### **UI Conflict of Interest Policy Summary of Changes**

Key changes in the University of Iowa Policy on Conflicts of Commitment, Conflict of Interest in the Workplace and Conflict of Interest in Research.

The basic standards in the policy have changed very little, as these are generally dictated by state law and federal regulation. Notable changes in the policy are:

- 1. The document is substantially shorter. This is primarily the result of removing redundant UI policies and referencing their location in the Operations Manual at the end of the Conflicts of Commitment and Interest Policy.
- 2. The Policy more clearly delineates conflict of commitment, conflict of interest in the workplace, and conflict of interest in research.
- 3. Conflict of commitment and conflict of interest in the workplace will now require a written disclosure and management plan. This was recommended but not required in the past. This change is to ensure documentation of disclosures of conflicts as well as the approval, management or disapproval of the situation.
- 4. The existing requirement for annual reporting of outside paid professional activities by faculty will be expanded to provide additional detail. This has been requested by the Board of Regents.
- 5. Conflict of interest in research has been expanded from sponsored research to all research, irrespective of funding.
- 6. The revised policy includes notification of and consultation with an investigator's DEO and Dean in situations involving conflict of interest in research.
- 7. Using technology in research when the researcher is named as an inventor on the technology's patent is now identified as a conflict requiring disclosure and management. In the past, this was not considered a conflict of interest if the University of Iowa held the patent even though the inventor/investigator stands to gain financially from these inventions under University policy. This change recognizes that potential for financial benefit by the inventor/investigator.
- 8. The policy contains new restrictions on involvement in human subjects research that is reflected in policy statements from the <u>American Association of Medical Colleges</u>, <u>American Association of Universities</u>, and the <u>Department of Health and Human Services</u>.

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### University of Iowa

# MANAGEMENT PLAN FOR A CONFLICT OF COMMITMENT AND/OR CONFLICT OF INTEREST IN THE WORKPLACE

### **Instructions**

All University employees must disclose to their Departmental Executive Officer (DEO) any activity that may create a conflict of commitment or conflict of interest in the workplace as defined in the University of Iowa Policy on Conflicts of Commitment and Interest in the Workplace (<u>UI Operations Manual Part II, Chapter 18</u>). The DEO must review the disclosure and, if s/he believes that the activity meets the University definition of conflict of commitment or conflict of interest in the workplace, must devise a <u>written management plan</u>. If the DEO has or shares the conflict, the disclosure must be made to, and the plan developed by, the next neutral supervisor (e.g., Dean, Vice President or Provost).

### The plan must address:

- 1. for conflicts of commitment, how the employee's overlap of outside activities with his/her workplace obligations is being accommodated (use of vacation, unpaid leave, reduction in % time of appointment, etc.);
- 2. for conflicts of interest in the workplace, how the employee's conflict will be managed or eliminated, including, but not limited to, conflicts involving:
  - a. classroom obligations, service as an undergraduate/graduate advisor or other instructional or service obligations,
  - b. other employees (co-workers, subordinates, etc.) involved in or affected by the outside activity, and
  - c. business decision-making (purchasing, spending, hiring, etc.);
- 3. how the management plan will be monitored; and
- 4. how a third party can bring forward concerns confidentially regarding the employee's actions relating to the conflict.

### CHAPTER 18: CONFLICTS OF COMMITMENT AND INTEREST

(President 9/95; 2/03; 4/05; 2/06)

Note: This chapter is one of several that address conflicts of interest of various types at The University of Iowa. Others include: <u>II-5 Consensual Relationships Involving Students</u>, which addresses faculty-student relationships that are either prohibited or discouraged due to role conflicts; and <u>III-8 Conflict of Interest in Employment (Nepotism)</u>, which addresses role conflicts when there is a direct reporting line between two employees. See also <u>II-18.7</u> below for a complete list of policies that address or are related to conflicts of interest.

- 18.1 Introduction
- 18.2 Definitions
- 18.3 Principles of Conflict Disclosure and Management
- 18.4 Conflict of Commitment
- 18.5 Conflict of Interest in the Workplace
- 18.6 Conflict of Interest in Research
- 18.7 Other University of Iowa Policies Related to Conflict of Interest

### 18.8 Federal Conflict of Interest Regulations

#### 18.1 INTRODUCTION.

The University of Iowa and its employees are committed to the principle of free, open, and objective inquiry in the conduct of its teaching, research, and service missions. Accordingly, it is crucial that University activities be conducted in an atmosphere that is free of conflicts of interest compromising this principle. For the purpose of protecting both the integrity and objectivity of its employees in the performance of their University obligations, it is the policy of the University that conflicts of interest should be avoided where possible, or otherwise disclosed and managed. University employees are compensated for the performance of all assigned duties arising from their employment with the University. In addition, however, there are many opportunities to develop relationships with outside entities and engage in other activities that enhance one's professional competency, render valuable service to the community, and benefit the individual and University. Such activities and relationships must be conducted in a manner consistent with institutional and public values. Occasionally, such relationships or activities create a conflict of either commitment or interest that must be disclosed and managed so as to avoid violation of state or federal law and/or basic principles of ethics and fairness. The existence of a conflict is not always clear-cut. University employees are expected to make a reasonable effort to determine whether their relationships and activities create, or appear to create, such conflicts. If there is any uncertainty, employees should consult their departmental executive officer (DEO) or equivalent.

This policy describes: 1) situations that may raise the question of the existence of conflicts of commitment or interest, and 2) disclosure and management mechanisms to ensure that such conflicts are properly reviewed and resolved or managed. It details the University of Iowa policy for conflict of commitment (II-18.4), conflict of interest in the workplace (II-18.5), and conflict of interest in research (II-18.6).

Failure to disclose a conflict and/or comply with required management strategies constitutes a violation of University policy and may violate state and federal law. Official records of disclosure will be deemed confidential personnel information and not available under the State of Iowa open records law.

After consultation with their employees, individual units within the University may adopt more stringent rules, which must be approved by the vice president (or Executive Vice President and Provost) responsible for that unit. Other University policies that address other types of conflicts of interest not covered by this policy are referenced at the end of this chapter.

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#### 18.2 DEFINITIONS.

(Amended 2/06)

- a. "Compensation" is remuneration or valuable goods received for work performed and does not include reimbursement for reasonable expenses.
- b. "Conflict of commitment" involves a situation in which an employee engages in an outside activity that interferes, or appears to interfere, with fulfillment of the employee's obligations to the University, even if the outside activity is valuable to the University or contributes to the employee's professional development and competence.
- c. "Conflict of interest" involves a situation in which faculty, staff, or student employees have significant financial or other personal considerations that may compromise, or have the appearance of compromising, their professional judgment or integrity in teaching, conducting or reporting research, or performing other University obligations.
- d. "Department Executive Officer (DEO)," as used in this policy, is the individual so designated or the equivalent unit director in colleges or other units that do not formally designate departments and in University-recognized non-departmental units (e.g., centers).

- e. "Employee" means any person who is a member of the faculty, professional and scientific staff, merit staff, or is a student employee.
- f. "Immediate family" includes the employee's spouse or domestic partner and dependent children.
- g. "Outside activities" involve work, either professional or non-professional, for a non-University entity or for oneself. Outside professional activities involve the use of employees' expertise, the practice of their profession, or any activity that contributes to employees' professional competence and development.
- h. "Business day" means every Monday through Friday during regular business hours for all faculty, and the time on any Saturday, Sunday, or evening when a faculty member is scheduled to work, other than any University holiday or day that the faculty member takes a vacation day or sick leave.
- i. "Institutional official" means the President, Provost, other vice presidents and General Counsel, vice provost, associate/assistant vice presidents, associate/assistant provosts, treasurer, controller, deans, associate and assistant deans, departmental executive officers, unit directors, and the heads of centers, programs, and institutes.

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## 18.3 PRINCIPLES OF CONFLICT DISCLOSURE AND MANAGEMENT. (Amended 4/05)

- a. Disclosure and management are critical to the application of this policy. Under this policy, few activities that represent, or appear to represent, a conflict are actually prohibited. Rather, these rules require conflicts to be disclosed and managed appropriately. Management of conflicts is designed to ensure that unavoidable conflicts not interfere with the integrity of employees' performance of University obligations.
- b. Addressing conflicts and development of management strategies requires the collaboration of all parties involved and may require one or more of the following:
  - (1) No action beyond disclosure:
  - (2) Disclosure and management (including alteration or elimination of the conflict); or
  - (3) Prohibition of the activity.
- c. This policy dictates disclosure and development of management procedures which must occur prior to initiating the activity for all conflicts of commitment and conflicts of interest in the workplace or research. Additionally, The University of Iowa requires all full-time faculty to submit annual reports of-all outside professional activities, both paid and unpaid of any duration. If a faculty member—reports any ongoing activity on this annual report form that he or she should have disclosed previously as a conflict of commitment or interest (see II-18.4c(2)) but failed to do so, the activity must be disclosed in writing on the-University of Iowa Disclosure of an Outside Activity form immediately.
- d. Effect on salary. A management strategy for a conflict of interest or commitment shall not include any reduction in an employee's salary unless the management strategy also includes a formal reduction in employee effort or a leave of absence from the University. Furthermore, in setting the salary of an employee, no account shall be taken of any payments received by any employee from outside sources that are disclosed in connection with the employee's disclosure of any conflict of interest.

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### 18.4 CONFLICT OF COMMITMENT.

(Amended 4/05)

Outside professional activities are a normal expectation of employees at a research university provided they do not create a conflict of commitment. Many of these activities generally do not require a written disclosure because they are expected to enhance and not interfere with University obligations. However, if the activities do create a conflict of commitment, written disclosure is required.

a. Disclosure and management of conflict of commitment. Disclosure regarding conflict of commitment must be made in writing to the DEO prior to initiating the activity (or at the point at which a non-disclosed activity exceeds the disclosure threshold), using the University of Iowa Disclosure of an Outside Activity form. This form is available at <a href="https://www.uiowa.edu/~provost/docs/coi/discoutact.pdf">www.uiowa.edu/~provost/docs/coi/discoutact.pdf</a>.

When a conflict of interest is disclosed, the DEO (see "Definitions") shall develop a written management plan. The Management Plan for a Conflict of Commitment and/or Conflict of Interest in the Workplace form is available at <a href="https://www.uiowa.edu/~provost/docs/coi/mgmtplan.pdf">www.uiowa.edu/~provost/docs/coi/mgmtplan.pdf</a>. A copy of this management plan shall be maintained in the employee's personnel file. For faculty, a copy also shall be forwarded to the Office of the dean and/or appropriate Vice President.

If an employee wishes to dispute the proposed management plan, the governing procedures for faculty are the Faculty Dispute Procedures (III-29) and that portion of those procedures dealing with faculty grievances (III-29.6); for non-organized professional and scientific staff the governing procedures are the Grievance Procedures for Professional and Scientific Personnel (III-28.4); and for organized professional and scientific or merit staff the grievance procedures are described in the relevant contract. Student employees may appeal through any existing contractual grievance procedures.

- b. Activities generally requiring no disclosure.
  - (1) Holding office in, or undertaking an editorial office or duties for a scholarly journal, academic press, or professional organization;
  - (2) Serving as a referee for a scholarly journal or an academic press;
  - (3) Serving on a professional review board or peer review bodies;
  - (4) Attending or presenting at professional meetings, workshops, colloquia, symposia, seminars, or training programs;
  - (5) Visiting other sites in connection with accreditation, audits, sponsored project reviews, or like activities;
  - (6) Writing or producing academically related books, articles, software and similar materials, or other creative works ordinarily considered in decisions relating to the employee's employment status or salary; or
  - (7) Participating in outside *non-professional* activities *unless* the time devoted to them interferes with the employee's University obligations.

The preceding rules governing outside professional activities do not apply to the intramural practice of medicine and dentistry conducted in the Colleges of Medicine and Dentistry by

members of those faculties according to the plan approved and regulated by the Board of Regents, State of Iowa, and specific provisions of the *Iowa Code*.

- c. Activities requiring disclosure and management. University employees must disclose for review and management outside activities, paid or unpaid, that involve a commitment of time that may interfere with the performance of their University obligations. This includes any activities that would require them to be physically absent from their place of employment during scheduled work hours, as described below.
  - (1) Professional and scientific or merit staff, or student employees. A member of the professional and scientific or merit staff, or a student employee, who engages in compensated outside professional activities can do so during regularly scheduled work hours only by taking vacation or leave without pay.
  - (2) Faculty. Nothing in these rules shall be construed to require the disclosure of outside activities for any period during which a faculty member is not on a University appointment.
    - (a) Nine-month appointments. Faculty with a full-time nine-month appointment must disclose to their DEO, using the University of Iowa <u>Disclosure of an Outside Activity form</u>, compensated outside professional activities if they require a commitment of time exceeding either three business days or more than two consecutive business days in any fall or spring semester.
    - (b) Twelve-month appointments. Faculty with a full-time twelve-month faculty appointment must disclose to their DEO, using the University of Iowa Disclosure of an Outside Activity form, compensated outside professional activities if they require a commitment of time exceeding either nine business days or more than two consecutive business days over the period of the twelve-month appointment.
    - (c) One-, two-, or three-month appointments. Faculty with a one-, two-, or three-month faculty appointment (e.g., for summer-session teaching or research) must disclose to their DEO, using the University of Iowa <u>Disclosure of an Outside Activity form</u>, compensated outside professional activities if they require a commitment of time exceeding an aggregate of one business day per month over the period of the appointment.
    - (d) Other appointments. In the case of other appointments, the number of business days devoted to outside activities allowed before written disclosure to the DEO is required (using the University of Iowa <u>Disclosure of an Outside Activity form</u>) shall be adjusted proportionately to the length of appointment and percent of the appointment.

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### 18.5 CONFLICT OF INTEREST IN THE WORKPLACE.

Conflict of interest in the workplace involves situations in which faculty, staff, or student employees have significant financial or other personal considerations that may compromise, or have the appearance of compromising, their professional judgment in teaching or otherwise performing their University obligations. (See also II-18.6 Conflict of Interest in Research [below]; and III-8 Conflict of Interest in Employment [Nepotism].)

a. Disclosure of conflict of interest in the workplace. Disclosure regarding conflict of interest in the workplace must be made *in writing* to the DEO *prior to initiating the activity*, using the

University of Iowa Disclosure of an Outside Activity form available at www.uiowa.edu/~provost/docs/coi/discoutact.pdf.

When a conflict of interest is disclosed, the Departmental Executive Officer (DEO) shall develop a written management plan. The Management Plan for a Conflict of Commitment and/or Conflict of Interest in the Workplace form is available at <a href="www.uiowa.edu/~provost/docs/coi/mgmtplan.pdf">www.uiowa.edu/~provost/docs/coi/mgmtplan.pdf</a>. A copy of this management plan shall be maintained in the employee's personnel file. For faculty, a copy also shall be forwarded to the offices of the dean and/or appropriate vice president. University employees planning the development of a start-up company should consult the guidance document entitled "Start-Up Company Conflict of Interest Issues/Policies" for additional information. If an employee wishes to dispute the proposed management plan, the governing procedure for faculty is the Faculty Dispute Procedure (III-29) and that portion of those procedures dealing with faculty grievances (III-29.6); for staff the governing procedures are the Grievance Procedures for Professional and Scientific Personnel (III-28.4) for non-organized professional and scientific or merit staff. Student employees may appeal through any existing contractual grievance procedures.

b. Activities requiring disclosure and management. As described earlier in this section, any activity that has significant financial or personal considerations for employees that may compromise, or appear to compromise, their professional judgment must be disclosed and managed.

Examples include, but are not limited to:

- (1) Owning or acquiring a financial interest in, or having a consulting or other relationship with, any business entity that supplies goods, services, or finances to the University when the employee has decision-making authority for those transactions;
- (2) Promoting or providing information about goods or services to the University community when the employee or his or her immediate family has a financial interest in or other paid relationship with the relevant business entity;
- (3) Assuming or accepting any non-University duties requiring, or appearing to require, the use of University data, processes, procedures, or proprietary or confidential information;
- (4) Assigning duties or offering employment to another faculty or staff member for any of the employee's outside activities.
- (5) Assigning duties or offering employment related to an employee's outside activities to a student when the student is enrolled in a course being taught by the employee or the student's academic work (including work as a teaching or research assistant) is being supervised by the employee.
- c. Prohibited activities. The following are prohibited under this policy in accordance with state law governing the behavior of state employees.
  - (1) Using University property or facilities in a way that may result in personal financial gain to an employee without approval of and payment to the University.
  - (2) Undertaking a business or research opportunity ordinarily conducted by or for the University before the University has been offered the right of first refusal. For faculty members and staff within a college, a written waiver of University interest must be

obtained from the dean of the college. For other faculty or staff members, a written waiver must be obtained from the director of the unit in which the person is employed.

- (3) Using University stationery or letterhead in connection with outside activities, other than activities having a legitimate relation to the performance of the employee's University obligations:
- (4) Receiving compensation without the approval of the President or the Board of Regents, State of Iowa, for serving on the board of directors of business entities when the employee is appointed to that position by the University or is representing the University;
- (5) Using University facilities, or one's position at the University, to advocate, endorse, or market a product or a service, unless in conjunction with one's University duties or requested or approved by one's dean or other appropriate University official.
- (6) Other prohibited activities under related University policies may be found through the web links at the end of this policy (II-18.7). [top]

### 18.6 CONFLICT OF INTEREST IN RESEARCH.

(Amended 2/06)

Conflict of interest in research involves situations in which an investigator (faculty, staff, or student) has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research.

Investigators conducting research funded by the Public Health Service (including National Institutes of Health) and National Science Foundation, as well as those conducting studies regulated by the Food and Drug Administration, are subject to agency specific regulations (II-18.8). These regulations set forth the obligations of investigators, sponsors and institutions for research involving significant financial or other conflicts of interest, and affected parties are advised to review the relevant regulations prior to submission of a research proposal or application.

- a. "Significant financial interest" means a financial interest in a sponsor of research or sponsor's competitor, or intellectual property (patents, copyrights, or trade secrets) held by an investigator or the investigator's immediate family, individually or in aggregate, including:
  - (1) Payments in excess of \$10,000 including salary, consulting fees, royalty or licensing payments from intellectual property, honoraria and/or gifts received within the past 12 months or anticipated for the next 12 months (excluding salary and other payments for services from the University);
  - (2) Equity interest worth more than \$10,000 or more than 5% of the business entity as determined by reference to its publicly listed price (excluding mutual funds);
  - (3) Any equity interest if the value cannot be determined by reference to publicly listed prices (e.g., start-up companies);
  - (4) A position as director, officer, partner, trustee, employee, or any other position of management; or
  - (5) Patent rights or royalties from such rights whose value may be affected by the outcome of the research, including royalties under any royalty-sharing agreements involving the University.

b. Disclosure of a significant financial interest in research. University of Iowa investigators holding a significant financial interest as defined above must disclose this interest in writing prior to submission of a grant or contract application or, for non-sponsored research, prior to initiation of the activity. The research may not begin until the University has reviewed the disclosure and all parties have agreed to any necessary management strategies. If a new significant financial interest is created or if a new investigator with a significant financial interest is hired to work on the research project, that interest must be disclosed within 60 days. Statement of Financial Interest disclosure forms are available on the Research Administration web site.

### When a significant financial interest exists:

- (1) The investigator must submit a disclosure form to the Division of Sponsored Programs or Clinical Trials Office when submitting a grant or contract proposal.
- (2) Disclosures for non-sponsored research shall be made to the Office of the Vice President for Research prior to initiating the research.
- (3) Any change in the nature or amount of the interest must be reported within 60 days.
- (4) Investigators who have submitted an initial disclosure will receive an annual request to update or confirm the status of their financial interest.
- (5) All conflicts of interest arising from a significant financial interest must be reviewed and a management strategy fully developed and in place prior to initiation of the research or expenditure of funds.
- c. Review and management process.
  - (1) The Vice President for Research shall appoint a Conflict of Interest Officer (COIO) and a Conflict of Interest in Research Committee (CIRC).
  - (2) The COIO will review disclosures of financial interests and determine if disclosure alone is adequate or if CIRC review is required (see "Financial Interests Generally Requiring Disclosure Only" below).
  - (3) If the COIO determines that no conflict exists or that disclosure only is required, he or she will notify the individual who filed the disclosure, the Vice President for Research, and the relevant DEO and dean.
  - (4) Disclosures of financial interests that require the development of a management plan will be forwarded to the DEO and dean for their review and recommendation. University employees planning the development of a start-up company should consult the guidance document entitled "Start-Up Company Conflict of Interest Issues/Policies" for additional information.
  - (5) Upon receipt of the DEO and dean recommendations, these recommendations and the investigator's disclosure materials will be provided to the CIRC for review.
  - (6) The CIRC will consider the nature of the research, the magnitude of the interest and the degree to which the conflict is related to the research, the extent to which the interest could be directly and substantially affected by the research, and any conflict management strategies proposed or already in place. The CIRC will develop a management plan (which may involve elimination of the conflict prior to initiating the activity) and notify the Vice President for Research of its recommendation.

- (7) The Vice President for Research will review the recommendations of the COIO and CIRC and make a final determination regarding the management plan. This final determination will be forwarded to the Investigator and copied to the DEO and dean. In the case of research involving human participants, a copy of the determination will be forwarded to the Institutional Review Board.
- (8) The investigator must agree in writing to accept the management plan prior to initiating the research.
- (9) No individual who holds a significant financial interest in a project may participate in the review of its management strategy.
- (10) CIRC meetings are closed to the public and documentation/records are confidential personnel records.
- (11) Any investigator may appeal the decision of the Vice President for Research regarding the management plan for a conflict of interest in research to the President of the University, and thereafter to the Board of Regents, State of Iowa.
- (12) The University shall withdraw applications for funding in all cases in which the investigator chooses not to comply with the management plan adopted in accordance with these rules if the project cannot otherwise be completed without the services of that investigator.
- (13) Institutional officials holding a significant financial interest in an externally sponsored research project may not participate in the solicitation, negotiation of terms and conditions, oversight of the research (unless named as a member of the research team), or the management of any conflict of interest held by members of the research team.
- d. Financial interests requiring no disclosure. Income from, or equity interest in, a research sponsor or sponsor's competitor below the threshold definition of a "significant financial interest" does not require disclosure and/or management.
- e. Financial interests generally requiring disclosure only. The COIO will review significant financial interests that do not exceed \$25,000 of salary or other payment for services. The COIO will also review those interests representing an interest in any publicly traded entity having a value that does not exceed \$25,000 or represent more than a 10-percent ownership interest in such entity when aggregated for an investigator and any member of the investigator's immediate family. In these cases, the COIO will recommend a management strategy for these interests to the Vice President for Research. Prior to making any recommendations to the Vice President for Research, the COIO may request additional information from and/or an interview with the investigator whose significant financial interest is under review. The COIO or the Vice President for Research may at his or her discretion refer any financial interest described above to the CIRC for its consideration and recommendation.
- f. Financial interests requiring disclosure and management. Disclosure is an essential element of the conflict of interest review and management process. In some cases, the extent of the significant financial interest and the nature of the research may be such that disclosure, alone, is adequate. This determination will be made through the standard conflict of interest disclosure and review process described above. Most projects in which an investigator holds a significant financial interest will require management in addition to disclosure.

- (1) Investigators holding a significant financial interest in research involving human subjects must disclose the existence of this interest to the Institutional Review Board (IRB) in addition to submitting the Statement of Financial Interest form to the Conflict of Interest Office. The IRB will work with the Conflict of Interest Office regarding any special subject protection issues. In certain situations, investigators' roles may be restricted because they hold a significant financial interest (see, for example, paragraph f below, "Research Involving Human Participants").
- (2) Investigators holding a significant financial interest must not delegate the conduct of research to trainees or other employees over whom the investigator has direct supervision (e.g., student, graduate student, postdoctoral fellow, resident physician or dentist, or research assistant) without the written approval of the DEO and dean (no "per" signatures accepted). This approval must accompany the Statement of Financial Interest form when it is submitted to the Conflict of Interest Officer.

Additional management strategies may include (but are not limited to):

- (3) Disclosure in publications, presentations, and, in the case of human research, the informed consent document;
- (4) Monitoring of research by independent reviewers;
- (5) Disqualification of the investigator from a portion of the research;
- (6) Designation of a co-investigator (peer or superior) who has no significant financial interest in the project;
- (7) The sale or other divestiture of the financial interest and restrictions on re-investment after the project is completed for an appropriate period to provide for publication and critique of the project;
- (8) Placing interests in escrow for the term of the project and perhaps a period beyond the end of the project to provide for publication and critique of the project; or
- (9) Severance of other relationships with the sponsor or competitor that create actual or potential conflicts of interest.
- g. Research involving human participants. As a general policy, an investigator will not be permitted to conduct research involving human participants in which the investigator holds a significant financial interest. An investigator may submit an appeal for a waiver to this policy, which in addition to the standard disclosure form must include the nature of the research, the magnitude of the interest and the degree to which it is related to the research, the extent to which the interest could be directly and substantially affected by the research, and the degree of risk to the human participants involved that is inherent in the research protocol. The CIRC will also consider the extent to which the interest is amenable to effective oversight and management.

In clinical research posing a greater than minimal risk because the study is designed to answer questions about the effects or impact of particular drugs, treatments, or diagnostic/therapeutic devices, disclosure or standard conflict management strategies are inadequate, and adequate monitoring plans may be difficult or impossible to implement. The University will not allow an investigator to conduct clinical research in the areas noted above and in which he or she holds a significant financial interest unless he or she 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. In addition, it is important to be mindful of the physician/human participant relationship and the special demands it involves -- to do no harm and to safeguard the human participant's welfare above all things. When a waiver is justified by compelling circumstances, the project and a plan of rigorous oversight must be reviewed and approved by the DEO, dean, CIRC, and Vice President for Research. The outcome of these reviews will be communicated to the Institutional Review Board for consideration in their deliberations on the project.

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#### 18.7 OTHER UNIVERSITY OF IOWA POLICIES RELATED TO CONFLICT OF INTEREST.

- a. II-4 Sexual Harassment
- b. II-5 Consensual Relationships Involving Students
- c. II-33 Use of University Name
- d. II-35 Prohibition on Giving and Receiving Gifts
- e. II-19 Acceptable Use of Information Technology Resources
- f. II-27.6 Policy on Ethics in Research
- g. III-8 Conflict of Interest in Employment (Nepotism)
- h. III-15 Professional Ethics and Academic Responsibilities
- i. III-17.17 Supplemental Activities and Extra Compensation
  - (1) III-17.17(1) Use of University Supplies
  - (2) III-17.17(2) Usurpation of Universities Opportunities
  - (3) III-17.17(3) Royalties from Course Materials
- j. V-11 Purchasing
  - (1) V-11.14 Conflict of Interest
  - (2) V-11.15 Purchases from University Faculty or Staff
  - (3) V-11.22 Items Which May Not Be Purchased
- k. V-30 University of Iowa Intellectual Property Policy

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### 18.8 FEDERAL CONFLICT OF INTEREST REGULATIONS.

- a. Public Health Service (including NIH) Investigator Objectivity in Research Regulation <a href="http://grants/guide/notice-files/not95-179.html">http://grants/guide/notice-files/not95-179.html</a>
- b. National Science Foundation Investigator Conflict of Interest Policy <a href="https://www.nsf.gov/bfa/cpo/gpm95/ch5.htm#ch5-6">www.nsf.gov/bfa/cpo/gpm95/ch5.htm#ch5-6</a>
- c. Food & Drug Administration Financial Disclosure by Clinical Investigators Regulation <a href="http://fr.cos.com/cgi-bin/retrieve?db=fr\_1998&ac2=19980202a121">http://fr.cos.com/cgi-bin/retrieve?db=fr\_1998&ac2=19980202a121</a> <a href="mailto:[top]">[top]</a>

## Disclosure of An Outside Activity

Name:		Position:		
Dept.:		College:		
Start date of o	outside activity:	End date, if known:		
Name of outs	ide entity to which you will provid	le services or that inv	olves your a	etivity:
Check all that	apply (see OM Part II, Chapter 18	B for definitions):		
Conflict of co	mmitment Conflict or	f interest in the workp	olace	
If you checke	d "Conflict of interest in the work	place," complete the t	following:	
Does the a	activity involve co-workers?		yes	no
Does the a	activity involve students?		yes	no
Does the a	activity involve:			
i	nformation provided to or by the U	Jniversity?	yes	no
{	goods provided to or by the Univer	sity?	yes	no
S	ervices provided to or by the Univ	versity?	yes	no
f	inances provided to or by the Univ	versity?	yes	no
ι	se of University data, processes, o	or procedures?	yes	no
ι	se of any University resources?		yes	no
Ç	ny other significant financial or peronsiderations that may compromise ocompromise, your professional j	se, or appear	yes	no
If you checke	d yes to any question, explain in ye	our written disclosure	<b>).</b>	
•	d <b>no</b> to <u>all</u> questions, submit to you description of your outside activ	-	_	
DEO to make	ption, please describe the accomm so that the activity does not interfolanned any accommodations, stat	ere with your Univers		•
Employee Sig	nature:	Ī	Date:	

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