, complete a retrospective review of the Investigator's/Support Personnel's activities and the PHS-funded research project. This review shall determine whether there was any bias in the design, conduct, or reporting of the PHS-funded research, or any portion thereof, conducted during the time period of the noncompliance. The University shall document the retrospective review, including, but not limited to, all of the following key elements:
1. Project number
 2. Project title
 3. Project Director/Principal Investigator (or contact Project Director/Principal Investigator, if a multiple Project Director/Principal Investigator model is used)
 4. Name of the Investigator/Support Personnel who has the Financial Conflict of Interest
 5. Name of the entity with which the Investigator/Support Personnel has a Financial Conflict of Interest
 6. Reason(s) for the retrospective review
 7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
 8. Findings of the review
 9. Conclusions of the review

If an Investigator's/Support Personnel's failure to comply with this Policy or a management plan appears to have biased the design, conduct, or reporting of the PHS-

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funded research, the University shall promptly notify the PHS awarding component of the corrective action taken or to be taken.

ii. PHS Notification

1. Prior to the University's expenditure of any funds under a PHS-funded research project, the University shall provide to the PHS awarding component a Financial Conflict of Interest report regarding any Investigator's/Support Personnel's Financial Conflict of Interest, and ensure that the University has implemented a management plan.

In cases in which the University identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of PHS-awarded funds, the University shall not submit a Financial Conflict of Interest report to the PHS awarding component.

2. For any Financial Conflict of Interest that the University identifies after its initial report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator/Support Personnel who is new to the research project), the University shall provide to the PHS awarding component, within 60 days, an updated Financial Conflict of Interest report regarding the conflict and ensure that the University has implemented a management plan.
3. **Mitigation Report:** If, after conducting a retrospective review, the University finds that it is warranted, it shall update the previously submitted Financial Conflict of Interest report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the University shall notify the PHS awarding component promptly and submit a mitigation report to the PHS awarding component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review, as well as a description of the impact of the bias on the research project (e.g., extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable) and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias. Thereafter, the University shall submit Financial Conflict of Interest reports annually.
4. Any Financial Conflict of Interest report required under paragraphs (1) (2), or (3) above shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the Financial Conflict of Interest, and to assess the appropriateness of the University's management plan.

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Elements of the Financial Conflict of Interest report shall include, but are not limited to, the following:

- a. Project number
 - b. Name of the Investigator/Support Personnel who has the Financial Conflict of Interest
 - c. Name of the entity with which the Investigator/Support Personnel has a Financial Conflict of Interest
 - d. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
 - e. Value of the financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
 - f. A description of how the financial interest relates to the PHS-funded research, and the basis for the University’s determination that the financial interest conflicts with the research
 - g. A description of the key elements of the University’s management plan, including:
 - i. Role and principal duties of the conflicted Investigator/Support Personnel in the research project
 - ii. Conditions of the management plan
 - iii. How the management plan is designed to safeguard objectivity in the research project
 - iv. Confirmation of the Investigator’s/Support Personnel’s agreement to the management plan
 - v. How the management plan will be monitored to ensure Investigator/Support Personnel compliance
 - vi. Other information as needed
5. For any Financial Conflict of Interest associated with an ongoing PHS-funded research project that was previously reported by the University, the University shall provide to the PHS awarding component an annual Financial Conflict of Interest report that addresses the status of the conflict and any changes to the management plan. These annual reports will be required for the duration of the PHS-funded research project, including extensions with or without funds.

The annual Financial Conflict of Interest report shall specify whether the Financial Conflict of Interest is still being managed, or explain why the Financial Conflict of Interest no longer exists.

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6. In some cases, the Federal Department of Health and Human Services (HHS) may determine that a PHS-funded clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator/Support Personnel with a Financial Conflict of Interest that was not managed or reported by the University as required. In these cases, the University shall require the Investigator/Support Personnel involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research, and to request an addendum to previously published presentations.
 - c. **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 Financial Conflict of Interest under an NSF-funded project.
 - d. **Other Sponsors:** The Associate Vice President for Research and Compliance shall notify any other sponsor of Financial Conflicts of Interest and management plans imposed, as required by sponsor policy or contractual obligation.

7. Other Requirements

- a. **PHS Certification.** The appropriate University official shall certify on each PHS-funded proposal that the University:
 - i. Has in effect an up-to-date, written, and enforced administrative process to identify and manage Financial Conflicts of Interest.
 - ii. Shall promote and enforce Investigator/Support Personnel compliance with the requirements of 42 CFR Part 50, including those pertaining to disclosure of Significant Financial Interests.
 - iii. Shall manage Financial Conflicts of Interest and provide initial and ongoing Financial Conflict of Interest reports to the PHS awarding component, consistent with 42 CFR Part 50.
 - iv. Agrees to make information available to HHS, promptly upon request, relating to any Investigator /Support Personnel disclosure and the University's review of and response to such disclosure, whether or not the disclosure results in the University's determination of a Financial Conflict of Interest.
 - v. Shall fully comply with the requirements of 42 CFR Part 50.

8. Public Accessibility

- a. **Policy Availability.** The Office of Research and Compliance shall post and maintain this Policy on a publicly accessible Creighton University web site.

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b. **Financial Conflict of Interest Public Accessibility Notice:** Within a reasonable time after determining an Investigator/Support Personnel has a Financial Conflict of Interest and, for PHS-funded research, prior to the University's expenditure of any funds for that research, the Office of Research and Compliance shall ensure the public accessibility of information concerning any Financial Conflicts of Interest held by Investigators/Support Personnel participating in PHS-funded research. Response to all written requests for information shall be provided within five business days of receipt of the request. Written requests may be sent via email to COI@creighton.edu, or by mail to Office of Research and Compliance, 2500 California Plaza, Omaha, NE 68178. This information will also be available on the Office of Research and Compliance [Conflict of Interest web site](#).

- i. The information included in a response to a request for information shall include, at a minimum, the following:
 1. The Investigator's/Support Personnel's name
 2. The Investigator's/Support Personnel's title and role with respect to the research
 3. The name of the entity in which the Significant Financial Interest is held
 4. The name/title of the research project
 5. The nature of the Significant Financial Interest
 6. The approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- ii. The Office of Research and Compliance shall update the information annually.
- iii. In addition, the Office of Research and Compliance shall update the information within 60 days of the University's receipt or identification of information concerning any additional Financial Conflict of Interest of the Investigator/Support Personnel that was not previously disclosed, or upon the determination of Financial Conflict of Interest of Investigators/Support Personnel new to the research project.
- iv. Information concerning the Financial Conflict of Interest of an individual shall remain available via written request for three years from the date that the information was most recently updated.

9. Education/Training

- a. **Initial Training:** All current Investigators/Support Personnel shall be informed of and trained on this Policy, including the Investigator's/Support Personnel's responsibilities regarding disclosure of Significant Financial Interests, and the PHS Federal regulations on Financial Conflict of Interest. All Investigators/Support Personnel must complete initial Financial Conflict of Interest training before beginning work on any research project.

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- b. **Training Updates:** Investigators/Support Personnel shall complete re-training on Financial Conflict of Interest every four years after initial training, or more often when any of the following circumstances apply:
 - i. The University revises its Financial Conflict of Interest policies or procedures in any manner that affects the requirements of Investigators/Support Personnel.
 - ii. The University finds that an Investigator/Support Personnel is not in compliance with this Policy or a management plan.
- c. **Office of Research and Compliance Services.** The Office of Research and Compliance shall provide and/or arrange for and track required training. Training can be via live presentation or CITI or any successor educational service.

10. Federally Funded Subcontracts

If the University carries out Federally funded research through a subrecipient, the University shall take reasonable steps to ensure that any subrecipient Investigator/Support Personnel complies with Federal requirements for Financial Conflicts of Interest by:

- a. Incorporating as part of the written agreement with the subrecipient terms that require the subrecipient to:
 - i. apply its Financial Conflict of Interest policy to its Investigators/Support Personnel;
 - ii. certify that its policy complies with applicable Federal regulations; and
 - iii. agree to report all identified Financial Conflicts of Interest to the University within a certain time period. Such time period(s) shall be sufficient to enable the University to provide timely Financial Conflict of Interest reports, as necessary, to the Federal agency.
- b. Providing Financial Conflict of Interest reports to the Federal agency regarding all Financial Conflicts of Interest of all subrecipient Investigators/Support Personnel (i.e., prior to the expenditure of any funds and within 60 days of any subsequently identified Financial Conflict of Interest.

If the subrecipient does not have a Financial Conflict of Interest policy or refuses to apply the policy or certify compliance of the policy with Federal regulations, the agreement with the subrecipient shall:

- a. require the subrecipient's Investigators/Support Personnel to comply with this Policy, and
- b. specify time period(s) for the subrecipient to submit all Investigator/Support Personnel disclosures of Significant Financial Interests to the University. Such time period(s) shall be sufficient to enable the University to comply with its review, management, and reporting obligations.

Disclosures submitted by subrecipients shall be reviewed by the CIRC, and any Financial Conflicts of Interest shall be managed and monitored as set forth in this Policy.

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ADMINISTRATION AND INTERPRETATION

Questions regarding this Policy may be directed to the Office of Research and Compliance or the Office of General Counsel at the 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 the University and its employees.

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Creighton University Research and Compliance

2500 California Plaza, Omaha, NE 68178 • Phone: 402-280-3074
Fax: 402-280-4766 • <http://www2.creighton.edu/researchcompliance/>

DISCLOSURE OF FINANCIAL RELATIONSHIP FOR SPONSORED PROJECTS (08/24/2012—8/23/2013)

Name (Print): _____ Date: _____
Department: _____ Phone: _____
E-mail Address: _____

Please check appropriate boxes:

- | | | |
|---|--|--|
| <input type="checkbox"/> Initial Disclosure | <input type="checkbox"/> Annual Disclosure | <input type="checkbox"/> Update |
| <input type="checkbox"/> Investigator | <input type="checkbox"/> Co-Investigator | <input type="checkbox"/> Support Personnel |
| <input type="checkbox"/> Committee Member | <input type="checkbox"/> PHS-funded | <input type="checkbox"/> Student |

This Form shall be completed by all Investigators/Support Personnel/Research Committee Members pursuant to University Policy 3.1.10, Financial Conflict of Interest in Research.

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. For Publicly Traded Entities: Payment for Services (Remuneration) and/or Equity (Ownership) Interests. 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; any interest that could be affected by the outcome of the research) from any one entity or group of related entities, or do you and/or your spouse or dependents hold any equity interests or ownership interest (e.g., stock, stock options, partnership) that when totaled together for any entity or group of related entities exceeded **\$5,000** in value during the previous 12 months or that currently as of the date of this disclosure exceed **\$5,000**? **NOTE:** Equity interests exclude interests in diversified mutual funds, unless you or your spouse/dependents have the ability to directly control the direction of the investments.

Yes No

If Yes, note exact amount with explanation of source(s):

2. For Non-publicly Traded Entities: Payment for Services (Remuneration). 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;

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any interest that could be affected by the outcome of the research) from any one entity or group of related entities, that when totaled together for any entity or group of related entities exceeded \$5,000 in value during the previous 12 months or that currently as of the date of this disclosure exceed **\$5,000**?

Yes No

If Yes, note exact amount with explanation of source(s):

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3. For Non-publicly Traded Entities: Equity (Ownership) Interests. Do you and/or your spouse or dependents hold any equity interests or ownership interests (e.g., stock, stock options, partnership) in non-publicly traded entities? **NOTE:** The threshold for equity (ownership) interests is **\$0**; you must report all such interests here. **NOTE:** Equity interests exclude interests in diversified mutual funds, unless you or your spouse/dependents have the ability to directly control the direction of the investments.

Yes No

If Yes, note exact amount with explanation of source(s):

4. Reimbursed Travel (for Investigators/Support Personnel involved in PHS-funded projects): Have you and/or your spouse or dependents received or will you and/or your spouse or dependents receive reimbursement of \$5,000 or more (aggregated per entity) for travel and related expenses (e.g., transportation, lodging, meals, incidentals) that are related to your institutional (professional) responsibilities? **NOTE:** This does not include travel that is reimbursed by a Federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institution that is affiliated with an institution of higher education.

Yes No

If Yes, note the following:

The purpose of the trip: _____
 The identity of the sponsor/organizer: _____
 The destination of the travel: _____
 The duration of the travel: _____
 The monetary value of the travel: _____

5. Sponsored Travel (for Investigators/Support Personnel involved in PHS-funded projects): Have you and/or your spouse or dependents received or will you and/or your spouse or dependents had travel and related expenses (e.g., transportation, lodging, meals, incidentals) of \$5,000 or more (aggregated per entity) paid on your behalf (i.e., are not reimbursed) that are related to your institutional (professional) responsibilities? **NOTE:** This does not include travel that is sponsored by a Federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institution that is affiliated with an institution of higher education.

Yes No

If Yes, note the following:

The purpose of the trip: _____
 The identity of the sponsor/organizer: _____
 The destination of the travel: _____
 The duration of the travel: _____
 The monetary value of the travel: _____

6. Contingent Compensation. Have you and/or your spouse or dependents received or will you and/or your spouse or dependents receive any compensation that will be contingent on the outcome of the research?

Yes No

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If Yes, note exact amount with explanation of source:

7. 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 that are in any way related to your institutional (professional) responsibilities?

Yes No

If Yes, note exact amount with explanation of source:

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8. 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 exact amount with explanation of source:

9. Intellectual Property or Proprietary Interests. Do you and/or your spouse or dependents have any intellectual property or proprietary interests related to your institutional (professional) responsibilities, including, but not limited to, a patent, trademark, copyright, licensing agreement, or royalties, licensing fees, or other monies related to the intellectual property or proprietary interest not paid through the University?

Yes No

If Yes, note exact amount with explanation of source:

10. 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 exact amount with explanation of source:

Section B. Attestation

I affirm that I:

Have read the University Policy 3.1.10, Financial Conflict of Interest in Research, 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 where a conflict of interest has been identified by the CIRC.

Understand that, if I am a PHS-funded Investigator/Support Personnel, information on all financial conflicts of interest will be made publicly accessible.

Understand and agree that if I submit this electronically with a typed signature, this will be considered my legally binding signature.

Signed: _____ Dated: _____

➤ Submit the completed form and send a signed PDF copy OR a copy with a typed signature via email to

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COI@creighton.edu

OR mail a signed paper copy to:

Sara Coolman, Associate Director for Research and Compliance
Research Compliance Office, CRISS I, Room 109