DES MOINES UNIVERSITY

Origination:	*05/2014*
Last Approved:	*06/2015*
Last Revised:	*06/2015*
Next Review:	*06/2018*
Owner:	*Erika Linden: Chief Compliance Officer*
Area:	*Compliance*
References:	
Applicability:	*Des Moines University*

Conflict of Interest and Commitment

I. PURPOSE

As an academic health center, Des Moines University (DMU or the University) is committed to the principle that its activities be carried out with integrity and be free from outside conflicts of interest that might compromise, or give the appearance of compromising, the sound professional judgment of its employees and activities. This policy sets forth that position and provides a mechanism for DMU to comply with federal conflict of interest regulations and ensure institutional integrity when such conflicts arise. This policy also establishes guidelines for interaction between industry representatives and faculty, staff and students.

II. BACKGROUND

DMU recognizes the importance of relationships with external organizations, and seeks to encourage such relationships. Those associations can lead to significant innovations and to the translation of those discoveries into useful products and treatments. Productive relationships with external entities may also prompt new paths of inquiry and provide opportunities to test academic research. However, the financial incentives that accompany those relationships may lead to financial conflicts of interest or commitment which, left unmanaged, may create real or perceived bias. DMU supports principled relationships with Industry and other organizations with which its employees and students collaborate and interact.

In September 2011, the Public Health Service (PHS) and the Office of the Secretary of the U.S. Department of Health and Human Services (HHS) published revised regulations on the Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought and Responsible Prospective Contractors: Final Rule (42 CFR Part 50, 45 CFR Part 94), generally referred to as the Financial Conflict of Interest (FCOI) regulations, to "…address the increasing complexities of the financial interests held by biomedical and behavioral researchers and the resulting interactions among Government, research institutions, and the private sector." (HHS Frequently Asked Questions, September 30, 2011). The purpose of the revised regulations is to establish new standards and clarify existing requirements, increase accountability, add transparency, increase management of investigators' financial conflicts of interest, and bolster oversight by the National Institutes of Health (NIH).

This policy has been adopted to reflect the changes implemented by PHS and HHS, and to promote the public's trust in the University and the healthcare profession. The policy promotes the highest level of patient care, supports the objectivity of education, and protects the reputations of its employees, volunteers and students, and their professional commitment to the University. The policy is also designed to protect the integrity of research and the safety of human subjects involved in research. "Objectivity in research is of

paramount importance and the basis for obtaining and maintaining public trust." (HHS Frequently Asked Questions, September 30, 2011).

III. SCOPE

This policy applies to all DMU employees, including faculty members, adjunct faculty, staff, students, and volunteers. All DMU employees are required to disclose to the University any outside interests, including time commitments and financial relationships, with Industry or other outside organizations, and the outside interests of immediate family members that are related to the employee's Institutional Responsibilities. Disclosure of potential conflicts of interest is addressed in sections VI and VII.

In addition to this policy, two other conflict of interest policies exist: Conflict of Interest – Board of Trustees and Executive Leadership and Conflict of Interest Policy – CME Programs. This Conflict of Interest and Commitment policy shall take precedence, whenever a conflict exists related to a research project.

IV. PUBLIC ACCESSIBILITY TO WRITTEN POLICY

This Conflict of Interest and Commitment policy shall be available on the DMU public website in compliance with federal regulations (42 CFR Part 50.604(a)).

V. ABBREVIATIONS AND DEFINITIONS

A. Abbreviations

1. CE	Continuing Education
2. CCO	Chief Compliance Officer
3. CFR	Code of Federal Regulations
4. COI	Conflict of Interest
5. COIC	Conflict of Interest Committee
6. FCOI	Financial Conflict of Interest
7. HHS	Health and Human Services
8. IRB	Institutional Review Board
9. OOR	Office of Research
10. PHS	Public Health Service
11. SFI	Significant Financial Interest
12. VPR	Vice President of Research

B. Definitions

1. Conflict of Commitment: a situation in which an Individual engages in an outside activity which interferes, or appears to interfere, with fulfillment of the Individual's Institutional Responsibilities, even if the outside activity is valuable to DMU or contributes to the Individual's professional development and competence. Any relationship with an outside Entity that requires frequent and/or prolonged hours of effort spent

outside DMU may present a Conflict of Commitment, regardless of the amount of income received or the number of days, time of day or day of the week devoted to these activities.

2. Conflict of Interest: a situation in professional and scientific endeavors in which financial or other. personal considerations may compromise, or have the appearance of compromising, an Individual's professional judgment in conducting or reporting research, providing patient care, or carrying out or directing other types of Institutional programs and responsibilities. The bias that may result from such conflicts could impact not only the collection, analysis, interpretation and reporting of data, but also the delivery of patient care, hiring of staff, procurement of materials, or other activities.
3. Conflict of Interest Committee (COIC): an ad hoc committee of faculty, administrators, and employees responsible for ensuring that individual Conflicts of Interest in: 1) research are identified, managed, or eliminated, in accordance with federal regulations and in the best interests of research subjects, students, researchers and the Institution, and 2) clinical care and education are identified, managed, or eliminated, to ensure the best interest of patients, students, clinicians and the Institution. Ad hoc committee members are appointed by the individual that has oversight of the area in which a concern exists such as the Provost, Vice President for Research, Chief Compliance Officer, or Manager of Continuing Medical Education.
4. Conflict of Interest Officer: the individual responsible for implementing procedures governing the disclosure, review and management of potential Conflicts of Interest. At DMU the Vice President for Research serves as the Conflict of Interest Officer.
5. Designated Officials: the persons designated by the Institution to review all financial disclosures to determine whether any Significant Financial Interest (SFI) is related to research or an Individual's Institutional Responsibilities by making a reasonable determination that the SFI could be affected by NIH-funded research or is in an entity whose Financial Interest could be affected by the research. At DMU, members of the COIC are the Designated Officials.
6. Entity: any outside organization (excluding a Federal agency) from which an Investigator or Individual (and his/her spouse/domestic partner and dependent children) receives remuneration, has an ownership or Equity Interest, or spends considerable time.
7. Equity Interest: the ownership interest of shareholders in a for-profit corporation, partnership, or similar organization, as determined through reference to public prices or other resources of fair market value.
8. Financial Conflict of Interest (FCOI): a situation in which the Institution' Designated Official(s) reasonably determine that an Individual's Significant Financial Interest (SFI) is related to: 1) a Public Health Service (PHS)-funded research project and could directly and significantly affect the design, conduct, or reporting of PHS-funded research, and/or 2) other types of Institutional programs and responsibilities.
9. Financial Interest: anything of monetary value, whether or not the value is readily ascertainable, including, but not limited to, income for services, ownership, Equity Interest, and fiduciary or management relationships, whether paid or unpaid.
10. Ghostwriting: a circumstance in which an Individual is credited with authorship of a document that was substantially written by an uncredited third party.
11. Income: an amount of money received during a period of time in exchange for labor or services, from the sale of goods or property, or as a profit from financial investments.
12. Individual: a DMU faculty member, adjunct faculty, employee, student, or volunteer who owes a primary duty of loyalty and support to the Institution, including part-time appointments. Individual includes spouse, domestic partner, and dependent children when considering financial or fiduciary interests.

13. Industry: biomedical, pharmaceutical and medical device companies, and manufacturers of other products used in the treatment of patients or the provision of medical care; this definition does not include University Vendors/Suppliers who provide other non-clinical goods and services to the Institution.
14. Industry Representatives: all sales, marketing and other product-oriented personnel who interact with faculty, staff or students to promote Industry products.
15. Institution: Des Moines University.
16. Institutional Responsibilities: an Individual's professional responsibilities on behalf of the Institution, which may include, for example, activities such as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
17. Intellectual Property: includes issued patents, patent applications, copyrights, trademarks and trade secrets.
18. Investigator: the Project Director or Principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research and may include, for example, collaborators or consultants. It also includes all Individuals who have the authority to make independent decisions about the direction of the research and the subsequent conclusions about the results. Also includes Key Personnel listed on an Institutional Review Board application or Grants and Contracts routing form. Individuals who are likely to be authors on manuscripts or present research findings at national conferences are also considered Investigators. Administrative personnel or Individuals who perform routine, pre-defined service or incidental tasks related to the research project are not considered Investigators.
19. Key Personnel: Individuals, including the Project Director/Principal Investigator (PD/PI) and other personnel, considered to be essential to work performance in accordance with HHSAR Subpart 352.242-70 and identified as Key Personnel in a contract proposal, contract, and/or research compliance application.
20. Management Strategy: the written plan developed to address a FCOI, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct and reporting of research or an Individual's Institutional Responsibilities will be free from bias, and that clinical care and education are in the best interest of patients, students and the Institution.
21. Outside Employment: personal services provided by an Individual for Entities outside the Institution for which the Individual spends considerable time and/or receives compensation.
22. Outside Interest: a personal professional relationship with any Entity (excluding a Federal agency) with which an Individual (or spouse/domestic partner or dependent children) has a Financial Interest or regular time commitment.
23. PD/PI: means a Project Director or Principal Investigator; the PD/PI is included in the definitions of Key Personnel and Investigator.
24. Significant Financial Interest (SFI): a financial interest consisting of one or more of the following interests of the Individual (and of the Individual's spouse/domestic partner and dependent children) that reasonably appears to be related to the Individual's Institutional Responsibilities:
    a. 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. For purposes of this definition, 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;

b. 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 Individual (or the Individual's spouse/domestic partner or dependent children) holds any Equity Interest (e.g., stock, stock option, or other ownership interest); or

c. Intellectual Property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

d. Significant Financial Interest EXCLUSIONS:

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

- Salary, royalties, or other remuneration paid by the Institution to the Individual if the Individual is currently employed, including Intellectual Property rights assigned to the Institution and agreements to share in royalties related to such rights;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Individual 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, a U.S. institution of higher education as defined at 20 U.S.C. 1001(a), 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, U.S. institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

25. Sponsored or Reimbursed Travel Disclosure: a form that serves as the disclosure for reimbursed or sponsored travel and must be completed in its entirety prior to any professional travel. Reimbursed or sponsored travel information will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of travel. The Office of Research (OOR) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest (FCOI) with PHS-funded research.

    Travel to participate in annual meetings or professional societies are excluded from the requirements for Sponsored or Reimbursed Travel Disclosure.

26. Sponsored Travel: any travel that is paid on behalf of the Individual and related to the Individual's Institutional Responsibilities, and is not reimbursed to the Individual in a way so that the exact monetary value may is readily available, provided by an outside Entity other than the following:

    a. A federal, state, or local government agency

    b. A U.S. institution of higher education as defined at 20 U.S.C. 1001(a)

    c. An academic teaching hospital

    d. A medical center

e. A research institute that is affiliated with a U.S. institution of higher education.

27. Start-Up Company: a newly formed, privately-held, for-profit company, usually based on the Intellectual Property of an Institutional employee.
28. Subrecipient: a party that receives a sub-award from a recipient or another Subrecipient under a Federal financial assistance award and is accountable to the recipient or Subrecipient for the use of the Federal funds provided by the sub-award.
29. University Vendor/Supplier: an organization from which the Institution purchases non-clinical goods and services; this definition does not include organizations in the biomedical, pharmaceutical or medical device industry which are defined in this policy as Industry.

VI. CONFLICT OF COMMITMENT AND DISCLOSURE

Individuals, in recognizing that their primary professional responsibility is to the Institution, will devote their energies to external activities in congruence with the Institution's mission and will conform to each section of this policy. Faculty members and employees are required to disclose any outside commitments annually through procedures established by the OOR. Department Chair/Director/Vice President/ELT Member are responsible for reviewing, evaluating and managing any Conflict of Commitment identified in their area of responsibility.

A. Commitment of Time to Consulting and Outside Employment

The use of time for Outside Employment and consulting activities is a privilege and not a right. Individuals who participate in consulting or Outside Employment must discuss these commitments with their supervisors prior to commencement of the outside activity in accordance with the provisions in section VIII.A of this policy.

1. Reportable Conflicts of Commitment include, but are not limited to, arrangements with outside Entities, including consulting, speaking, expert testimony, paid court appearances, research, laboratory testing, and teaching. Other reportable activities are fiduciary and management roles in organizations outside the Institution, including boards of directors, officer, manager, or medical director of a for-profit company, non-profit organization or charitable foundation.
2. Non-reportable Conflicts of Commitment include membership on peer review panels, visiting professorships or lectureships at academic medical centers, Federal and non-federal study section membership, grant review panels, textbook editorships, membership on advisory groups/councils for not-for-profit organizations, and fiduciary and management roles in academic societies.

B. Use of the Institution's Resources

1. DMU personnel are prohibited from using DMU resources, including but not limited to, paid time, staff and student time or effort, information, equipment, supplies, services such as email systems, server space, copy services, etc., in any external endeavor in which the Individual or an outside Entity will profit.
2. Because consulting arrangements and publication of books involve an Individual's personal effort, contracts for publications and payment of related royalties are not subject to sharing of income with the Institution, although they still must be reported and approved by the Individual's immediate supervisor, prior to any activity.

3. Prior written approval must be obtained and approved by the Individual's immediate supervisor if the Institution will be investing its resources and sharing in the risks of a venture or in any other way subsidizing the activity, whether or not DMU is sharing in any revenues generated by the activity.

C. Use of the Institution's Names, Symbols or Logos

Since collaborative relationships can be of great value to an outside Entity, opportunities for outside activities may be offered to an Individual in part because of their association with DMU. Individuals cannot participate in such activities completely independently of their affiliation with the Institution. In addition, if an outside Entity wishes to use any of the Institution's names, symbols or logos, written approval from Marketing and Communications must be obtained prior to such use.

D. Sharing of Intellectual or Tangible Property

Individuals must also disclose any relationship they are considering or are engaged in with an outside Entity, a) if the Entity anticipates providing financial or other support for the Individual's work, or b) if the Entity anticipates utilization of Intellectual Property (e.g., inventions, know-how) or tangible property (e.g., research materials) or original works of authorship (e.g., computer software but not textbooks) of that Individual's academic work or the work of a subordinate Individual, in compliance with the Intellectual Property policy.

E. Employment of Relatives (Nepotism)

Individuals acting as Investigators or otherwise conducting industry-sponsored research will report their intention to employ an immediate family member as required in the Nepotism Policy. Such Individuals will cooperate with the Chief Human Resources Officer to minimize or eliminate the appearance of bias that may be created by collaborating or working directly with an immediate family member.

VII. CONFLICT OF INTEREST AND DISCLOSURE

A. Annual Disclosure

The Institution requires that all DMU full-time and regular part-time (0.5 FTE or greater) employees, except Guest Lecturers, Standardized Patients, Fellows, Exercise Instructors, Temporary/Leased Employees, and Students, review this policy and disclose annually all Outside Employment and other outside interests, both research and non-research related, through the disclosure process. Annual disclosure must be completed within 30 days of receipt of the reminder notification from the OOR. All annual disclosures will be reviewed by the employee's Department Chair/Director/Vice President/ELT Member as defined by Human Resources, prior to submission of the disclosure to the OOR. Upon receipt of a disclosure of outside interest from an Individual, the OOR will work with the Individual to identify any Financial Interest and provide guidance to the designated COIC regarding coordination of review and management of any identified Conflict of Interest. Individuals must update their disclosure within 30 days of a substantial change in external activities to the OOR; disclosure must occur prior to initiating the activity (or at the point at which a non-disclosed activity exceeds the disclosure threshold).

1. Disclosure of sponsor-specific interests is required with submission of grants, contracts, and regulatory protocols and through requisitions to Institutional purchasing committees.
2. In clinical research, all financial relationships with Industry must be disclosed to the human subjects

enrolled in the project.

3. Public disclosure of outside interests is required for all publications (including news releases), presentations (including posters), and approved media contact related to a Individual's relationship with the research sponsor or in the ownership of related Entity or Intellectual Property, such as new or experimental drugs, devices or therapies.
4. Prior to professional travel funded by Industry, the Individual will disclose the sponsor's name, the destination, purpose and duration of travel by fully completing the Sponsored or Reimbursed Travel Disclosure Form.
5. Clinicians with past and/or present financial relationships with Industry (e.g., consulting and speaking agreements, research contracts) must verbally disclose relationships to patients when such a relationship might appear to be a Conflict of Interest.
6. Disclosure of Financial Interests will be made by all IRB members and by all Institutional purchasing and formulary committee members. Committee members with a Financial Interest in an Industry sponsor or University Vendor/Supplier will recuse themselves from voting on decisions involving the Entity in which they have an interest, and the recusal will be documented in minutes of committee proceedings.

B. Conflict of Interest in Research

The OOR evaluates all disclosures of outside interests for any disclosed FCOI, including a review of related research projects, to determine if a SFI exists. This review will be conducted for all research (i.e., funded, unfunded, or sponsored). If the OOR determines that a FCOI exists, the VPR shall appoint an ad hoc COIC to review the design, conduct, and reporting of the research and implement the appropriate Management Strategy and Federal reporting in accordance with PHS Regulations 42 CFR, Part 50, Subpart F and 45 CFR, Part 94, to protect the credibility and integrity of the PD/PI, Institution and its employees. The COIC will follow a documented process developed by the OOR.

C. Conflict of Interest in Human Subject Research

If a Conflict of Interest is identified in research involving human subjects, the IRB and the ad hoc COIC will conduct their respective reviews in parallel, and the IRB will withhold final approval pending the completion of the COIC review, resolution of the issues, and recommendations for a Management Strategy.

1. Investigators with Significant Financial Interest (SFI) Conducting Research Involving Humans

   As a general policy, an Investigator will not be permitted to conduct research involving human participants when the Investigator holds a related SFI. In clinical research posing a greater than minimal risk (i.e., the study is designed to answer questions about the effects or impact of particular drugs, treatments, or diagnostic/therapeutic devices), disclosure and standard conflict Management Strategies are inadequate, and adequate monitoring plans may be difficult or impossible to implement. The University will not allow an Investigator holding a SFI to conduct clinical research in the areas noted above unless the Investigator presents a compelling justification for a waiver to this policy based on the unique qualifications of the Investigator. The conduct covered by this policy includes selection of participants, administering informed consent, and/or protocol-mandated clinical care. If compelling circumstances justify a waiver of this policy, the research will be subject to stringent management measures to ensure the safety of the human participants and the integrity of the research.
2. Delegation of Conduct of the Research

Investigators holding a SFI may not delegate the conduct of research to trainees or other employees over whom the Investigator has direct supervision (e.g., student, graduate student, or research assistant) unless written approval of the Department Chair, Dean and the VPR is obtained. This written approval must accompany the Conflict of Interest and Commitment Disclosure form when submitted.

3. Compliance with Other Federal Conflict of Interest Regulations

   Investigators conducting research funded by the National Science Foundation or regulated by the Food and Drug Administration are subject to additional agency-specific regulations. These regulations set forth the obligations of Investigators, sponsors, and affected parties should review the relevant regulations prior to submission of a research proposal or grant.

   - National Science Foundation Investigator Conflict of Interest Policy.
   - Food and Drug Administration Financial Disclosure by Clinical Investigators Regulation

D. Compliance with PHS Regulation 42 CFR, Part 50, Subpart F and 45 CFR, Part 94

Prior to the expenditure of funds and within 60 days of any subsequently identified FCOI in PHS-funded research:

1. The Institution shall adhere to this policy and provide reports regarding identified FCOI to the PHS Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed in the Federal regulation.
2. The Institution will ensure that each Investigator is informed of this FCOI policy, the Investigator's responsibilities regarding disclosure of SFIs, and of the Federal regulations. Each Investigator must complete training regarding FCOI requirements prior to engaging in research related to any PHS-funded contract and at least every three years, and immediately when any of the following circumstances apply:
   a. The Institution revises its FCOI policies or procedures in any manner that affects the requirements of Investigators;
   b. An Investigator is new to the Institution; or
   c. The Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or Management Strategy.
3. If an Investigator carries out PHS-funded research through a Subrecipient (e.g., subcontractors or consortium members), the Institution will take reasonable steps to ensure Subrecipient Investigator compliance through:
   a. A written agreement with the Subrecipient that establishes whether the FCOI policy of the awardee Institution or that of the Subrecipient will apply to the Subrecipient's Investigators.
   b. The OOR will provide FCOI reports to the PHS Awarding Component regarding all FCOI of all Subrecipient Investigators consistent with this regulation.
4. If an Investigator's SFI is related to PHS-funded research:
   a. The COIC will determine if the SFI could impact PHS-funded research, or is in an Entity whose Financial Interest could be affected by the research; and
   b. The COIC will determine if a FCOI exists when the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

5. Identification of a FCOI initiates development and implementation of a Management Strategy by the COIC and, if necessary, a retrospective review and mitigation report pursuant to §94.5(a).
6. The Institution will maintain records relating to all Investigator disclosures of Financial Interests, the COIC's review of, and response to, such disclosures, and all actions under Institutional policies or retrospective review, if applicable, for at least three years from the date of the final expenditure of funds.
7. The Institution will maintain enforcement mechanisms and will provide sanctions and other administrative actions to ensure Investigator compliance as appropriate.
8. The Institution will ensure public accessibility, via written response to any requestor within five business days of a request, for information concerning any SFI disclosed to the Institution that meets the following three criteria:
    a. A SFI was disclosed and is still held by Investigator;
    b. The Institution determined that the SFI is related to the PHS-funded research; and
    c. The Institution determined that the FCOI is a SFI.
9. The information available via written response to any requestor within five business days of a request shall include, at a minimum, the following:
    a. Investigator's name;
    b. Investigator's title and role with respect to the research project;
    c. Name of the Entity in which the SFI is held;
    d. Nature of the SFI; and
    e. Approximate dollar value of the SFI, 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.
10. Public accessibility instructions for a written request shall be posted on the publicly accessible DMU website.

VIII. PERMITTED OUTSIDE EMPLOYMENT AND OTHER EXTERNAL PROFESSIONAL RELATIONSHIPS REQUIRING PRIOR APPROVAL

A. Outside Employment

All full-time and regular part-time (0.5 FTE or greater) employees, except Guest Lecturers, Standardized Patients, Fellows, Exercise Instructors, Temporary/Leased, and Students, will be asked to identify all Outside Employment activities annually when completing the Conflict of Interest disclosure.

Employees are required to discuss and obtain approval, using the Outside Employment Form, from their supervisor and Dean/ELT Member, prior to engaging in Outside Employment. Outside Employment may include external adjunct faculty appointments, consulting, scientific advisory board memberships, clinical trial review panels, developing educational materials, teaching, laboratory testing, expert legal testimony, paid court appearances, and legal expert witness consultation activities or similar activities. Other activities considered Outside Employment for this purpose are fiduciary and management roles in outside organizations,

including board member appointments, and serving as an officer, manager, or medical director of a for-profit company, non-profit organization or charitable foundation.

The purpose of the discussion with the supervisor is to articulate how the Outside Employment will impact the employee's ability to meet his or her DMU obligations and ensure there is no Conflict of Interest created by the Outside Employment. The Outside Employment Form documents the discussion, mutual understanding regarding time away from DMU, any compensation arrangements, or any conditions for moving forward with the Outside Employment. The employee, supervisor and Dean/ELT Member should retain a copy of the Outside Employment Form for a period of one year following the termination of the Outside Employment arrangement. A copy of the Outside Employment Form should also be forwarded to Human Resources for the employee's personnel file.

The following conditions apply for Outside Employment:

1. The Outside Employment should not diminish the employee's ability to commit adequate time to his or her DMU duties.
2. Employees may consult with Industry to provide scientific advice, provided any compensation for consulting services is reasonably related to specified services and is at fair market value; the arrangement is governed by written agreement specifying the service(s) to be provided: the consultant duties are based on relevant expertise; the consultant is free to provide advice and services that reflect his or her expertise and judgment; and the arrangement otherwise complies with this policy.
3. The Outside Employment, if possible, should occur outside of the Individual's regularly approved work schedule. Compensation for the Outside Employment may be retained by the employee provided that it was earned during non-University time (evenings, weekend, or vacation/personal leave). If the Outside Employment occurs during employee's regularly scheduled work hours, two options exist:
    a. The employee will use vacation or personal leave time to compensate for the time off campus.
    b. Payment for services rendered may be made payable to DMU and credited to the department's account.
4. Professional liability (malpractice) insurance coverage purchased by the University for employees does not extend to activities conducted outside the scope of employment at DMU. Verification of professional liability insurance to outside Entities will be provided only if the activity is within the scope of DMU employment.
5. University resources, including but not limited to, paid time, staff and student time or effort, equipment, supplies, services such as email systems, server space, copy services, learning management, may not be used for the Outside Employment. For example, if a faculty member is teaching at another institution in the evening, DMU support staff cannot be used to type or copy exams, handouts, etc., to be used at the other institution.
6. Consulting agreements are personal contracts between an employee and a separate Industry Entity, Vendor/Supplier or other business entity, and do not include the Institution as a party to the consulting agreement. Nor does the Institution provide review or insurance coverage for such arrangements. Any Individual considering entering into a consulting arrangement may wish to seek the advice of an attorney retained at the Individual's expense.

B. Receiving Travel Funds from an Industry Sponsor

Prior to receiving travel funds from an Industry sponsor, Individuals must complete a Sponsored or

Reimbursed Travel Disclosure Form in conjunction with other activity specific forms and receive approval from their supervisor. Individuals should evaluate carefully their attendance at meetings and conferences that are fully or partially sponsored by Industry because of the potential for perceived or actual Conflict of Interest. They should be especially cognizant of this potential when considering whether to play a leadership role in such meetings and conferences by giving lectures, organizing the meeting, and the like.

Individuals may accept travel funds or reimbursement from Industry in the following circumstances:

1. For reimbursement for travel to provide contractual services, such as approved consulting as described in section VI.A.
2. To participate in meetings directly related to ongoing sponsored research.
3. To view capital equipment or software in situ if the equipment is being considered for purchase by DMU; Individuals must submit prior request for approval by their supervisor and ELT Member.
4. To participate in initial and ongoing education necessary to operate or use products and devices which require specialized expertise and are currently being used at the Institution; Individuals must submit request for prior approval by their supervisor and ELT Member and such compensation for travel paid by Industry must be documented in the contract between Institution and Entity.
5. Funds for travel to scientific society meetings, whether or not Industry is the source of the funds, provided that the society controls the selection of the recipient of travel support, and the Individual does not have decision making authority for the society.

C. Licenses, Royalties and Equity

1. As specified in the Intellectual Property and Copyright Compliance policies, Individuals must report their proposed outside relationships with Industry and other Entities if it is anticipated that DMU-owned technology, Intellectual Property, or copyrights will be licensed and royalties or Equity Interest may be received.
2. These relationships must be reported in advance to the appropriate supervisor and ELT Member for review and written approval prior to agreeing to, engaging in, or accepting income for the activities.

D. Engaging in a Start-Up Company

1. Employees must disclose their proposed outside professional relationships with all Start-Up Companies in which they have or expect to have a Financial Interest or under which the Individual or DMU is expected to license DMU-owned technology, Intellectual Property, or copyrights, as defined in the Intellectual Property and the Copyright Compliance policies. These relationships must be discussed in advance with the appropriate Department Chair/Director/Vice President/ELT Member as described in section VII of this policy prior to agreeing to, engaging in, or accepting income for the activities.
2. University resources, including but not limited to, paid time, staff and student time or effort, facilities, equipment (computers, telephones, research equipment, etc.), supplies (such as office and laboratory supplies, University stationery or letterhead), services such as email systems, server space, copy services and including the Institutional Review Board, the Institutional Animal Care and Use Committee, etc., exist for use of the University and not for external company business or personal gain. Other than library materials and assigned office space, Individuals are not permitted to use University resources for extramural activities without first obtaining approval and arranging for the payment for such use.
3. Use of University Information and Biologic Materials. Unpublished research data may be shared with the

Start-Up Company only if permitted by the research agreement under which the data was generated. Data generated under grants are usually owned by the University. Unpublished data can be shared only if the Start-Up Company accepts a confidentiality obligation. Also, biologic materials owned by the University can be shared only with a Start-Up Company under a written Material Transfer Agreement. Contact the Grants and Contract Manager about initiating an outgoing Material Transfer Agreement or a written confidentiality agreement between the University and the Start-Up Company before sharing any unpublished data generated under research conducted at the University.

IX. INTERACTION WITH INDUSTRY (BIOMEDICAL, PHARMACEUTICAL AND MEDICAL DEVICE)

A. Prohibited Personal Professional External Activities with Industry

1. Speaking and Promotional Events. Individuals may not participate in promotional speakers' bureaus or other promotional events for Industry designed to influence purchasing or prescribing decisions. This includes advising or creating materials for Industry or marketing and promoting their products or services, and participating in focus groups where the focus is on marketing products for Industry. This section is not intended to prohibit legitimate, principled activities that meet the guidelines in section VI.A.
2. Ghostwriting and Guest or Honorary Authorship. Individuals may not be listed as authors on any materials ghostwritten by Industry representatives or someone acting on behalf of Industry. Individuals must always be responsible for the content of any publications or presentations, including slides. The International Committee of Medical Journal Editors (ICMJE) standards for authorization and contributorship must be followed.

B. Interactions of Industry Representatives with DMU Students

DMU does not allow Industry support for clinical training of students, residents or fellow. Students may have interactions with Industry Representatives under the following conditions:

1. The interaction has been requested in writing and approved as a curricular educational and/or club-sponsored event by the Program Director, OOR, or applicable college Dean. Examples of these events include, but are not limited to: casting or taping seminars; labs involving physical therapy modalities; suturing exercises; surgical lab skills; and similar club-sponsored educational activities. Club-sponsored educational events must follow standards established in the student Club and Organization Handbook, located on OrgSync and be approved by the faculty advisor and the Office of Student Affairs.
2. A DMU faculty member must be present during the interaction.
3. Industry Representatives must comply with the applicable industry guidance, including but not limited to, PhRMA Code on Interactions with Healthcare Professionals, ACCME Standards of Commercial Support, and AdvaMed Code of Ethics on Interactions with Health Care Professionals.
4. Promotional items and meals are prohibited.

C. Access of Industry Representatives to Institution

1. Industry Representatives who promote biomedical, pharmaceutical and medical device products must have an appointment with a specified individual in order to visit DMU and must follow the procedures outlined in the Industry and Pharmaceutical Samples policy. Industry Representatives are permitted on campus to interact with DMU personnel only when specifically invited to provide education or in-service assistance regarding products, devices or equipment. Industry Representatives must be accompanied by a DMU employee at all times. If interaction will include interaction with patients, patient consent for the Industry Representative's attendance must be obtained and documented. In these limited circumstances, an Industry Representative may be allowed to offer technical advice to a DMU clinician regarding their equipment or devices but may not give advice concerning patient care. Industry Representatives are prohibited from manipulating equipment or devices while in use on a patient and may not touch patients at any time or scrub in on any procedures.
2. Commercial exhibits intended to promote Industry drugs, devices, or other products to be prescribed or used in patient care are prohibited at DMU.

D. Free Services to Clinical Departments

Clinical departments may not accept free services provided by Industry. Examples include, but are not limited to, Industry personnel obtaining insurance preauthorization for their drugs or devices, conducting coding audits, and appealing denied claims or reimbursing departments for denied claims. For example, frequently providing a free service that is ordinarily performed by DMU clinic staff is not acceptable. Exceptions may be appropriate if the primary purpose of the service is to benefit the patient, and the benefit to the clinical department is *de minimus*. Requests for exceptions should be made to the Vice President for Research and the OOR; approvals for exceptions will be in writing and retained by the clinical department.

E. Advertising Materials

Industry advertising and advertising materials are prohibited at programs provided or sponsored by the Institution. For purposes of this policy, Industry advertising does not include advertisements for clinical trials or industry sponsored patient education materials such as those permitted under section XI.B. Industry-supported advertising materials (for example, print, radio, and television) designed to promote physician practices or clinical services are not permitted. Consult the Conflict of Interest Policy – CME Programs for additional information.

X. GIFTS FROM INDUSTRY

A. Gifts of Medications, Pharmaceutical, and other Industry Product Samples

Medications, pharmaceuticals, and other Industry product samples will be accepted by DMU Clinic only when approved by the DMU Pharmaceutical Review Committee (PRC) and Clinic Administration, consistent with DMU's Industry and Pharmaceutical Samples policy. Individuals may not solicit medications, pharmaceutical or other industry product samples for personal use.

B. Gifts of Industry Promotional Items

1. Industry promotional items may not be accepted for use in the DMU Clinic. Prohibited promotional items include Industry-branded non-educational or practice-related items such as pens, notepads, or office supplies.
2. Gifts which have an educational value and are for the benefit of patient care or medical education, including items such as books, anatomical models, illustrations, and clinical diagrams, are permitted provided they are of nominal value (estimated at less than $100). These educational gifts must be received for general use by the department. These items may not promote Industry products or services. Industry-branded charts or anatomic models that are deemed critical for patient education are permitted, but the Industry branding (e.g., logo, company name, and representative contact information) should be removed or covered.

C. Gifts to Individuals

Personal gifts from Industry may not be accepted by Individuals. Examples of personal gifts include, but are not limited to: computers, food baskets, restaurant gift certificates, cash or gift cards, event tickets, and entertainment, regardless of the value. This is not an exhaustive list. Personal gifts of educational materials and textbooks are not permissible, except for evaluation copies.

D. Gifts of Food (Meals)

Industry-supplied or -supported food and drinks are prohibited at DMU except that DMU personnel may accept modest meals (e.g., of nominal value estimated at less than $20) funded by Industry when they are provided incidental to sponsored research or when the activity complies with the provisions of sections V.A and VII.A. Individuals may accept Industry-sponsored meals or food while attending external conferences when such meals or food are offered to all attendees.

E. Gifts of Funds to Departments to Support Education and Other Professional Activities

Departments may establish a departmental education fund or account in which all unrestricted gifts and donations from Industry intended for education or professional support may be deposited. There may be no expressed or implied quid pro quo for the funds. The department may use monies from this fund to pay for reasonable travel expenses and registration fees as determined by the Department Chair/Director/VP/ELT Member. Unless prior approval has been made, continuing education activities must have an account established and managed by the CME Department.

F. In-Kind Gifts to the Institution

Gifts and loans of equipment, devices, supplies and similar items from Industry to the Institution for use in education, research or clinical care cannot suggest any expectation of return benefit to the donor, or quid pro quo. The gift transaction will be documented on the In-Kind Gift Receipt form and submitted to Chief Development Officer, OOR and the receiving department. In-kind donations made for any non-curricular educational activity will be managed through the CME office.

XI. INTERACTION WITH AND GIFTS FROM

UNIVERSITY VENDORS/SUPPLIERS

A. Vendor/Supplier Exhibits and Fairs

Exhibits, sometimes referred to as vendor fairs, intended to promote products or services of a University Vendor/Supplier are permitted under the following circumstances**:**

1. Event meets the definition of a curricular educational or club-sponsored event as outlined in section IX.B of this policy.
2. Event is organized to enable DMU decision-makers to evaluate several brands of a product or service prior to purchasing or standardization decisions for products to be purchased and used at the University.
3. Event is coordinated by Human Resources to allow employees to learn about benefits or services offered exclusively to employees by the University.
4. Event meets requirements articulated in the Conflict of Interest Policy – CME Programs policy.

B. Gifts from University Vendors/Suppliers

This section provides guidance to Individuals regarding acceptance of gifts from University Vendors/Suppliers or entities wishing to do business with the University. These rules do not apply to gifts from Industry (see Section X above).

1. General rule: Individuals are not permitted to accept any gift, regardless of value, that is given by an Entity seeking to influence decision making or gain a financial or business benefit through a relationship with, the University. Individuals are prohibited from accepting gifts of cash or cash equivalents (e.g., gift card), regardless of the amount, at any time. As long as the general rule is not violated, the following standards apply to gifts from University Vendors/Suppliers:
    - Individuals may accept gifts with a value of less than $50 (single gift or aggregate value of multiple gifts from a single vendor in a year).
    - Individuals receiving gifts or prizes valued at more than $50 should decline the gift or turn it over to Finance so it can be used to benefit the University.
    - Holiday gifts of food should be shared with the office/department staff even if addressed to a single employee. Flowers and plants should be displayed in a lobby or other central location in the office/ department.
    - Branded or promotional items (e.g., t-shirts, magnets, pens, mugs, etc.) distributed to attendees at conferences, vendor fairs or trade shows may be accepted as long as these items are offered equally to all attendees.

XII. TRAINING REGARDING POTENTIAL CONFLICTS IN INTERACTIONS WITH INDUSTRY

A. Training for DMU Faculty and Staff

DMU faculty and staff will be directed to review this policy as part of the new employee orientation process and annually thereafter when making their annual disclosures outlined in section VII.

B. Training for DMU Students

Each of DMU's Colleges provides instructional programming designed to help students understand the potential conflicts that may arise between Industry Representatives and health care and higher education professionals and guide them on how to develop and sustain productive and ethical relationships. The programs include evidence-based medical education, literature search strategies and critical appraisal of the healthcare literature. The emphasis on pharmaceutical versus medical device industry context is program-appropriate and determined by each College, with oversight by the program-specific Curriculum Committee.

XIII. ADMINISTRATIVE ACTIONS BY DMU EMPLOYEES RELATED TO THEIR RELATIONSHIPS WITH INDUSTRY

A. Administrative Actions by Key Officials

Key officials in the Institution include the president, vice presidents, officers, directors, managers, advisors, deans, department chairs, and section heads. Because of their leadership roles, their authority to make important decisions, their fiduciary duty to act in the best interests of the Institution, and their positions as role models for other Individuals, key officials are held to an even higher standard of ethics, integrity, professionalism, and objectivity in their decisions and conduct. Key officials might not be permitted to engage in some personal, professional relationships with Industry that are allowable for others, when actual or perceived conflicts of commitment or interest would result, or may have restrictions on their ability to make certain decisions. Key officials should always be aware that their decisions may create Institutional Conflicts of Interest.

B. Committee Participation When Members Have Personal External Relationships with Industry

Individuals who serve as voting members on committees that recommend purchases and utilization of goods and services, including pharmaceutical and medical devices, shall recuse themselves from participation in voting and similar decision-making processes when the decision or discussion may pose a real or perceived Conflict of Interest. In addition, the Chair of the committee may remove a member from the committee in the event the Chair reasonably determines that the member cannot substantially contribute to and participate in the work on the committee due to the member's actual or perceived Conflict of Interest. Additionally, committee members are required to verbally identify during a meeting any potentially conflicting relationships to be documented in the meeting minutes.

C. News Releases and News Media Contact

Prior to participating in a media event, Individuals must disclose to the Marketing and Communications Department any potential or actual COI related to a personal or family member's outside interest in the sponsor of the Individual's research or in the ownership of a related Entity or Intellectual Property, such as new or experimental drugs, devices or therapies, or of a start-up business. All such disclosures will be reported to the Vice President for Research and the OOR.

XIV. ENFORCEMENT OF POLICY

A. Obligation to Comply

Individuals have an obligation to comply with this policy. Examples of conduct that violate this policy include, but are not limited to:

1. Failure to submit required outside interest disclosure statements;
2. Intentional deception or dishonesty in disclosures;
3. Repeated omission of industry relationships in disclosures;
4. Failure to comply with Management Strategy requirements, or
5. Repeated failure to submit required travel and/or education related forms.

These examples are not intended to be exhaustive.

B. Reporting Suspected Violations

Reports of suspected violations may be made to any of the individuals listed below or anonymously through the Compliance Hotline (Lighthouse Services) using any of the following methods:

a. Compliance Hotline

◦ Telephone:	(877) 472-2110
◦ Web:	http://www.lighthouse-services.com/dmu
◦ E-mail:	reports @lighthouse-services.com (must include name of DMU)
◦ Fax:	(215) 689-3885 (must include the name of DMU with report)

b. DMU Representatives

◦ Students:	Conduct Officer
◦ Staff:	Human Resources
◦ Faculty:	Dean and Provost
◦ All:	Vice President for Research or Chief Compliance Officer

C. Sanctions

The Institution will take appropriate disciplinary actions for violations of this policy. Possible sanctions may include, but are not limited to, the following:

1. Reimbursement to the Institution for misused resources;
2. Written disciplinary action placed in employee or student file;
3. Ineligibility to participate in grant applications or on committees;
4. Dismissal from an educational or training program; or
5. Suspension or termination of employment.

XV. REPORTING

If the failure of a research Investigator to comply with this policy has, or appears to have, biased the design, conduct, or reporting of PHS-funded research, in accordance with 42 CFR Part 50 Subpart F, Section 50.606 (a) and 45 CFR, Part 94, the VPR and OOR on behalf of the Institution will promptly notify the PHS Awarding Component of the findings and corrective action taken or to be taken. The PHS Awarding Component will consider the situation and may take appropriate action or refer the matter to the Institution for further action, such as determining how to maintain appropriate objectivity in the funded project.

Allegations of research misconduct are addressed in the Alleged Misconduct in Research and Scholarly Activities policy. If, while investigating allegations of research misconduct, evidence of violations of this Conflict of Interest and Commitment policy is discovered, the OOR and the Scholarly Activity Standards Committee conducting the research misconduct investigation may consult with the Vice President for Research to determine the need for any additional course of action.

XVI. CONFLICT OF INTEREST BOARD OF TRUSTEES AND EXECUTIVE LEADERSHIP MEMBERS POLICY

The Conflict of Interest Board of Trustees and Executive Leadership Members policy applies to all members of the Board of Trustees, the President, and the Executive Leadership Team; it complements, but does not replace, any other conflict of interest or conflict of commitment disclosure obligations related to funded research, continuing medical education, or other relationships with Industry that may apply to these individuals as outlined in this Conflict of Interest and Commitment policy.

XVII. REVIEW/REVISION/IMPLEMENTATION

This policy shall be reviewed by the Director of Research Regulatory Affairs and Vice President for Research at least every three (3) years from the effective date and revised as needed. The Vice President for Research will be responsible for implementation of this policy. The Chief Compliance Officer will be responsible for general oversight of compliance of this policy.

XVIII. RELATED POLICIES AND RETIRED CONFLICT OF INTEREST POLICIES

A. Related Policies

1. Alleged Misconduct In Research and Scholarly Activities
2. Approval Process for Hiring Personnel Using Grant
3. Conflict of Interest Board of Trustees and Executive Leadership Members
4. Code of Conduct
5. Compliance – Treatment of Immediate Family by Clinicians
6. Conflict of Interest Policy – CME Programs
7. Copyright Compliance

8. Industry and Pharmaceutical Samples
9. Intellectual Property
10. IRB Standard Operating Procedures
11. Nepotism Policy
12. Travel – Non Local and International Regulations

B. Retired COI Policies

1. The following policies have been incorporated within this COI policy and will be retired from the University policy library.
2. Conflict of Interest Policy – Pharmaceutical and Industry Representative
3. Conflict of Interest Policy (dated 10.20.11)
4. Disclosure and Resolution of Conflict of Interest Policy & Procedures
5. Disclosure of Industry Relationships and Secondary Employment
6. Financial Conflict of Interest in Sponsored Projects

XIX. GOVERNING LAW OF REGULATIONS/ GUIDELINES

A. Public Health Service (PHS)

PHS regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94)

http://grants.nih.gov/grants/policy/coi/

B. Bayh-Dole Act (1980), 37 CFR 401.1-16

https://grants.nih.gov/grants/bayh-dole.htm

C. Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)

https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7b.pdf

D. "Stark Law" Section 1877 of the Social Security Act 42 U.S.C. 1395nn,

https://www.cms.gov/PhysicianSelfReferral/

E. PhRMA

http://www.phrma.org/about/codes-and-guidelines

F. AdvaMed

http://www.advamed.org/issues/code-ethics

Approved By:

Angela Franklin, PhD, President

Attachments

1: Sponsored or Reimbursed Travel Disclosure
2: Conflict of Interest and Commitment Disclosure
3: Outside Employment Form
4: Clubs, Events and Organizations Handbook

Applicability

Des Moines University