

Policies and Procedures

<i>SECTION:</i> Financial	<i>NO.</i> 3.1.24.		
<i>CHAPTER:</i> General	<i>ISSUED:</i> 12-11-13	<i>REV. A</i>	<i>REV. B</i>
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1. PURPOSE

An Institutional Conflict of Interest (Institutional COI) describes a situation in which the financial interests of Creighton University (the University) or a University official, acting within his or her authority on behalf of the University, may affect or appear to affect the research, education, clinical care, business transactions, or other activities of the University. Institutional COIs are of significant concern when financial interests create the potential for inappropriate influence over the University's activities. The risks are particularly acute in the context of Human Subjects Research, when the protection of human subjects and the integrity of the University's research may be threatened. Because research subject safety is not an issue in the case of non-Human Subjects Research, the primary reasons to manage Institutional COI in this type of research focus on protection of the integrity of the University's research and educational missions. This Policy is intended to protect against exposure from these risks as they may affect research performed at or under the auspices of the University.

The University, including its officials, must balance many competing pressures. It engages in relationships with a variety of sponsors that may lead to financial benefit for the University in many forms, including major gifts, royalty payments, and equity from licensing intellectual property, as well as sponsored educational and research agreements. In addition, university-industry relationships advance scientific frontiers and enable the commercial development of academic discoveries to the benefit of the public. Nonetheless, while generally part of legitimate educational, research, and business activities, relationships with commercial entities cannot be allowed to compromise, or appear to compromise, the integrity of the University's primary missions, including the safety and integrity of its research, education, and clinical care. The protection of human research subjects and integrity of the University must remain of highest priority.

The University has addressed potential individual Conflicts of Interest with respect to University operations, sponsored research, and continuing medical education in a variety of related policies referenced below. The purpose of this Policy is to address potential Institutional COIs in Research.

2. POLICY

The University shall ensure that no potential or actual Institutional COI shall affect the design, conduct, reporting, review, or oversight of Research.

3. SCOPE

This policy applies to Covered Officials, as defined below, with regard to potential Institutional COIs in Research.

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4. DEFINITIONS

Covered Officials: Board members, the president, vice presidents, the provost, vice provosts, deans and associate deans, department chairs, division chairs, institute and center directors, IRB (Institutional Review Board) chairs, IACUC (Institutional Animal Care and Use Committee) chair, the Conflict of Interest Review Committee (CIRC) chair, the chair of the Human Subjects Radiation Committee, the chair of the Radiation Safety Committee, and the chair of the Institutional Biosafety Committee.

Human Subjects Research: Any activity that requires review by the University IRB.

Institutional Conflict of Interest: The University may have a Conflict of Interest in Human Subjects or Non-Human Subject Research whenever the financial interests of the University, or of a Covered Official acting within his or her authority on behalf of the University, might affect—or reasonably appear to affect—University processes for the design, conduct, reporting, review, or oversight of Human Subjects or Non-Human Subject Research.

Investigational Product: The product to be studied or tested in Human Subjects or Non-Human Subject Research at or under the auspices of the University.

Non-Human Subjects Research: A systematic investigation designed to develop or contribute to generalizable knowledge that does not involve human subjects.

Research: Human Subjects Research and Non-Human Subjects Research conducted at or under the auspices of Creighton University.

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

- (i) With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any Remuneration received from the entity in the twelve 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.)
- (ii) 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 twelve months preceding the Disclosure, when aggregated, exceeds \$5,000, or when the Covered Official holds any Equity Interest. (Note: Remuneration has a \$5,000 threshold but there is a \$0 threshold for Equity Interests.)

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(iii) Reimbursed Travel in any amount or Sponsored Travel in excess of \$5,000 (Note: \$5,000 threshold aggregated per entity). For the purposes of this Policy, Reimbursed Travel means travel and related expenses (transportation, lodging, meals, incidentals) that are reimbursed to the Covered Official and related to the Covered Official's Institutional Responsibilities. Sponsored Travel means travel and related expenses (transportation, lodging, meals, incidentals, etc.) that are paid on behalf of the Covered Official and not reimbursed to the Covered Official and related to the Covered Official's Institutional Responsibilities. These terms do 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.

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

- (i) salary, royalties, or other remuneration paid by the University to the Covered Official;
- (ii) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Official does not directly control the investment decisions made in these vehicles;
- (iii) 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
- (iv) 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.

5. PROCEDURE

5.1. Identification of Potential Institutional Conflicts of Interest

The following offices will identify potential Institutional COI within their respective areas using the significant financial and fiduciary interest of the University that warrants formal review as outlined in this policy:

- 5.1.1. Research and Compliance
- 5.1.2. Sponsored Programs Administration Office
- 5.1.3. IRB
- 5.1.4. IACUC
- 5.1.5. Intellectual Resource Management—Technology Transfer Office
- 5.1.6. Office of the Vice President for Finance
- 5.1.7. Office of Development

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The following significant financial and fiduciary interests of the University warrant formal review of potential Institutional COI with respect to Research, as provided in this Policy:

- 5.1.8. Royalties: Institutional COI may be present when the University has the potential to receive significant milestone payments and/or royalties from the sales of an Investigational Product;
- 5.1.9. Non-publicly traded equity: When, through its technology licensing activities or investments related to such activities, the University has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded company that is i) the sponsor of Research at the University, or ii) the manufacturer of an Investigational Product;
- 5.1.10. Publicly traded equity: When, through technology licensing activities or investments related to such activities, the University has obtained an ownership interest or an entitlement to equity (including options or warrants) exceeding \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a publicly-traded company that is i) the sponsor of Research at the University, or ii) the manufacturer of an Investigational Product; and
- 5.1.11. University receipt of substantial or reoccurring gifts, grants, equipment donations or promises thereof (direct or implied) that are not a part of a disclosed sponsorship or sponsored program from commercial research sponsors if there is a *quid pro quo* owed to the donor/research sponsor that relates to, or could give the appearance of relating to, the research.

The following significant financial and fiduciary interests of Covered Officials warrant formal review of potential Institutional COI with respect to Research:

- 5.1.12. When, with regard to a specific research project to be conducted at or under the auspices of the University, Covered Officials with direct responsibility for Research hold a Significant Financial Interest in the commercial research sponsor or an entity that owns or controls the Investigational Product.

6. ADMINISTRATION OF INSTITUTIONAL CONFLICTS OF INTEREST POLICY

- 6.1. Administration of Institutional COI matters will be handled by the Office of Research and Compliance Services (“Research and Compliance Office”). To make the Research and Compliance Office aware of potential Institutional COI situations and transactions, the following offices will report quarterly to the Research and Compliance Office on interests described in Section 1, above, and will provide a supplemental report when any additional investments, interests, arrangements, patents, donations, gifts, etc., are received:

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- 6.1.1. Sponsored Programs Administration Office (for grants, fellowships, or financial relationships outside sponsored research projects)
 - 6.1.2. IRB
 - 6.1.3. IACUC
 - 6.1.4. Intellectual Resource Management—Technology Transfer Office (for licensing arrangements, patents, invention disclosures)
 - 6.1.5. Office of the Vice President for Finance (in the event that the University or any University-related investment entity invests directly in an entity whose stock is not publicly traded, the Vice President for Finance will provide a list of such entities)
 - 6.1.6. Office of Development (for gifts and donations)
- 6.2. The Office of General Counsel will also provide the Research and Compliance Office with an annual report on disclosures submitted by members of the Board of Directors that the Office of General Counsel determines may be related to Research. This COI report will be reviewed by the Research and Compliance Office, and in the event a disclosure reveals a potential Institutional COI, by the Conflict of Interest Review Committee as set forth below. The Research and Compliance Office shall annually query University Vice Presidents or Vice Provosts who are responsible for obtaining disclosures from officers and senior administrators under the University Conflict of Interest Policy for Officers and Senior Administrators, or any successor policy, as to any disclosures that may be related to Research. In the event a disclosure reveals a potential Institutional Conflict of Interest, the matter will be reviewed by the Conflict of Interest Review Committee as set forth below. The Research and Compliance Office, in the course of obtaining disclosures under the Financial Conflict of Interest in Research Policy, 3.1.10, shall obtain disclosures from Covered Officials who are not subject to the University Conflict of Interest Policy for Officers and Senior Administrators.

7. CONFLICT OF INTEREST REVIEW COMMITTEE

The University's Conflict of Interest Review Committee (CIRC) shall serve as the Institutional Conflict of Interest Committee. The CIRC shall have the composition set forth in its Policies and Procedures; provided, however, that the CIRC shall add to its membership a member of the public with no institutional affiliation (including, but not limited to, active transactional relationships with the University). A quorum for any meeting of the CIRC at which a potential Institutional COI will be reviewed must include the public member. All members of the CIRC shall abstain from Institutional COI business before the CIRC when they have a personal COI or involvement in the Institutional COI that relates to a research proposal under review, as provided by University policy.

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8. REVIEW AND MANAGEMENT OF INSTITUTIONAL CONFLICT OF INTEREST

8.1. When a potential Institutional COI that involves Research is identified, the Research and Compliance Office will notify the IRB and the Sponsored Programs Administration Office (if the Institutional COI involves a sponsored project). The Research and Compliance Office will review the potential Institutional COI and prepare a document describing the case and the nature of the real or potential Institutional COI and refer the matter and the document to the CIRC.

8.2. When a potential Institutional COI is identified with respect to Human Subjects Research, the CIRC shall apply a rebuttable presumption that either the financial interest should be eliminated or the Human Subjects Research should not be conducted at the University. The presumption may be rebutted if the circumstances are deemed compelling by the CIRC, and provided that the CIRC approves an effective Institutional COI management plan. Whether the presumption is successfully rebutted will depend in each case upon an analysis of:

- 8.2.1. the nature of the science,
- 8.2.2. the nature of the overlapping interests,
- 8.2.3. how closely the interest is related to the research,
- 8.2.4. the degree to which the interest may be affected by the research,
- 8.2.5. the degree of risk that the research poses to human subjects and the integrity of the research, and
- 8.2.6. the degree to which the Institutional COI can be effectively managed.

The CIRC should consider whether the University is uniquely qualified, by virtue of its attributes (e.g., special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and safeguard the welfare of the human subjects involved. If it is determined that there are compelling circumstances for allowing the Human Subjects Research to proceed in the presence of the Institutional COI without elimination or significant reduction of the financial interest, those circumstances should be documented in the CIRC report on the matter.

8.3. For Research, management plans for approved Institutional COI arrangements should be designed effectively to address

- 8.3.1. the nature of the conflict;
- 8.3.2. the specific risks to human subjects;
- 8.3.3. the perceived risk to the integrity of the research as a result of the conflict; and
- 8.3.4. the perceived risk to the reputation of the University.

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- 8.4. One or more of the following management strategies should be used:
- 8.4.1. Disclosure of the Institutional COI in the informed consent process.
 - 8.4.2. When the Institutional COI involves a Covered Official, formal recusal of the conflicted Covered Official from the chain of authority over the project and possibly also from authority over salary, promotion, and space allocation decisions affecting the Investigator, as well as communication of the recusal arrangements to the Covered Official's superior and colleagues (Note that recusal is not an effective management strategy when the individual, by virtue of conflicts arising from personal financial holdings, would be precluded from fulfilling the responsibilities of his or her position. In such cases, the best interests of the institution may necessitate that the individual divest the interests or vacate the position.).
 - 8.4.3. When the Institutional COI involves a senior Covered Official, designation of a "safe haven" (e.g., a senior Covered Official without Institutional COI) with whom the Investigator can address Institutional COI-related concerns.
 - 8.4.4. Use of an external Institutional Review Board (IRB) (since most institutional IRBs are composed of faculty and staff from the institution).
 - 8.4.5. External monitoring of the study, particularly endpoint assessments.
 - 8.4.6. Use of an external Data Safety Monitoring Board (DSMB) or similar review board to evaluate the design, analytical protocols, and primary and secondary endpoint assessments, and to provide ongoing evaluation of the study for safety, performance issues, and the reporting of results.
 - 8.4.7. Disclosure of the Institutional COI in public presentations and publications.
 - 8.4.8. Disclosure of the Institutional COI to other centers in a multi-center trial.
- 8.5. The determination and report of the CIRC shall be transmitted to the IRB, the applicable Dean, the Research and Compliance Office, the Sponsored Programs Administration Office, and, when the Institutional COI involves a Covered Official subject to the [Board of Directors Conflicts of Interest Policy] and/or the University Conflict of Interest Policy for Officers and Senior Administrators, to the Office of General Counsel. Review of compliance with management plans will be performed by the Research and Compliance Office and CIRC.
- 8.6. The Research and Compliance Office should provide the CIRC's decision and the underlying report to the IRB and the Sponsored Programs Administration Office (if the Institutional COI involves a sponsored research project) so that the IRB review of the project can consider the deliberations and recommended handling of the Institutional COI, and so that the sponsored research office can meet any applicable reporting obligations.

9. IMPLEMENTATION

Each Institutional COI management plan should state specifically who will be responsible for the plan's implementation. Adherence to the management plan will be evaluated by the Research and Compliance Office and CIRC.

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10. APPEAL

If a Covered Official or Investigator impacted by a decision of the CIRC disagrees with the CIRC's determination and management 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.

11. ROLE OF THE UNIVERSITY'S 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 it is not satisfied that the CIRC's final determination will protect the rights and welfare of human subjects, shall independently review the potential Institutional COI and either refuse to approve the Human Subjects Research project at issue or recommend to the CIRC its requirements to manage, reduce, or eliminate the Institutional COI.

12. RECORD RETENTION

The Research and Compliance Office shall retain records of disclosure reports and actions taken by the CIRC and University with respect to each potential Institutional COI for seven (7) years after termination or completion of the Research project at issue.

13. ADMINISTRATION AND INTERPRETATION

Questions regarding this policy may be directed to the Associate Vice Provost for Research and Compliance or the Office of General Counsel.

14. AMENDMENTS OR TERMINATION OF POLICY

The 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.

15. RELATED POLICIES

Conflict of Interest Review Committee Policies and Procedures

Creighton University Guide to Policies:

Financial Conflict of Interest in Research, Policy No. 3.1.10.

Conflict of Interest Policy for All Employees, Policy No. 3.1.11.

Conflict of Interest Policy for Officers and Senior Administrators, Policy No. 3.1.12.

Board of Trustees Conflict of Interest Policy