



ADMINISTRATIVE POLICY

Individual Business or Financial Conflict of Interest (DRAFT 11 09 09)

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Effective Date: January 1998

Last Updated:

Responsible University Officer:

Director, Office Of Institutional Compliance

Policy Owner:

Director, Office of Institutional Compliance

Policy Contact:

POLICY STATEMENT

Guiding Principle

Professionalism lies at the heart of the teaching, research, outreach and public service in which University of Minnesota ("University") employees are engaged. Relationships with business entities represent a vital aspect of University work, as they promote the application to the greater society of innovations developed at this institution. To this end, University employees are encouraged to share their expertise with business entities through consulting, training, product development, research and other arrangements. At the same time, the University recognizes that conflicts of interest often arise in the context of these relationships. The University, therefore, has an obligation to be aware of the potential for conflicts of interest, increase its employees' awareness about conflicts of interest through educational programs, implement systems to effectively identify and manage conflicts of interest when they arise, and fairly and consistently enforce compliance with its conflict of interest policies and procedures. The overriding purpose of this policy is to ensure that the relationships into which University employees enter with business entities are principled and do not erode the public's trust but rather sustain the public's confidence that the work that we do here, at all times, furthers the mission of the University, and is grounded in objectivity and free of bias.

Introduction

Covered individuals at the University must comply with Board of Regents Policy: *Individual Business or Financial Conflict of Interest* and all applicable federal and state laws related to conflict of interest. Covered individuals must report relationships with business entities in accordance with Administrative Procedure: *Disclosing Relationships with External Entities*. These relationships will be reviewed by a conflict of interest review committee to determine if a conflict of interest exists.

Covered individuals must report external relationships annually, upon notification by the Conflict of Interest Program, Office of Institutional Compliance, or within 30 days of a substantial change in a financial or business interest. Deans, unit heads, and staff of the Conflict of Interest Program are responsible for reviewing these disclosures in accordance with Administrative Procedure: *Evaluating and Managing Disclosures of Relationships with External Entities*. Potential conflicts of



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This draft is being shared as part of a consultative process at the University and should not be considered a final document. Comments received through this consultative process will be considered before a revised policy is published.

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interest will be referred to the appropriate conflict of interest review committee. Potential conflicts of interest that involve research with human subjects have additional restrictions and are reviewed with extra scrutiny because of the potential to compromise the welfare of the human subjects.

Where a conflict of interest is identified, the covered individual must follow an approved conflict management plan which provides mechanisms to manage, reduce or eliminate the conflict. University administration has the responsibility to defend the covered individual engaged in the activity that gave rise to a conflict of interest finding so long as the covered individual complies with the approved conflict management plan, reporting and disclosure obligations, other applicable University policies, and applicable law.

When covered individuals participate in sponsored research involving sub-grantees, contractors, or collaborators outside the University, the University, at least to the extent required by the sponsor, will take reasonable steps to ensure that investigators working for these outside associates comply with appropriate conflict of interest reporting, disclosure and review requirements. These steps may include requiring the investigators working for these outside associates to comply with the University's policy or to obtain appropriate assurances from the outside associate that it complies with applicable federal regulations or sponsor policies on conflict of interest.

Scope

This policy governs covered individuals whose financial and business interests and relationships of a non-business, non-financial nature relate to or overlap with the individual's University-related expertise and/or responsibilities.

Section I. Reporting and Evaluating a Covered Individual's Relationships with External Entities

Reporting Requirements for Covered Individuals

- **On an annual basis, all covered individuals must complete a Report of External Professional Activities (REPA) to provide information regarding the following:**
 - The covered individual's (1) financial and/or business interests and those of immediate family members which relate to or overlap with the covered individual's University responsibilities; and (2) the covered individual's relationships of a non-business, non-financial nature which relate to or overlap with his or her University responsibilities
 - Where the financial interest involves income, the dollar amount of the income, in specified increments, must be reported. There is no dollar threshold. *The following increments will be used for reporting purposes for each compensated relationship with a business:*
 - \$0.00 to \$5,000
 - \$5,001 to \$10,000
 - \$10,001 to \$25,000
 - \$25,001 to \$50,000
 - \$50,001 to \$100,000
 - \$100,001* to \$150,000

- \$150,001 to \$200,000
- \$200,001 to \$250,000
- >\$250,000

*(*All income amounts that exceed \$100,000 will be forwarded by the Conflict of Interest Program to the covered individual's unit head for a "conflict of commitment" review under the Outside Consulting and Other Commitments Policy and the procedure titled Outside Consulting and Other Commitments by Faculty and Academic Professional and Administrative (P&A) Staff.)*

- Where the financial interest involves an equity interest, it must be reported if the equity interest:
 - Is in a publicly traded entity and is valued at \$5,000 or more or represents 0.1 percent ownership (regardless of worth); or
 - Is in a non-publicly traded entity, in which case any equity interest must be reported.
- All relationships of a non-business or non-financial nature (e.g., close friend, immediate or extended family member) that may create a real or perceived institutional conflict of interest or that might influence the way a covered individual allocates University resources must be reported.
- An updated REPA must be submitted within 30 days of a substantial change in financial or business interests.
- The following activities are exempt from these reporting standards:
 - Receiving income from seminars, lectures, or teaching engagements sponsored by governmental agencies and entities;
 - Receiving income when serving as a special reviewer or on a review panel for a public or nonprofit entity;
 - Receiving royalties under the Board of Regents policy titled Commercialization of Intellectual Property Rights, but not having any other relationship with the royalty-granting entity that could result in a conflict of interest (add link to policy); and
 - Receiving income from a private practice plan or private professional practice plan pursuant to one of the following Board of Regents policies:
 - Private Practice Plan: Medical School - Twin Cities
 - Private Practice Plan: School of Dentistry
 - Private Practice Plan: School of Nursing
 - Private Professional Practice: University of Minnesota, Duluth School of Medicine
 - Professional Services Plan: University of Minnesota, College of Pharmacy
- Covered individuals who are temporarily away from campus (e.g., leave of absence, sabbatical, or summer schedule) must also report these external relationships. Conflict review committees take into consideration the covered individual's status when reviewing the reported information.

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Evaluating the information reported on REPAs

- REPAs will be reviewed and evaluated consistent with the provision of Administrative Policy: *Evaluating and Managing Relationships with External Entities*.

Section II. Determining Whether A Conflict of Interest Exists

- Whenever a "significant financial interest" exists that overlaps with a covered individual's University activities, the appropriate conflict review committee will make a finding that a conflict of interest exists. In these circumstances, the conflict review committee will require one of the following: (1) the termination of the financial and/or business interest that creates the conflict; or (2) the termination of participation in particular University activities; unless (3) the circumstances are compelling and/or a University conflict of interest committee determines that the conflict can be managed and approves a conflict management plan.
- A non-business, non-financial relationship that overlaps with a covered individual's University activities may or may not result in a conflict of interest finding.
- Whenever a covered individual's financial and/or business interest, or a relationship of a non-business, non-financial nature, is under review by a conflict review committee, the covered individual will have an opportunity to provide information to the committee either in person or by the submission of a written statement and/or the provision of other written information.

Section III. Managing Conflicts of Interest

- Once a conflict of interest review committee determines that a conflict of interest exists because of a covered individual's (1) financial and/or business interests; and/ or (2) relationships of a non-financial, non-business nature, a conflict management plan will be developed.
- In the context of human subjects research, a conflict management plan may be required whether or not a "financial interest" constitutes a "significant financial interest". Whenever a "significant financial interest" exists in this context, the relationship with the business that gives rise to the conflict must be terminated unless compelling circumstances exist *and* a determination is made that the conflict can be effectively managed.
- When a conflict review committee determines that a conflict of interest exists, the committee will consider the following factors to determine whether compelling circumstances exist and/or whether viable options are available for the development of a conflict management plan:
 - Generally:
 - The nature of the University activity;
 - The nature of the financial interest;
 - How closely the interest is related to one or more University activities; and
 - Whether the conflicted individual brings unique value to either the University activity or the business relationship.

- Where research is involved:
 - The degree of risk the research poses to human subjects as determined by the Institutional Research Board (IRB); and
 - The degree to which the financial interest may be affected by the outcome of the research.
 - The assessment of the appropriate associate dean to determine whether to resolve the conflict by terminating or modifying the covered individual's role in the research or whether the covered individual must relinquish part or all of the conflicting financial interest or whether another management mechanism is preferred.
- Additional considerations in the context of clinical trials
 - A determination must be made as to which of the following activities, if any, the conflicted covered individual may participate:
 - Subject recruitment;
 - Subject selection, including prescreening for inclusion/exclusion criteria;
 - Consent process;
 - Clinical treatment of subjects, separate from the research interventions or procedures; and/or
 - Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting.
- The conflict management plan will:
 - Describe the circumstances that give rise to the conflict of interest;
 - Identify the particular provisions of University conflict of interest policies and procedures that apply to the circumstances;
 - Set forth specific mandatory management mechanisms;
 - State the time intervals for management plan monitoring and follow-up;
 - Require a written confirmation of consent from the covered individual to all management mechanisms enumerated in the plan;
 - Require a written confirmation of support from the covered individual's dean or vice president for the plan and agreement to communicate an expectation of compliance to the covered individual; and
 - Be addressed to the covered individual and a copy forwarded to:
 - If faculty, the covered individual's dean, associate dean, department chair, and relevant others in the supervisory reporting line; and
 - If professional and academic administrative staff, the vice president of the covered individual's unit, the covered individual's immediate supervisor, and relevant others in the supervisory reporting line.
 - When appropriate, the Associate Vice President for Sponsored Projects Administration, the Director of the Research Subjects Protection Program, the Director of the Office of Technology Commercialization, and/or the Director of Research Animal Resources.

Section IV. Disclosures of a Covered Individual's Conflict of Interest as Required by a Conflict Management Plan

Whenever a conflict of interest review committee determines that a conflict of interest exists and the management plan developed to address the conflict has been issued, the covered individual must make the disclosures required by the terms of the management plan, consistent with the provisions below. A conflict of interest review committee may also require disclosures that are beyond the scope of this section.

Disclosure to students

- *Teaching:* Where a covered individual has a conflict of interest that involves the individual's teaching, the covered individual must disclose the relationship that gives rise to the conflict to students on each course syllabus. For independent studies or other classes without a syllabus, the covered individual must provide this information in writing to students before the course begins.
- *Advising:* Where the covered individual has a conflict of interest that involves the covered individual's role as an advisor to students, the covered individual must disclose the relationship that gives rise to the conflict in writing to each student affected by the conflict.
- *Research:* Where a covered individual has a conflict of interest that involves the individual's research, the covered individual must disclose the relationship that gives rise to the conflict to colleagues, students and trainees involved with the research.
- In each of the circumstances described above, the disclosure must include the name of the individual or business entity whose relationship with the covered individual gives rise to a conflict and the nature and duration of the relationship.

... Disclosure to professional journals

- When submitting reports for publication in, or serving as a reviewer for, a professional journal, covered individuals must comply with the journal's requirements for the disclosure of conflicts of interest. Where the journal has no specified requirements, the covered individuals must disclose conflicts of interest to the editor and provide the sources of funding of the project.

... Disclosure to Human Subjects

- Where a covered individual has a conflict of interest that involves human subjects research, subject to the determinations made by the IRB and at its discretion, the researcher will offer each human subject the opportunity to receive a written disclosure of the relationship that gives rise to the conflict. The substance of that disclosure will be at the direction of the IRB and may require the covered individual to report the amount of compensation received from a business for the provision of consulting services.
- Where a human subject requests disclosure of the relationship, the disclosure will inform the individual that the University has determined that a conflict of interest exists and that the relationship may influence the decisions made in the course of the research. The required disclosure will also inform the individual that the conflict has been reviewed by a University conflict of interest review committee which has imposed appropriate management mechanisms and that a determination has been made that the conflict of interest does not pose any additional risk to the welfare of the individual or to the integrity of the research. The precise language of the disclosure will be at the direction of the IRB.
- The offer, the subject's decision, and a summary of the information provided must be documented, at a minimum, in the research records.

Disclosure to Governmental Agencies

- Whenever a conflict of interest arises in the context of research sponsored by a governmental agency that has conflict of interest reporting requirements, the University will comply with those requirements.

Section V. Disclosures Made Outside of the Conflict Management Plan Context

Disclosure to the public

The University will maintain a website to disclose to the public the compensation that covered individuals received from external entities where the compensation earned results from the provision of consulting services that overlap with the covered individual's University-related expertise or University-related activities. Such disclosures will be made only with the permission of the covered individual until such time as public employees outside compensation becomes public data under the law. These disclosures, if made, will be reported in specified increments.

Disclosure to professional journals

When submitting reports for publication, covered individuals must comply with the journal's requirements for the disclosure of conflict of interest whether or not required by the provisions of a conflict management plan.

Section VI. Prohibited External Relationships or Activities

Covered individuals may not participate in relationships with business entities that:

- Result in direct payments to the covered individual that are intended to improperly generate business for a business entity or are solely or primarily intended to improperly influence how the covered individual conducts University-related activities. In a clinical setting, these payments may be intended to induce patient referrals or influence the recipient's prescribing practices or medical decision-making. This prohibition applies to "switching arrangements" in which a covered individual is influenced by financial gain to change the selection and/or use of an item used in University activities or in clinical practice from a competing product to the product of a particular business entity.
- Result in the payment of income (e.g., royalties or other income from a licensing agreement) to a covered individual when that person uses a particular device or product in his or her University activities unless that payment is made pursuant to the University's income sharing policy or that of another institution of higher education.
- Constitute ghost writing (having one's name and University affiliation associated with a publication or other article that was created by a business entity where the covered individual had no substantial input into the publication or article.) Authorship must be restricted to those individuals who meet all of the following criteria:
 - Made a significant contribution to the conceptualization and/or design of the project, the analysis and interpretation of the data, or other substantial scholarly work;
 - Participated in drafting, reviewing and/or revising the work; and
 - Approved the final version of publication.
- Involve the covered individual's endorsement of a product or service developed and/or sold by a particular business unless a contract entered into by the University permits the endorsement. This provision applies to both written and oral endorsements when the product or service relates to the covered individual's University-related expertise and/or University activities, whether or not the covered individual uses his or her University title in making the endorsement.

Section VII. Consulting Relationships with Business Entities

- Before consulting services are provided that overlap with a covered individual's University-related expertise and/or University-related activities, the covered individual and the business must enter into a signed, written agreement that:
 - Identifies a legitimate need for the services provided;
 - Provides specific information regarding compensation, deliverables, timeframe, and the services to be rendered; and
 - States that the covered individual is acting solely in his or her individual capacity and is not speaking for or on behalf of the University.
- Compensation must be consistent with and may not exceed the fair market value of the services provided. It may include reimbursement for reasonable and actual expenses for travel, meals and lodging. "Reasonable" means consistent with the provisions and requirements of the University administrative policy: *Traveling on University Business*.
- Documentation of the compensation received and the services provided must be maintained by the covered individual and include estimates of the time and effort committed to providing the services.
- The University retains the right to review all such agreements and related documentation in the context of a conflict of interest review.

Section VIII. Speaking Engagements Sponsored by Business Entities

- Covered individuals may not participate in sales or marketing speaking events sponsored by business entities where the subject matter of the event overlaps with the covered individual's University-related expertise and/or University-related activities unless the speaking event meets the following criteria:
 - The information presented is evidence-based;
 - The covered individual represents that the lecture materials fairly reflect his or her independent views; and
 - The following information is fully disclosed to the audience at the time of the event and in any brochure or other written communication describing or advertising the event:
 - The covered individual's relationship with the sponsoring entity; and
 - Whether the covered individual is being compensated for his or her participation in the event and, if compensated, the amount of any compensation paid.
 - The covered individual is acting solely in his or her individual capacity and is not speaking for or on behalf of the University.
- In the context of all other speaking engagements, the covered individual must disclose his or her relationship with the business entity to the audience at the time of the event and in any brochure or other written communication describing or advertising the event.

- Any compensation paid must be documented in a written agreement that meets the criteria described in Section VII. of this policy.

Section IX. Presence of Business Entities on Campus

- Representatives of business entities are not permitted in any University research, clinical or teaching areas, unless invited by faculty or staff.
- Any food provided in connection with a campus visit by a representative of a business entity must be provided and paid for by the University department or unit that approved the visit.

Section X. Education and Training Sponsored by Business Entities

- Covered individuals may attend on-site and off-site lectures and events sponsored by business entities.
- Covered individuals may not accept payment of or reimbursement for the expenses associated with attendance at education and training events sponsored by business entities.
- Business funding for continuing education events held at the University must be in the form of a grant made to a central administrative unit which is unrestricted with respect to the content or format of activities for which it may be used. These educational events must meet professional continuing education requirements for educational content.

Section XI. Using Educational Materials Developed and Provided by Business Entities

- Educational materials developed and provided by business entities, and used in connection with University activities, must have an educational purpose and must not be used to advertise or otherwise promote a product or service of a business.
- When using non-branded educational materials developed by a business for teaching purposes, faculty must disclose the name of the entity that developed the materials to students.

Section XII. Samples and Demonstration Items Provided by a Business for Use in a Health Care Setting

- Colleges, departments, or units may accept and distribute free or discounted samples or products provided by a business. However, the receipt and distribution of them must be documented. In this context, samples include medical devices, pharmaceuticals, and other medical-related products or software.
- Covered individuals may not accept free or discounted samples or products from a business.
- In the clinical context, it may be appropriate for covered individuals to use a product branded with the name of a particular business for educational and demonstration purposes with a patient for whom the product has been prescribed.

Section XIII. Gifts, Food, and Entertainment

- *Gifts:* Covered individuals may not accept gifts from a business, irrespective of the nature or value of the gift. Items that may not be accepted include, but are not limited to, pens, notebooks, coffee mugs and other promotional items; cash, stocks, equity, and other financial instruments; textbooks; software, computer hardware and accessories; electronic devices such as cell phones, pagers, music and video players, and PDAs; free services; and office and research supplies. However, covered individuals may accept products provided by business entities during off-site educational activities if acceptance is optional and these materials are offered to all attendees (e.g., tote bags at conferences).
- *Food and Entertainment:* Unless authorized by a Departmental Approver, covered individuals may not accept meals, food, refreshments, entertainment, or similar benefits from a business either on or off-site with the exception of modest meals offered to all attendees at educational events ("conference meals"), whether or not the costs associated with attendance at the educational event are reimbursed by the University.

Section XIV. Failure to Comply and Disciplinary Action

Sanctions for Covered Individuals Who Violate the Requirements of this Policy

A breach of this policy may be the basis for discipline of a covered individual. If sanctions are necessary, they will be imposed in accordance with other applicable Board of Regents and administrative policies and procedures. The potential sanctions may include, but are not limited to, the following:

- Warning letter
- Letter of admonition/reprimand
- Ineligibility of the covered individual to:
 - Submit grant applications
 - Seek approval from the Research Subjects Protection Program
 - Supervise graduate students
- Non-renewal of appointment
- Suspension
- Termination

Section IV. Special Situations:

There are some situations, such as conflicts of interest in purchasing, where the activity is prohibited regardless of a covered individual's classification or the value of the individual's outside interest. Purchasing conflicts and other special situations are addressed in Administrative Procedure: *Avoiding Conflicts of Interest in Special Situations*.

REASON FOR POLICY

Individual conflicts of interest are governed by Board of Regents Policy: *Individual Business or Financial Conflict of Interest* and various regulations, including federal regulations on research objectivity and state law related to conflicts in purchasing. The provisions of this policy are intended to ensure that covered individuals fully disclose financial and business interests, and relationships of a non-business, non-financial nature that overlap with their University-related expertise and responsibilities so that potential conflicts of interest can be identified and reviewed and, where conflicts of interest are found to exist, they can either be eliminated, reduced or effectively managed. To gain and maintain the public's trust, the University must demonstrate that the work that is conducted here is free from improper influence and bias that might otherwise result from these external interests and relationships.

PROCEDURES

- Disclosing Relationships with External Entities
- Evaluating Disclosures and Managing Individual Conflicts of Interest
- Avoiding Conflicts of Interest in Special Situations

FORMS/INSTRUCTIONS

- REPA: Annual Report of External Professional Activities

ADDITIONAL CONTACTS

Subject	Contact	Phone	Fax/Email
Primary Contact(s)			
Technical problems	EGMS helpline	612-624-1600	repa@egms.umn.edu
Policy questions	Policy helpline	612-626-1462	REPAmail@umn.edu

DEFINITIONS

Academic professional and administrative employee

Any person holding an academic appointment (paid or unpaid) at any percentage of time at the University, appointed in the Faculty (94xx) or Academic Professional or Administrative (93xx, 96xx, 97xx) employee groups.

Associated entity

Any trust, organization, or enterprise over which the covered individual, alone or together with an immediate family member, exercises a controlling interest.

Breach

A breach of this policy includes, but is not limited to, intentionally filing an incomplete, erroneous, or misleading report of external activities, failing to provide additional information as required by the approving authority, or failing to follow an approved plan for managing, reducing or eliminating a potential conflict.

Business

Any (1) corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or (2) any nongovernmental legal entity organized for profit, nonprofit, or charitable purposes.

Business interest

Holding any executive position (e.g., Chief Executive Officer, Chief Operating Officer, and Chief Financial Officer) in a business or membership on a governing board of directors of a business whether or not such activities are compensated. The term "governing board of directors" refers to the board of any business including boards of trustees, scientific advisory boards, medical advisory boards, and boards of professional societies.

Collegiate approver

The senior administrative officer for the college or administrative unit (typically a dean or vice president) or that officer's designee.

Conflict of Interest (individual)

An individual conflict of interest exists where there is a divergence between (1) an individual's private business and/or financial interests and/or relationships of a non-business/non-financial nature, and (2) the individual's obligations to the University such that an independent observer might reasonably question whether the individual's actions or decisions are determined or influenced by considerations of personal gain, financial or otherwise, and/or allegiance to a non-business, non-financial relationship, thereby compromising the objectivity with which the individual performs his or her responsibilities.

Conflict Management Plan

A formal document approved by the applicable conflict review committee that directs the covered individual's management of the conflict. Prior to the effective date of this policy, an approved conflict management plan may include one developed at the collegiate or departmental level and approved by a collegiate approver.

Conflict Review Committee (CRC)

Committees formed at the University, responsible for determining whether a given situation involves a conflict of interest and, if it does, also determining whether the conflict must be eliminated or, alternatively, identifying mechanisms to effectively manage the conflict. Each committee will consist of both voting and nonvoting members. Voting members include faculty and professional academic and administrative staff whose appointments to the committee have been approved by the University's Senior Vice Presidents. Nonvoting members may include representatives from the Office of Institutional Compliance, Office of Technology Commercialization, Sponsored Projects Administration, Research Subjects Protection Program, Office of Research Integrity and Oversight, and Office of the General Counsel.

Consulting

A relationship between a covered individual and a business in which the covered individual provides professional services, either compensated or uncompensated, to the business which involves the covered individual's University-related expertise and/or which overlap with the covered individual's University-related responsibilities. "Consulting", for the purposes of this policy, includes but is not limited to, the provision of services in the following contexts: product/service development and evaluation, teaching, demonstrating particular techniques and/or technologies, speaking engagements, scientific, technical or other professional advisory board membership, and position paper preparation. Activities that are excluded from this definition are set forth in Administrative Procedure: *Outside Consulting and Other Commitments by Faculty and Academic Professional and Administrative Staff*. All consulting relationships between a covered individual and a business entity must comply with the requirements of this Policy.

Covered individual

This term includes:

- Employees with a faculty appointment to include adjunct professors, whether paid or unpaid;
- Paid academic professional and administrative employees;
- Other individuals, to include Civil Service employees, who share responsibility for the design, conduct, or reporting of University research, which includes all principal investigators and all members of the University's Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Institutional Biosafety Committee (IBC); and
- Other employees, to include Civil Service employees, who share responsibility for academic programs and community outreach programs.

Covered relationship

Any business or financial interest or a relationship of a non-business, non-financial nature that may create a real or perceived conflict of interest or that might influence the way in which a covered individual conducts University activities.

Departmental approver

The immediate administrator; typically the department head, department chair, or department/division director.

Disclosure requirements

A requirement to disclose to students, colleagues within the University, and to entities outside the University, including governmental entities, information regarding the existence of a financial or business interest or a relationship of a non-financial, not business nature that has resulted in a conflict of interest finding by a conflict review committee.

Electronic Grants Management System (EGMS)

The electronic system used by covered individuals to complete the Report of External Professional Activities (REPA) (<http://egms.umn.edu>).

Executive Position

Any position that includes responsibilities for a significant segment of the operation or management of a business.

Fair Market Value

The rate of compensation paid under a consulting agreement to a covered individual that meets the following criteria:

- The compensation rate:
 - Reflects the expertise and credentials of the covered individual;
 - Is comparable to the compensation paid to the covered individual's peers at the University;
 - Is reasonable in the context of the services provided;
 - Does not include an enhancement in exchange for an agreement to improperly:
 - Make or induce others to make referrals to the business entity;
 - Make or induce others to endorse the products or services of the business entity, and/or
 - Improperly influence research results to benefit the interests of the business entity.
- Where there are no comparable peers at the University, the covered individual must obtain, at the covered individual's expense, the services of an outside consultant to establish a "fair market value" compensation rate unless the proposed rate does not exceed \$ _____ per hour or a per diem rate of \$ _____.
- In no circumstance should the total compensation earned in one calendar year exceed \$ _____.

Financial Interest and Significant Financial Interest

Anything of monetary value including, but not limited to, the examples provided below:

Financial Interest:

- An interest in a business consisting of any stock, stock option, or similar equity interest in such business (excluding any interest arising solely because the investment is in a pension, mutual fund, or other institutional investment fund over which the covered individual does not exercise control); or
- Receipt, or the right or expectation to receive, any income such as a consulting fee, honoraria, salary, allowance, royalty, or any other form of compensation.

Significant Financial Interest:

- More than \$5,000 in income and/or
- With respect to stock, stock options, or other ownership interest in a publicly traded entity:
 - An equity interest valued at \$5,000 or more; or
 - An equity interest of 0.1 percent or more (regardless of worth).
- With respect to stock, stock options, or other ownership interest in a non-publicly traded entity, or any ownership interest.

Immediate family member

The covered individual's spouse or domestic partner, parent, child, grandchild, sibling or in-law.

Outside associates

Researchers working for sub-grantees, contractors, or collaborators outside the University who participate in research for which the University has primary responsibility.

Participate

To be part of University activity in any capacity, including, but not limited to, serving as the principal investigator, co-investigator, research collaborator, or provider of direct services or patient care. The term does not apply to individuals who provide primarily technical or advisory support and have no direct access to the data or control over its collection or analysis. The term also does not apply to the study participants, unless they are in a position to influence the study's results or have privileged information as to the outcome. The term also applies to teaching, engaging in outreach activities, and/or providing administrative services.

REPA

The electronic form in the Electronic Grants Management System (EGMS) used by covered individuals to make their annual and updated disclosures of external professional activities.

Relationships of a non-business, non-financial nature

A personal relationship that may influence the manner in which a covered individual engages in University-related activities and/or carries out University-related responsibilities, to include decisions made with respect to the allocation of resources.

Reporting obligations

A requirement to report means to provide information regarding financial relationships and relationships of a non-business or non-financial nature that relate to or overlap with a covered individual's University responsibilities using an established reporting process internal to the University.

Sponsored project

Research, training, and instructional projects involving funds, materials, or other compensation from outside sources under agreements that contain any of the following: The agreement binds the University or an affiliated institution to a line of scholarly or scientific inquiry specified to a substantial level of detail; a line-item budget is involved; financial reports are required; the award is subject to external audit; unexpended funds must be returned to the sponsor at the conclusion of the project; or the agreement provides for the disposition of either tangible or intangible properties that may result from the activity.

Substantial change

A "substantial change" includes but is not limited to, an increase in the value of an existing financial interest to a value that qualifies it as a "significant financial interest".

Unit Head

The department, unit or division head, as appropriate.

University activities

Teaching, research, outreach, public service, and administrative activities. These activities also include clinical activities engaged in by faculty covered under private practice plans.

RESPONSIBILITIES

Collegiate Approver

Reviews disclosure form to verify the completeness and accuracy of the information. Approves REPAs where the covered individual answers "no" to all questions in Part 1 (General Questions). Submits the disclosure for review by the Conflict of Interest Program if any questions in Part 1 were answered "yes".

Conflict Review Committee (CRC)

Reviews financial disclosures reported on REPAs and Financial Disclosure for University Officials forms and, if a conflict of interest is identified, takes action to manage, reduce or eliminate the conflict and defines the elements of a conflict management plan.

Covered individual

Discloses activities and complies with approved plan to resolve conflict.

Department Approver

Reviews disclosure form to verify the completeness and accuracy of the information reported on the REPA. Discuss any known discrepancies with the collegiate approver.

Office of Institutional Compliance

Administers the conflict review and oversight process, convenes the CRCs, and directs the Conflict of Interest Program.

APPENDICES

- TBD

FAQ

- TBD

RELATED INFORMATION

Board of Regents Policies:

- *Code of Conduct*
- *Individual Business or Financial Conflict of Interest*
- *Institutional Conflict of Interest*
- *Purchasing*

Administrative Policies:

- *Managing Potential Institutional Conflicts of Interest*
- *Outside Consulting and Other Commitments*
- *Purchasing Goods and Services*
- *Purchasing a Professional Service*
- *Traveling on University Business*

Other Related Information:

- OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements"
- OMB Circular A-21, "Cost Principles for Educational Institutions"
- Minnesota Statute, Section 15.43, "Acceptance of advantage by state employee; penalty"
- Minnesota Statute 179A.01 and 179A.11, "External Subcontracting"
- Federal Acquisition Regulations

HISTORY

Effective:

Supersedes:

Individual Business or Financial Conflict of Interest policy, effective _____. See Board of Regents Policy: *Individual Business or Financial Conflict of Interest* for more details on the history of this policy.

The University of Minnesota's Perspective on Relationships with Outside Entities and the Potential for Conflicts of Interest.

The University of Minnesota's land-grant legacy originated in the passage of the Morrill Act of 1862 which provided public lands for the establishment of land-grant colleges and universities throughout the United States, effectively democratizing educational opportunities and forever linking land-grant universities with a tripartite mission of education, research and outreach. Then as now, a major emphasis was translation of the benefits of education and research to the improvement of the well-being of citizens and regional economic vitality. Outreach to individuals and companies outside of the walls of the academy was, and remains, an essential element in the linkage between translation of the first two elements of the land-grant mission and their intended benefits. While much has changed in the 150 years since passage of the historic Morrill Act, the essential need for universities to work effectively with the private sector in fulfillment of its mission has only intensified.

As recent history has demonstrated all too well, these important connections between universities, their faculty, their students and outside interests require careful attention and responsible stewardship to promote economic progress while protecting critical values of academic freedom, objectivity, research integrity, and public trust. In 2009, this stewardship requires enhanced institutional policies governing the disclosure and management of potential individual conflicts of interest. Certainly much recent interest has been focused on the University of Minnesota's position in this regard.

The University of Minnesota encourages faculty and staff to engage in outside activities that utilize their knowledge and expertise, and places a premium on the transfer of discoveries and intellectual property to the private sector where products and procedures that will improve our standard of living are made possible. Such transfer cannot happen without close linkages with private industry. However, potential conflicts of interest often arise in these relationships and the University has an obligation to be aware of that potential and to effectively manage it. We have been a leader in these efforts in the past and our current review of policies and practices is intended to identify areas where we can further enhance our management of potential conflicts in the interest of enhancing our relationships with the private sector in a manner that ensures the public's confidence.

While numerous definitions of "Conflicts of Interest" have been offered, they typically focus on a recognition that the potential for conflict and its adverse consequences resides in the perception that the design, conduct or reporting of research, or that the exercise of clinical judgment or responsibilities, might be influenced by the possibility of personal gain for the responsible individual(s). In recognition of this most fundamental feature of conflict of interest, the University believes that it is imperative that our policies and procedures effectively eliminate or manage to the extent possible those factors that contribute to the perception of conflict.

At the heart of an effective system of management is the promulgation of comprehensive, unambiguous policies. It is important to note that the intent of the review recently completed at the University is to establish responsible, effective and enforceable policies to ensure the stewardship required to manage these important relationships with entities outside of the University. Equally noteworthy is the acknowledgement that such policies are not intended to prevent, abridge or obstruct those relationships that are vital to the realization of our land-grant mission. If successful, these interventions will benefit equally the University community, our corporate partners, and the general public.

