
*University of Nebraska-Lincoln
Conflict of Interest in Research Policy
Effective August 24, 2012*

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I. Introduction

As an institution, the University of Nebraska-Lincoln (UNL) is committed to maintaining research integrity and academic freedom. Research objectivity, study participant rights and the freedom to publish are central issues in research related conflicts of interest. Typically, a conflict of interest is defined as a situation that may bias a decision. A conflict of interest arises when a University employee member has an opportunity to influence UNL's business or research decisions for personal gain. The general subject of conflict of interest is addressed in Section 3.8 of the Bylaws of the Board of Regents as follows:

3.8 Conflict of Interest. No employee of the University shall engage in any activity that in any way conflicts with duties and responsibilities at the University of Nebraska. The Board of Regents has adopted Regents Policy 3.2.8 and authorized the implementation of related policies and directives to properly avoid, disclose and manage potential conflicts of interest.

In addition to Section 3.8 of the Bylaws, Nebraska statutes relating to conflict of interest and nepotism apply to all employees of the University, including the provisions of §49-14,101 of the Nebraska Revised Statutes¹. Furthermore, federal funding agencies require that the University establish safeguards to prevent employees or consultants from using their positions for purposes that are motivated by (or even give appearance of) a drive for private financial gain.²

The Bylaws of the Board of Regents and Regents' Policy 3.2.8 require that each University of Nebraska campus implement a policy that ensures that broad University-wide principles are followed. These principles include:

1. Prospects of financial gain must not unduly influence faculty and the University with regard to commercially imminent, product oriented research programs versus fulfilling the University's objectives of educating students, advancing basic knowledge and serving Nebraskans through the development and application of knowledge that enables them to develop better lives, stronger communities and genuine economic opportunity.
2. The University must avoid situations where the possibilities for personal gain for the Covered Person may be judged to be so significant that it is unreasonable to expect the Covered Person to exercise the objectivity necessary for public trust in the University and the rigor of its research.
3. Research agreements should encourage the free exchange of ideas and the sharing of research results regardless of the sponsoring entity. However, some publication restrictions may be required to protect proprietary information or intellectual property.
4. To the extent practicable and consistent with applicable law, the University must be appropriately compensated for private, commercial use of the public property under its stewardship.

¹ No public employee shall use that person's office or any confidential information received through the holding of a public office to obtain financial gain, other than compensation provided by law, for himself or herself, a member of his or her immediate family or a business with which the individual is associated ..." and no "public employee shall use personnel, resources, property, or funds under that individual's official care and control, other than in accordance with prescribed constitutional, statutory, and regulatory procedures, or use such items, other than compensation provided by law, for personal financial gain ..."

² Including Public Health Service and National Science Foundation regulations and guidelines (42 CFR Part 50, Subpart F and 45 CFR Part 94.1), Department of Education regulations (34 CFR Part 75.524, 34 CFR Part 75.525 and 34 CFR Part 74.42), and FDA regulations (21 CFR Part 54).

UNL has developed the following policy to guide faculty, staff and students in structuring their relationships with outside entities in order to comply with the federal and state requirements. This policy applies to all covered persons defined as:

1. University administrative officers and employees, specifically including any University employees with delegated signature, purchasing or contracting authority on behalf of the University;
2. University employees engaged in outside employment or other activities specified in this policy (technology transfer/use of University facilities or equipment) that may create a conflict of interest; and
3. Sponsored Research investigators, including University employees, faculty, staff and support personnel (managerial/professional and office/service positions), volunteers, trainees, students, contractors and other persons under the direct control of the UNL, whether paid by the UNL or not, who participate in Sponsored Research as defined in Section 6 of Board of Regents policy 3.2.8.

II. Scope

This policy is intended to supplement Regents Policy 3.2.8 and address relevant federal policies³ that regulate activities that may result in conflicts of interest in research. In addition, this policy details the procedures for identifying conflict of interest, the reporting process, and best practices. Conflicts of interest referred to in this policy are defined in Appendix I of this policy and generally include situations in which a covered person's direct or indirect personal financial interests may compromise, or have the appearance of compromising, the covered person's professional judgment or behavior in carrying out his or her obligations to the University of Nebraska. Indirect personal financial interests of a covered person that may be obtained through third parties such as a covered person's immediate family, business relationships, fiduciary relationships, or investments are also subject to this policy. For the purposes of this policy, the immediate family of a covered person is defined as the spouse, child, parent, brother, sister, grandchild, or grandparent, by blood, marriage, or adoption, of the covered person, or an individual who is an Adult Designee of the covered person.

Other Board of Regents policies that apply to conflicts of interest in addition to the Section 3.8 of the BOR policies include the provisions of §49-14,101.01 of the Nebraska Revised Statutes⁴ on conflict of

³ Section 3.4.5 and 3.8 of the Bylaws of the Board of Regents of the University of Nebraska, Nebraska Conflict of Interest Statutes, Neb. Rev. Stat. §49-1493 *et. seq.*, Board of Regents Conflict of Interest Policy, RP-3.2.8, US Public Health Service (42 CFR Part 50, Subpart F and 45 CFR Part 94.1), Food and Drug Administration (21 CFR 54), National Science Foundation (Grant Policy Manual 05-131 § 510), US Department of Education (34 CFR 75.524, 34 CFR 75.525 and 34 CFR 74.42) and other relevant federal policies.

⁴ "A public official or public employee shall not use or authorize the use of his or her public office or any confidential information received through the holding of a public office to obtain financial gain, other than compensation provided by law, for himself or herself, a member of his or her immediate family, or a business with which the individual is associated," and " A public official or public employee shall not use or authorize the use of personnel, resources, property, or funds under his or her official care and control other than in accordance with prescribed constitutional, statutory, and regulatory procedures or use such items, other than compensation provided by law, for personal financial gain."

interest in employment, Board Policy 6.2.1.12 on conflict of interest in procurement of University Goods and Services, and BOR Bylaws 3.4.5 pertaining to conflict of commitment.

III. Institutional Responsibilities

According to Regents Policy 3.2.8, the Chancellor shall be responsible for overseeing the campus reporting process and submitting the campus processes and procedures to the President for review and approval. The procedures for disclosure must, at a minimum, include the following:

1. Annual disclosures by covered persons engaged in sponsored research activity.
2. A description of the process for developing, implementing, and overseeing conflict management plans, including a detailed process for managing and/or eliminating potential conflicts of interest.
3. A description of procedures for ensuring coordination among all University organizations with a role in oversight of conflicts.
4. A description of the process by which a covered person may address concerns regarding a conflict of interest situation or the management thereof.
5. A description of how:
 - a. Disclosures will be reviewed and retained
 - b. The number of conflicts of interest (i.e. Intellectual Property Rights, Sponsor IP/Publication Rights, Outside Employment, and Outside Ownership/Revenue) in each college, will be reported to the President annually;
 - c. Responsible campus officials are to review and manage potential conflicts of interest;
 - d. The campus will provide related training and advice about conflict of interest issues;
 - e. The campus will review and validate their program on a regular basis;
 - f. The campus will make its implementation procedures for this policy available publicly; and
 - g. The institution will enforce this policy and provide sanctions when necessary.

The UNL Office of Research and Economic Development is responsible for providing guidance and interpretation of the conflict of interest policy and training to UNL administrators, faculty, staff and students. The UNL Office of Research and Economic Development is also responsible for reporting a conflict of interest to the sponsor or federal agency as required⁵. If additional review and input are warranted, the matter may be forwarded to the conflict of interest committee⁶. The conflict of interest committee is responsible for the development and/or approval of management plans pertaining to conflicts of interest on the UNL campus. The conflict of interest management plan will be reviewed by the conflict of interest committee no less than every five years.

⁵ National Science Foundation regulations and guidelines (42 CFR Part 50, Subpart F and 45 CFR Part 94.1), Department of Education regulations (34 CFR Part 75.524, 34 CFR Part 75.525 and 34 CFR Part 74.42), and FDA regulations (21 CFR Part 54)

⁶ Board of Regents Policy 3.2.8

IV. Institutional Conflict of Interest

Institutional conflicts of interest may involve any University activity carried out in the pursuit of the University's mission. Of particular concern are conflicts that arise in the conduct of research involving human subjects, but any activity in which the judgment of those involved becomes affected by University financial relationships may lead to a violation of this Policy.

A. Procedures for Identifying and Managing Institutional Conflicts of Interest and Equity Interests for Senior Administrators

A conflict of interest may arise when a senior administrator, from the level of the Vice Chancellor and higher, or his or her family has a financial interest that impairs or appears to impair the Senior Administrator's judgment. Specific examples of these situations and the recommended management procedures are contained in Appendix II. Section 1.10.1 of the Bylaws of the Board of Regents requires University of Nebraska employees to conform to the following guidelines. University of Nebraska employees shall make certain that no outside activities interfere with the discharge of University obligations.

To satisfy these requirements, all senior administrators must disclose their financial interests to the Nebraska Accountability and Disclosure Commission. The Vice President and General Counsel are responsible for oversight and management of the outside interests and activities of senior administrators. If a senior administrator has a financial interest that relates to the conduct of research, the Vice President and General Counsel coordinate management with the institutional conflict of interest committee and Research Compliance Services within the Office of Research Responsibility.

B. Procedures for Identifying and Managing Institutional Conflicts of Interest and Equity Interests for the Institution

An institutional conflict may arise when an institution's own financial interests (e.g., royalties, equity, stockholdings, and gifts) pose risks of undue influence on decisions involving the institution's research. The University of Nebraska-Lincoln shall make certain that no financial interests interfere with the discharge of University obligations. The Vice President and General Counsel in coordination with the institutional conflict of interest committee are responsible for oversight and management of the institution's financial interests.

C. Institutional Conflict of Interest Committee

The purpose of the institutional conflict of interest committee is to review institutional-related conflicts of interest and approve plans to manage the conflict of interest. The institutional conflict of interest committee is a standing committee composed of the Vice Chancellor of Research and Economic Development, Vice Chancellor for Business and Finance, Vice Chancellor for Academic Affairs and Vice Chancellor for the Institute of Agriculture and Natural Resources (or their designees). A representative from the University of Nebraska Board of Regents, the Faculty Senate President and a non-university affiliated representative are additional members of this committee.

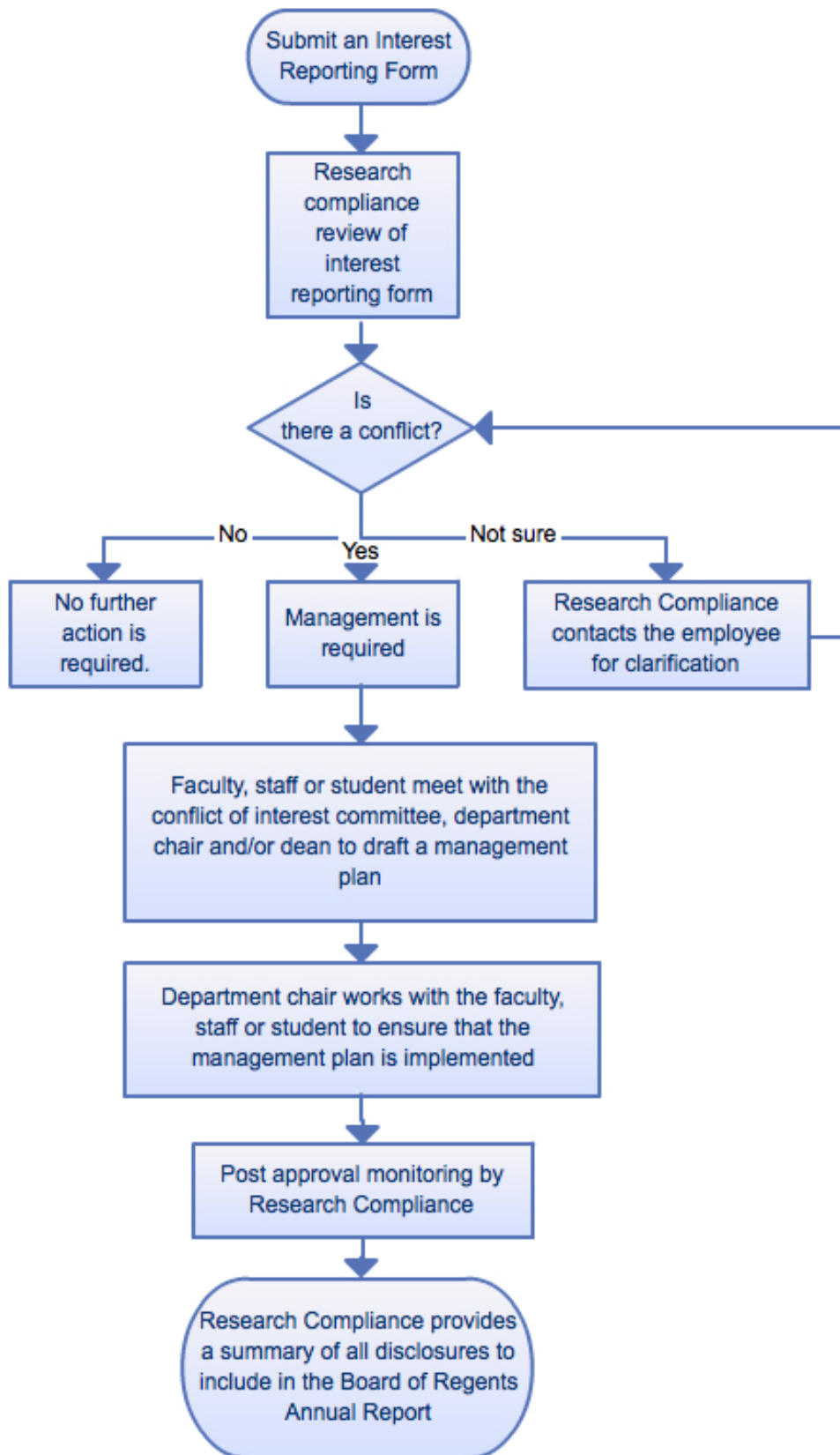
V. Individual Conflict of Interest in Research

The administrative process that pertains to conflicts of interest in research contains four basic steps: Disclosure, Review, Management (where indicated), and Reporting (where indicated); this process is outlined in the flowchart shown in Section A. Please note that before the University will accept a sponsored award,⁷ Interest Reporting Forms must be completed by all key personnel.⁸ Interest Reporting Forms will undergo a programmatic review to determine whether a real, perceived, or potential conflict of interest in research exists; should such a conflict exist, a management plan must be established and approved by the conflict of interest in research committee. In addition, information regarding the presence of conflicts of interest pertaining to all subawardees must be reviewed prior to accepting an award. Examples of conflicts of interest and the recommended management strategies are listed in Appendix III.

⁷ Note: PHS regulations indicate that key personnel must make a disclosure to the appropriate institutional representatives at the time of submitting an application for PHS funding. If award is funded, the institutional representative must submit a financial conflict of interest report (if applicable) to the PHS agency prior to the expenditure of funds.

⁸ PHS regulations refer to these key personnel as “Investigators.” The PHS defines Investigators as “the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS ... including consultants and contractors. Institutions should consider the role, rather than the title, of those involved in research and the degree of independence with which these individuals work.”

A. Management Process Flowchart



B. Reporting Process for Individual Financial Interest Related to Research

1. Annual Reporting

A UNL Interest and Outside Activity Reporting Form ⁹ must be completed annually through NUgrant by all UNL faculty, staff, students and affiliates involved in research.

2. Changes to the Interest and Outside Activity Reporting Form

Any changes to the information provided annually must be submitted within 30 days of the change. Changes include, but are not limited to:

- Creation of a new startup company
- Sponsorship of a research project by a new outside entity
- Changes in the amount of personal financial remuneration received from outside entities, e.g. additional consulting
- Engagement in or changes in an existing unremunerated service role or position, e.g. serving on a Board of Directors of a non-profit corporation
- Submission of an SBIR or STTR application
- Reimbursed or sponsored travel

C. Confidentiality

It is extremely important to guard the privacy of all of those disclosing financial interests. Therefore, all information shall be kept as a personnel record in NUgrant with restricted access. Information will be kept for seven years following the end of the research activity presenting the conflict of interest.

D. Conflict of Interest in Research Committee

The purpose of the conflict of interest in research committee is to review research-related conflicts of interest and approve plans to manage the individual conflict of interest in research.¹⁰ The conflict of interest in research committee ¹¹ is a standing committee selected by the Institutional Official acting on behalf of the Vice Chancellor for Research and Economic Development. The committee is composed of seven tenured or tenure track faculty members representing the College of Arts and Sciences, College of Engineering, College of Law, Institute of Agriculture and Natural Resources (the Agricultural Research Division and/or the Cooperative Extension Division) and including the Faculty Senate President and Academic Rights and Responsibilities Committee Chair (or their designees). The chair of the conflict of interest in research committee will be chosen by a vote of the committee members. In addition to the seven voting members, the Institutional Official and a single representative from the offices of Sponsored Programs, General Counsel and NUtech Ventures serve as *ex-officio*, non-voting committee members. The disclosing individual's department head/chair (and/or direct supervisor), dean and center director (if applicable) may also be invited to be present at the conflict of interest in research committee meetings to review the disclosed conflict of interest.

⁹ To satisfy the disclosure requirements of the Board of Regents Conflict of Interest Policy, RP-3.2.8

¹⁰ Articles 1.008, 1.009 & 1.016

¹¹ Articles 1.006, 1.008 and 1.011

The conflict of interest in research committee meetings are presided over by the chair. A management plan for the conflict of interest is voted on by the committee with a simple majority of the voting membership constituting a quorum required to conduct committee business.

E. Management Process

Management plans are the typical vehicle for managing most conflict of interest situations. The research compliance staff within the Office of Research Responsibility will work with the faculty, staff, or student and the appropriate administrator to develop a draft management plan.

The entire disclosure and management process is listed below.

1. The faculty, staff member or student completes an online Interest and Outside Activity Reporting Form via NUgrant.¹²
2. The research compliance staff within the Office of Research Responsibility evaluates each Interest and Outside Activity Reporting Form, consulting with individuals and offices involved as necessary.
3. If no management plan is necessary, the research compliance staff within the Office of Research Responsibility notifies the person who submitted the disclosure. [The disclosure will be included in a report that is submitted to the Board of Regents.]
4. If a management plan is necessary, the conflict of interest in research committee meets with the faculty, staff member or student and their immediate supervisor, department head/chair and/or dean/director as appropriate to develop and approve a management plan. A management plan may include elements such as:
 - Disclosure of the conflict of interest in all presentations and publications, written notification to the research sponsor, and in the informed consent to human research participants
 - Independent monitoring of the research or other academic project (Scientific Advisory Board)
 - Eliminate potential bias through means such as modifying the scope of the project, and/or setting timetables for delivery of the product
 - Designate a colleague or department chair with no conflict of interest relationship to the research to serve as an academic co-advisor or lead investigator
 - Divest the financial interest giving rise to the conflict
 - Sever relationships that are the source of the conflict of interest
 - Remove contract terms that create the conflict of interest in research (e.g., where payment depends upon the outcome of the research)
 - After careful consideration, disqualify an individual from participation in the project (*Only in rare instances will the committee determine that no management plan can manage, reduce, or eliminate the conflict of interest adequately.*)
5. The research compliance staff within the Office of Research Responsibility reports that the management plan has been established to the University of Nebraska Board of Regents and federal funding agencies, as required.

¹² <https://nugrant.unl.edu>

Once a management plan has been approved by the committee, everyone involved in the research project will be advised of the existing conflict of interest and to anticipate potential issues (e.g., forming student thesis committees, arrange an independent review of thesis projects by the graduate chair or co-advisors). Research participants will also be informed that the graduate chair, department head, dean and/or the research compliance staff within the Office of Research Responsibility are available for consultation at any time.

F. Training

Public Health Service (PHS) rules require that conflict of interest training occur prior to engaging in research and every 4 years following the initial training for all researchers applying for PHS funding. In addition, training may be required when there is a change in institutional policies, an investigator joins UNL or there is a case of noncompliance.

G. Disclosure of Sponsored Travel

Public Health Service (PHS) rules require increased transparency for reimbursement of travel expenses. Investigators now must disclose reimbursed or sponsored travel related to the investigator's institutional responsibilities. Travel that is reimbursed or sponsored by federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an Institution of higher education does not have to be disclosed. Reimbursed or sponsored travel will be disclosed via the NUgrant Interest and Outside Activity Reporting Form online as described in Section V. B. Reporting Process for individual financial interest related to research above.

H. Post-Approval Monitoring

An appropriate management plan must be in place before the University will accept any sponsored award in which a financial or management conflict is judged to exist. Post-approval monitoring processes may be put into place and can include updates to the Interest and Outside Activity Reporting Form, academic co-advisor reviews of student progress, and visits to the laboratory, research center, office, or place of business of the faculty, staff member or student. Any post-approval monitoring requirements will be included in the approved management plan.

All disclosure forms, records, management plans, and minutes from the conflict of interest in research committee meeting will be retained in NUgrant for seven years following the end of the research activity. This information is confidential and available only to pertinent personnel (e.g., the conflict of interest in research committee, institutional official, and Vice-Chancellor for Research and Economic Development).

I. Corrective Action

Failure of the faculty, staff or students to disclose a conflict of interest, comply with the conflict of interest policy or failure to comply with the management plan will be referred to the Institutional Official, the conflict of interest in research committee and the department head/chair for non-compliance review. Failure to comply will also be reported to the awarding agency and corrective action may affect the award process. The University may also decline or withhold funding in all cases in which the investigator does not comply with the established conflict of interest management plan. Other consequences may include a letter of reprimand or the removal of an investigator from an ongoing project and corrective action may result up to and including termination of employment.

For PHS research and any other sponsor with reporting requirements, the Director of the Office of Sponsored Programs will notify the relevant agency when the Institutional Official and the conflict of interest in research committee has determined that a noncompliance issue exists.¹³

PHS also requires each institution to conduct a retrospective review in those cases of non-compliance with the regulation but it is not required to report the review to the PHS Awarding Component. The Institution will be required to notify the PHS Awarding Component promptly and submit a report to the

¹³ 42 CFR §50 Subpart F, 34 CFR §74.51

PHS Awarding Component only in cases where bias is found. The report will address the impact of the bias on the research project and the actions the Institution has taken, or will take, to eliminate or mitigate the effect of the bias.

J. Appeal Process

A decision by the conflict of interest in research committee may be appealed to the Chancellor within 30 days of the date the committee notifies the faculty, staff or student of the committee's decision.

Appendix I. Definitions (for the purposes of this policy)

- A. *Compensated Professional/Commercial Activity (Outside Activity)* includes outside consulting, refers to paid service as a technical or professional adviser or practitioner. It is the use of one's professional capabilities to further the agenda of a third party for personal financial gain, whether one is on the payroll of the organization, working as an independent contractor, or serving as director or manager.
- B. *Conflict of Commitment* occurs when the time devoted to external activities adversely affects a faculty member's capacity to meet University responsibilities.
- C. *Conflicts of Interest* are situations where a *Covered Person's* direct or indirect personal financial interests may compromise, or have the appearance of compromising, the *Covered Person's* professional judgment or behavior in carrying out his or her obligations to the University of Nebraska-Lincoln. This includes indirect personal financial interests of a *Covered Person* that may be obtained through third parties such as a *Covered Person's Immediate Family*, business relationships, fiduciary relationships, or investments.
- D. *Covered Person* means:
 - 1) University administrative officers and employees, specifically including any University employees with delegated signature, purchasing or contracting authority on behalf of the University;
 - 2) University employees and faculty engaged in outside employment or other activities specified in this policy (technology transfer/use of University facilities or equipment) that may create a *Conflict of Interest*; and
 - 3) Sponsored Research investigators, including University employees, faculty, staff and support personnel (managerial/professional and office/service positions), volunteers, trainees, students, contractors and other persons under the direct control of the University of Nebraska, whether paid by the University of Nebraska or not, who participate in *Sponsored Research* as defined in Section 6 of the Board of Regents policy 3.2.8.
- E. *Disclosure of Financial Interests* means a *Covered Person's* disclosure of financial interests to the University of Nebraska - Lincoln.
- F. *Equity Interest* includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- G. *Financial Interest* means anything of monetary value, whether or not the value is readily ascertainable.
- H. *Immediate Family* shall mean an individual who is the spouse, child, parent, brother, sister, grandchild, or grandparent, by blood, marriage, or adoption of the *Covered Person*, or an individual who is the Adult Designee of the *Covered Person*.
- I. An *Institutional Conflict of Interest* may occur when the University or a *Covered Person* in a senior administrative position has a financial interest in a commercial entity that itself has an interest in a University research project, including potential conflicts with equity/ownership interests or royalty arrangements.
- J. *Key Personnel/Investigators* means those who are responsible for the design, conduct, or reporting of research, this may include collaborators or consultants.
- K. *Non-compensated Professional Activities* are those outside activities that extend and enhance the normal institutional responsibilities of teaching, research, and service to serving public institutions, educational organizations, and professional societies for the faculty or staff member.
- L. *Remuneration* includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- M. *Research Compliance Staff* are the staff members of the Office of Research Responsibility that handle issues related to conflicts of interest. These include, the Director of Research Compliance Services, and Research Compliance Services Specialists.
- N. *Senior Administrators* are University administrative officers and employees, specifically including any University employees with delegated signature, purchasing or contracting authority on behalf of the University.
- O. *Significant Financial Interest* means a financial interest consisting of one or more of the following interests of the *Covered Person* or their *Immediate Family* that reasonably appears to be a conflict of interest:
 - 1) With regard to any publicly traded entity, 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;
 - 2) With regard to any non-publicly traded entity, 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 person or their immediate family holds any equity interest (*e.g.*, stock, stock option, or other ownership interest);
 - 3) Intellectual property rights and interests (*e.g.*, patents, copyrights).
- P. *Sponsored Research* means research, training, and instructional projects performed by *Covered Persons* using any University space, materials, equipment or property that involves funds, materials or other compensation from sources outside the University through a grant or contract that obligates the University to a specified statement of work, sets forth binding financial terms in the form of a budget or up-front payment, or contains terms related to ownership of any rights to use intellectual property developed thereunder.
- Q. *Sponsored Travel* includes travel expenses paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available.

Appendix II. Institutional Conflict of Interest can result from a variety of situations - the following table represents some common situations along with the recommended management.

| Institutional Conflict of Interest | |
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| <p>Issue I.a: University having financial holdings in a company sponsoring research at the University</p> <p>Conflict: Administrator(s) may be conflicted about:</p> <p>(a) Allowing researchers to publish potentially damaging research findings without regard for the company's reputation</p> <p style="text-align: center;">- OR -</p> <p>(b) Pressuring the investigator to censor research findings that might damage the sponsoring company</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Establish separate reporting structure for the management of the University's equity holdings and its research affairs • Maintain and update annually: <ul style="list-style-type: none"> ○ University equity holdings ○ Companies that hold option or licensing rights ○ Corporate donors |
| <p>Issue I.b: Senior administrators having equity or ownership interest in a company sponsoring research at the university</p> <p>Conflict: Administrator(s) may be conflicted between their:</p> <p>(a) Personal financial holdings</p> <p style="text-align: center;">- AND -</p> <p>(b) Institutional Responsibilities: making decisions that have institution-wide impact and are made on behalf of the University without regard to their own financial benefit</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Disclose all financial interests <ul style="list-style-type: none"> ○ Compensation (e.g., consulting fees or honoraria); ○ Equity interests ○ Intellectual property rights • All disclosures must be reviewed by the institutional conflict of interest committee • Any administrators with a financial interest in a company sponsoring research at the University, must recuse themselves from decision making processes involving these companies. |
| <p>Issue I.c: Senior administrators holding a management position in a company sponsoring research at the university</p> <p>Conflict: Administrator(s) may be conflicted between their:</p> <p>(a) Personal financial holdings</p> <p style="text-align: center;">- AND -</p> <p>(b) Institutional Responsibilities: making decisions that have institution-wide impact and are made on behalf of the University without regard to their own financial benefit</p> | <ul style="list-style-type: none"> • Disclose all financial interests <ul style="list-style-type: none"> ○ Compensation (e.g., consulting fees or honoraria); ○ Equity interests ○ Intellectual property rights • All disclosures must be reviewed by the institutional conflict of interest committee • Any administrators with a financial interest in a company sponsoring research at the University must recuse themselves from decision making processes involving these companies. |

Institutional Conflict of Interest involving Clinical Trials

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| <p>Issue I.d: University financial holdings in a company involved in a clinical trial at the University</p> <p>Conflict: Administrator(s) may be conflicted about:</p> <p>(a) Allowing researchers to publish potentially damaging research findings without regard for the company's reputation</p> <p style="text-align: center;">- OR -</p> <p>(b) Pressuring the investigator to censor research findings that might damage the sponsoring company</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Establish separate reporting structure for the management of the University's equity holdings and its research affairs • Maintain and update annually: <ul style="list-style-type: none"> ○ University equity holdings ○ Companies that hold option or licensing rights ○ Corporate donors |
| <p>Issue I.e: Senior administrators having equity or ownership interest in a company involved in a clinical trial at the university</p> <p>Conflict: Administrator may be conflicted between their:</p> <p>(a) Personal Financial Holdings</p> <p style="text-align: center;">- AND -</p> <p>(b) Institutional Responsibilities: making decisions that have institution-wide impact and are made on behalf of the University without regard to their own financial benefit</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Disclose all financial interests <ul style="list-style-type: none"> ○ Compensation (e.g., consulting fees or honoraria); ○ Equity interests ○ Intellectual property rights • All disclosures must be reviewed by the institutional conflict of interest committee • Any administrators with a financial interest in a company sponsoring research at the University, must recuse themselves from decision making processes involving these companies |
| <p>Issue I.f: Senior administrators holding a management position in a company involved in a clinical trial at the university</p> <p>Conflict: Administrator may be conflicted between their:</p> <p>(a) Personal Financial Holdings</p> <p style="text-align: center;">- AND -</p> <p>(b) Institutional Responsibilities: making decisions that have institution-wide impact and are made on behalf of the University without regard to their own financial benefit</p> | <ul style="list-style-type: none"> • Disclose all financial interests <ul style="list-style-type: none"> ○ Compensation (e.g., consulting fees or honoraria); ○ Equity interests ○ Intellectual property rights • All disclosures must be reviewed by the institutional conflict of interest committee • Any administrators with a financial interest in a company sponsoring research at the University must recuse themselves from decision making processes involving these companies |
| <p>Issue I.g : Senior administrators being an inventor on intellectual property licensed to a company involved in a clinical trial at the university</p> <p>Conflict: Administrator may be conflicted between their:</p> <p>(a) Personal Financial Holdings</p> <p style="text-align: center;">- AND -</p> <p>(b) Institutional Responsibilities: making decisions that have institution-wide impact and are made on behalf of the University without regard to their own financial benefit</p> | <ul style="list-style-type: none"> • Disclose all financial interests <ul style="list-style-type: none"> ○ Compensation (e.g., consulting fees or honoraria); ○ Equity interests ○ Intellectual property rights • All disclosures must be reviewed by the institutional conflict of interest committee • Any administrators with a financial interest in a company sponsoring research at the University must recuse themselves from decision making processes involving these companies |

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Appendix III. Individual Conflict of interest can result from a variety of situations - the following table represents some common situations along with the recommended management.

| Research Bias | |
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| <p>Issue III.a: Having a financial interest or holding a management position in a company that sponsors research may lead to biased research results.</p> <p>Conflict: Investigator(s) may be conflicted about:</p> <p>(c) Publishing potentially damaging research findings in the open literature without regard for the company's reputation</p> <p style="text-align: center;">- OR -</p> <p>(d) Censoring research findings that might damage the sponsoring company</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Prior to submission for publication, authors should have the manuscript internally reviewed by a peer without COI issues • Authors should disclose their business relationships with research sponsors in publications • Student authors should be reminded of the Student Advocate for COI issue • Anyone holding an ownership or management position in the Entity may not be the chair of the thesis committee. • The voting majority of the committee must not have an ownership or management position in the entity. • The research compliance staff within the Office of Research Responsibility will meet with the student annually |
| <p>Issue III.b: Having a financial interest or holding a management position in a company with a license to technology invented at UNL may lead to biased research results.</p> <p>Conflict: Investigator(s) may be conflicted about:</p> <p>(a) Publishing potentially damaging research findings in the open literature without regard for the company's reputation</p> <p style="text-align: center;">- OR -</p> <p>(b) Censoring research findings that might damage the sponsoring company</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Prior to submission for publication, authors should have the manuscript internally reviewed by a peer without COI issues • Authors should disclose their business relationships with research sponsors in publications • Student authors should be reminded of the Student Advocate for COI issues • Anyone holding an ownership or management position in the Entity may not be the chair of the thesis committee. • The voting majority of the committee must not have an ownership or management position in the entity. • The research compliance staff within the Office of Research Responsibility will meet with the student annually |
| <p>Issue III.c: Having a financial interest or holding a management position in a company receiving a subcontract from a UNL grant may lead to biased research results.</p> <p>Conflict: Investigator(s) may be conflicted about:</p> <p>(a) Using grant funds to support university research</p> <p style="text-align: center;">- OR -</p> <p>(b) Using the funds to further advance the company efforts</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Authors should disclose their business relationships with research sponsors in publications • Student authors should be reminded of the Student Advocate for COI issues • Vice Chancellor for Business and Finance approval is required |

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| <p>Issue III.d: Accepting sponsored research from a company with a license to technology invented at UNL may lead to biased research results.</p> <p>Conflict: Investigator(s) may be conflicted about:</p> <p>(a) Publishing potentially damaging research findings in the open literature without regard for the company's reputation</p> <p style="text-align: center;">- OR -</p> <p>(b) Censoring research findings that might damage the sponsoring company</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Prior to submission for publication, authors should have the manuscript internally reviewed by a peer without COI issues • Authors should disclose their business relationships with research sponsors in publications • Student authors should be reminded of the Student Advocate for COI issues • Anyone holding an ownership or management position in the Entity may not be the chair of the thesis committee. • The voting majority of the committee must not have an ownership or management position in the entity. • The research compliance staff within the Office of Research Responsibility will meet with the student annually |
| <p>Issue III.e: Allowing an outside entity to provide salary for investigator(s) may lead to biased research results.</p> <p>Conflict: Investigator(s) may be conflicted about:</p> <p>(a) Publishing potentially damaging research findings in the open literature without regard for the company's reputation</p> <p style="text-align: center;">- OR -</p> <p>(b) Censoring research findings that might damage the sponsoring company</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Prior to submission for publication, authors should have the manuscript internally reviewed by a peer without COI issues • Authors should disclose their business relationships with research sponsors in publications • Student authors should be reminded of the Student Advocate for COI issues • Anyone holding an ownership or management position in the Entity may not be the chair of the thesis committee. • The voting majority of the committee must not have an ownership or management position in the entity. • The research compliance staff within the Office of Research Responsibility will meet with the student annually |
| <p>Issue III.f: Consulting for companies or businesses that university employees endorse in their university position may lead to biased research results</p> <p>Conflict: Investigator(s) may be conflicted about:</p> <p>(a) Publishing potentially damaging research findings in the open literature without regard for the company's reputation</p> <p style="text-align: center;">- OR -</p> <p>(b) Censoring research findings that might damage the sponsoring company</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Authors should disclose their business relationships with research sponsors in publications • Student authors should be reminded of the Student Advocate for COI issues • Anyone holding an ownership or management position in the Entity may not be the chair of the thesis committee. • The voting majority of the committee must not have an ownership or management position in the entity. • The research compliance staff within the Office of Research Responsibility will meet with the student annually |

Student Welfare

Issue III.g: A student may be adversely affected if they are an employee of a company that sponsors research at UNL

Conflict:

Student may be conflicted about:

- (a) Publishing potentially damaging research findings in the open literature without regard for the company's reputation
- OR -
- (b) Censoring research findings that might damage the sponsoring company

Recommendation:

- Prior to submission for publication, authors should have the manuscript internally reviewed by a peer without COI issues
- Authors should disclose their business relationships with research sponsors in publications
- Student authors should be reminded of the Student Advocate for COI issues
- Anyone holding an ownership or management position in the company may not be the chair of the thesis committee.
- The voting majority of the thesis committee must not have an ownership or management position in the entity.
- The research compliance staff within the Office of Research Responsibility will meet with the student annually

Conflict of Commitment

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| <p>Issue III.i: Having a financial interest or holding a management position in a company that rents university facilities and/or equipment may represent a conflict of commitment for university employees.</p> <p>Conflict: University employees may be conflicted about:</p> <p>(a) Spending time teaching and conducting research - OR -</p> <p>(b) Spending time otherwise spent teaching on outside activities that produce supplemental income</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Vice Chancellor for Business and Finance approval is required. • Documentation of the separation of equipment and supplies that are owned by the university or the company on file with the interest reporting form • If applicable, have Outside Activities Form approved through Academic Affairs on file with the Interest Reporting Form |
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Unfair Competitive Advantage

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| <p>Issue III.j: UNL employees have an unfair competitive advantage when holding stock or a management position in a company that responds to a RFP from the University of Nebraska</p> <p>Conflict: Investigator may be conflicted about:</p> <p>(a) 'Scouting' for information regarding the decision making process to enhance the funding probability - OR -</p> <p>(b) Not participating in the funding decision making process and risk having the proposal not be funded</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • A detailed funding procedure not involving the investigator should be developed. • Department Chair should approve the proposal submission • If applicable, have Outside Activities Form approved through Academic Affairs on file with the Interest Reporting Form |
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| <p>Issue III.k: Serving on the Board of Directors or Scientific Advisory Board of a company from which university employees receive sponsored research funding may lead to an unfair competitive advantage.</p> <p>Conflict: University employee may be conflicted about:</p> <p>(a) Funding research proposals that compete with their own research - OR -</p> <p>(b) Deny funding proposals that may compete with their own research</p> | <p>Recommendation:</p> <ul style="list-style-type: none"> • Investigator(s) should disclose their funding relationships with the company to the scientific advisory committee or board • If applicable, have Outside Activities Form approved through Academic Affairs on file with the Interest Reporting Form |
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Other