

CONSECUTIVE MEETINGS OF:

**THE UNIVERSITY SENATE
THE FACULTY SENATE**

THURSDAY, APRIL 14, 2011

2:30 - 5:00 P.M.

**25 Mondale Hall--Twin Cities Campus
105 Kiehle Hall--Crookston Campus
173 Kirby Plaza--Duluth Campus
7 Humanities/Fine Arts Building--Morris Campus
Room 398--Rochester Campus
Southwest Research and Outreach Center**

This is a consecutive meeting of the University Senate and Faculty Senate. There are 257 voting members of the University Senate and 163 voting members of the Faculty Senate. A simple majority must be present for a quorum. Most actions require only a simple majority for approval. Actions requiring special majorities for approval are noted under each of those items.

**1. SENATE CONSULTATIVE COMMITTEE
Individual Conflicts of Interest: Standards that Govern
Those Involved in Clinical Health Care
Action by the University Senate
(15 minutes)**

MOTION:

To approve the following policy:

**Policy Individual Conflicts of Interest: Standards that Govern
Those Involved in Clinical Health Care**

KEY POLICY CHANGES (from appendix):

1. Replaces the prior AHC clinical health care appendix (Appendix A), with a standalone policy.
2. Expands applicability of these standards to all units within the University who have faculty and staff involved in clinical health care.
3. Adds two situations to Reporting Not Required section (income from making presentations at a continuing education event if the remuneration is paid by a professional association and not by a business entity; and salaries, royalties, or other remuneration paid to adjunct faculty by their primary employer).
4. Provides a new section on the sponsorship of fellowships, scholarships, and other University activities by business entities.
5. Expands the disclosure requirements to include serving on vendor selection committees.

ADMINISTRATIVE POLICY

Individual Conflicts of Interest: Standards that Govern Those Involved In Clinical Health Care

Policy Contents

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Effective Date: Month, YYYY**Last Updated:** Month, YYYY**Responsible University Officer:**

Director, Institutional Compliance

Policy Owner:

Director, Institutional Compliance

Policy Contact:

Lynn Zentner

POLICY STATEMENT

All covered individuals will be held to a shared ethical standard of ensuring that their relationships with business entities are transparent, grounded in objectivity, and do not improperly influence covered individuals' professional judgment, exercise of University responsibilities, or performance of University-related activities.

Individuals engaged in one or more higher-risk activities, however, are subject to a higher level of conflict of interest-related oversight and management. The higher-risk activities pertain to covered individuals who are:

- Involved in clinical health care;
- involved in human subjects research subject to review by the Institutional Review Board (IRB) where the IRB has determined that research conducted by the covered individual involves "more than minimal" risk to subjects;
- involved in technology commercialization;
- in a position to exert control over the content of University curriculum that could benefit the commercial interests of a business entity and, at the same time, create opportunity for or further an existing financial relationship between the covered individual and that business entity; or
- in a position to take any other action on behalf of the University that could benefit the commercial interests of a business entity and, at the same time, create opportunity for or further an existing financial relationship between the covered individual and that business entity.

Standards for Covered Individuals Involved in Clinical Health Care

This administrative policy establishes individual conflict of interest standards for covered individuals involved in clinical health care. For administrative ease, the general provisions from administrative policy: *Individual Conflicts of Interest* that apply to all covered individuals at the University are also incorporated into this policy. Persons involved in clinical health care, therefore, can rely on this policy alone for standards governing conflicts of interest.

Standards for All Other Covered Individuals

All other covered individuals whose relationships with business entities relate to their University expertise and responsibilities, including all faculty and staff; all individuals with responsibility for the design, conduct, or reporting of University research; and other individuals authorized to act on behalf of the University to fulfill its research and discovery, teaching and learning, and outreach and public service missions, are governed by the administrative policy: *Individual Conflicts of Interest*.

SECTION I. Reporting Business and Financial Relationships with Business Entities, and Identifying and Managing Conflicts of Interest

A. Annual Reporting: Annually, covered individuals, including those who are temporarily away from campus (e.g., leave, sabbatical), must complete a Report of External Professional Activities (REPA) to report financial interests and business interests, with respect to themselves and their family members, that are related to the covered individual's University expertise or responsibilities as described below.

1. **Remuneration.** All remuneration received from one or more business entities in the calendar year preceding REPA reporting or anticipated during the calendar year following REPA reporting in ranges specified on the REPA (e.g., \$1 to \$1,000). Remuneration includes salary and payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, and paid authorship).
2. **Equity Interests in Both Publicly Traded and Non-Publicly Traded Entities.** The dollar value of all equity interests (e.g., stock, stock options, or other ownership interest) in both publicly traded and non-publicly traded business entities as determined through reference to public prices or other reasonable measures of fair market value. Where no dollar value is available, the percentage of ownership interest must be reported.
3. **Royalties Paid in Connection with Intellectual Property Rights** such as patents and copyrights, including agreements to share in royalties related to such rights.

Business Interests include holding any executive position in a business or membership on a board of a business entity, whether or not such activities are compensated.

B. Reporting Not Required: Covered individuals are not required to report the following:

- Salaries, royalties, or other remuneration paid by the University to the covered individual;
- Salaries, royalties or other remuneration paid to adjunct faculty by their primary employer.
- Income from seminars, lectures, or teaching engagements sponsored by governmental agencies or by non-profit entities organized solely for educational, religious, philanthropic, or research purposes (with the exception of non-profit entities created by for-profit corporations);
- Income from serving as a special reviewer or review panelist for a public (governmental) or nonprofit entity;
- Income from services provided to professional organizations;
- Income from a private practice plan or private professional practice plan pursuant to Board of Regents policy;
- Income from making presentations at a continuing health education event if the remuneration is paid by a professional association and not by a business entity; and
- Royalties received under Board of Regents Policy: *Commercialization of Intellectual Property Rights*, where the covered individual who received the royalties does not have any other relationship with the business entity paying the royalties that could result in a conflict of interest.

C. Periodic Reporting: In addition to the annual reporting requirements, all covered individuals must complete a new REPA within 30 days of a substantial change in a business or financial interest that relates to their University expertise or responsibilities, or a change in

their University responsibilities that relates to an existing business or financial interest. 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 or the acquisition of a new financial interest.

- D. Application of These Reporting Requirements to Adjunct Faculty:** Adjunct faculty who are involved in one or more of the higher risk activities as part of their University-related responsibilities or who are responsible for the design, conduct, or reporting of research, whether compensated or uncompensated, are subject to these reporting requirements. However, even if an adjunct faculty member is not involved in any higher risk activity, a chancellor, dean, or administrative unit head, may, in the exercise of discretion, determine that the nature of an adjunct faculty member’s relationship with one or more business entities is such that it should be reported on a REPA.
- E. REPA Review.** Covered individuals are responsible for the accuracy and completeness of the information reported on the REPA. Chancellors, deans and administrative unit heads or their designee are responsible for reviewing that information and following up with the covered individual if they have questions or if they have reason to believe the information may not be accurate or complete. All potential conflicts of interest will be reviewed and managed centrally.
- F. Conflict of Commitment Review.** All covered individuals who receive remuneration from one of more business entities that in total exceeds \$100,000 in a single calendar year will be forwarded by the Conflict of Interest Program to the individual’s chancellor, dean or administrative unit head for a “Conflict of Commitment” review under the administrative policy: *Outside Consulting and Other Commitments* and the administrative procedure: *Outside Consulting and Other Commitments by Faculty and Academic Professional and Administrative (P&A) Staff*.

SECTION II. Conflict of Interest Thresholds

Thresholds for Conflict of Interest Review. REPAs will be referred to the Conflict of Interest Program for review when a covered individual has a financial or business interest as described below, that interest relates to the covered individual’s University expertise or responsibilities, and the interest meets one or more of the following thresholds:

A. Financial

- Remuneration received from a business entity in the calendar year preceding the REPA reporting or anticipated during the calendar year following the REPA reporting that, when aggregated, annually exceeds \$5,000 during one or both calendar years;
- Equity interests in a publicly traded business entity as of the date of REPA reporting that, when aggregated, annually exceed \$5,000;
- Equity interests in a non-publicly traded business entity in any amount; and
- With the exception of royalties exempted from the reporting requirements of this policy, the value of any royalties paid by a business entity in connection with intellectual property rights, e.g., patents and copyrights, and any agreements to share in royalties related to such rights that, when aggregated, annually exceeds \$5,000.

B. Business

- Any executive position in a business entity or membership on a board of a business entity.

SECTION III. Conflict of Interest Determinations

A. **Determinations.** University conflict review committees are authorized to determine whether a conflict of interest exists. Before a determination is made that a conflict of interest exists, conflict review committees or their corresponding executive committees will confer with the covered individual. Conflict review committees determine whether a conflict exists by considering the nature of the University activity, the nature of the financial interest or business interest, and how closely the interest is related to the covered individual's University expertise or responsibilities.

SECTION IV. Conflict of Interest Management and Compliance

A. **Management.** Once a conflict review committee has determined that a conflict of interest exists, the committee will also determine whether the conflict must be eliminated or reduced or whether it can be effectively managed. In either circumstance, a conflict management plan will be developed in consultation with the covered individual and, in appropriate circumstances, with the covered individual's chancellor, dean, administrative unit head or designee. Management mechanisms that may be imposed include those delineated in the procedure titled *Evaluating Disclosures of Financial and Business Interests and Managing Conflicts of Interest* and the following:

- Corroboration by a colleague of any prescription for a product of a commercial entity in which the provider has a significant financial interest and documenting this corroboration in the medical record;
- Appointment of an oversight committee to monitor practice patterns;
- Transfer of a patient's care to another colleague; and
- Cessation or modification of the relationship with a commercial entity.

B. **Compliance.** Covered individuals must fully comply with all management elements set forth in their conflict management plan and must confirm compliance with their conflict management plan in writing at least annually. When required by the terms of a conflict management plan, covered individuals must also provide documentation demonstrating compliance.

C. Covered individuals may not engage in University activities where a determination has been made that a conflict of interest exists, except in accordance with the terms of a University conflict management plan.

SECTION V. Standards Governing Relationships with Business Entities

A. Consulting with Business Entities

1. **Written Agreement:** Covered individuals who provide consulting services related to their University expertise or responsibilities must enter into a signed, written agreement with the business entity prior to providing the contemplated consulting services. The written agreement must:
 - state the need for the services provided;
 - describe the services and any deliverables to be provided;
 - state the remuneration to be paid;
 - state the timeframe covered by the agreement; and
 - make clear that the covered individual is acting solely in his or her individual capacity and is not speaking for, or acting on behalf of the University.

2. **Fair Market Value:** Professional fees paid for the consulting services provided must be consistent with and may not exceed the fair market value of the services provided. In addition to professional fees, covered individuals may also accept a business entity's payment of or reimbursement for reasonable and actual expenses for travel, meals, and lodging.
3. **Travel Expenses:** Payment for or reimbursement by the business entity for travel, meals, and lodging should be consistent with the standards set forth in administrative policy: *Traveling on University Business*, unless a chancellor, dean, or administrative unit head approves a different standard.
4. **Documentation Required:** Covered individuals who enter into a consulting relationship with a business entity must maintain documentation reflecting: (a) the remuneration received from, and any travel expenses paid for or reimbursed by, the business entity; and (b) the services provided, including estimates of the time and effort committed to providing the services. This documentation must be retained for the duration of the consulting relationship plus two years and must be available upon request.
5. **The University's Right to Review.** The University retains the right to review all such agreements and related documentation in the context of a conflict of interest review. Any review conducted by the University is done solely for the purpose of a conflict of interest review and is not to be construed as a legal review or a review conducted on behalf of the covered individual.
6. **Additional Compliance Obligations:** Covered individuals must also comply with the requirements of Board of Regents Policy: *Outside Consulting and Other Commitments*, the administrative policy: *Outside Consulting and Other Commitments* and related administrative procedures.

B. Using Products Developed and Provided by Business Entities

1. **Educational Materials:** In connection with their University responsibilities, covered individuals may use educational materials developed and provided by business entities but may not use educational materials that advertise or otherwise promote a product or service of the business. This provision does not prohibit the use of scientific articles published in peer reviewed journals even if some sections of the journal contain advertising.

When using educational materials developed by a business entity that do not reflect the name of the business entity that developed them, covered individual must disclose the name of the business entity to students, if known.

2. **Samples and Demonstration Items:** Units must centrally receive, document and disseminate free or discounted samples and demonstration items provided by a business entity. If such items are offered to a covered individual, he or she must refer the individual offering the items to a central location as designated by the particular campus, college or administrative unit.

This requirement does not apply to: (a) textbooks, software and related educational items that are provided in limited quantity to covered individuals to review for potential course adoption; or (b) laboratory supplies, reagents or pharmaceutical products and medical devices, also provided in limited quantity for evaluative purposes.

In the clinical context, for demonstration and educational purposes, covered individuals are permitted to use a product or product insert information branded with the name of a particular business entity with a patient for whom the product has been prescribed.

C. Attending or Participating in Events Sponsored by Business Entities

1. **Education and Training Events.** Covered individuals may attend on-site and off-site education and training events sponsored by business entities but may or may not be reimbursed for the expenses associated with attendance at off-site events.

Chancellors, deans, and administrative unit heads will determine whether it is appropriate for the University or the sponsoring business entity to pay for or reimburse the covered individual for the expenses associated with the individual's attendance at off-site events or whether the covered individual should pay for them, taking into consideration:

- (a) the educational value of the event; and
- (b) whether the commercial interests of the company served by the participation of the covered individual outweigh the educational benefit to be derived by the covered individual from attendance at the event.

Factors to consider include:

- the frequency of the same or similar sponsored trainings;
- the venue; and
- the substance of the agenda.

Payment for or reimbursement of expenses by a business entity for attendance at an education and training event may be permitted where the training is mandated by law.

On-site educational and training events sponsored by a business entity that do not constitute "continuing education events" must comply with the requirements set forth below in the "Business Funding for Continuing Educational Events" section of this policy with the exception of the accreditation requirements. These events also require prior approval by a chancellor, dean or administrative unit head.

Covered individuals may not accept compensation (e.g., an honorarium or consulting fees) simply for attending an education or training event sponsored by a business entity, listening to an audio presentation, or reviewing web based training developed by a business entity unless this activity is conducted in the context of a written consulting agreement which meets the requirements of Section II of this policy and the activity has been approved by a chancellor, dean or administrative unit head or designee.

2. **Business Funding for Continuing Educational Events.** Business entities may fund on-site continuing health education events if:

- the funding is in the form of a grant to the unit;
- the grant is unrestricted as to content and format of the activities for which it will be used;
- the University co-sponsor retains ultimate control with respect to the final selection of speakers, the order of presentations, and their content; and

- the event meets the requirements of the Accreditation Council for Continuing Medical Education or other applicable professional continuing health education requirements.
3. **Sales and Marketing Events:** Covered individuals may give presentations at sales and marketing events sponsored by business entities where the subject matter of the event relates to the individual's University expertise or responsibilities if:
- the information presented is evidence-based;
 - the covered individual represents that the lecture materials fairly reflect his/her independent views and not solely the views of the business entity; and
 - the following information is disclosed to the audience;:
 - the covered individual's business or financial relationship with the business entity, if any; and
 - a representation that the covered individual is speaking and acting solely in his or her individual capacity and not on behalf of the University.

D. Presence of Business Entities in the AHC, in Clinical Health Care Areas Outside the AHC, and in University/Fairview Facilities

Representatives of business entities are not permitted in:

- any AHC research, clinical or teaching areas, unless invited by faculty or staff;
- any clinical areas in colleges and departments outside the AHC unless invited by faculty or staff; or
- any University/Fairview facilities unless they have been "vendor certified" consistent with University/Fairview's vendor certification requirements.

E. Gifts, Food and Entertainment

1. **Gifts:** Covered individuals may not accept gifts from a business entity, irrespective of the nature or value of the gift (including items of de minimus value such as coffee mugs, pens, free services, items with the name or logo of a business entity), unless accepted on behalf of the University or unless a chancellor, dean or administrative unit head determines that the acceptance of a gift is appropriate in an international context.

However, gifts offered at large off-site educational events or professional conferences, where acceptance of the gift is optional and the gift is offered to all attendees (e.g., tote bags and door prizes at a conference) are an exception to this restriction and may be accepted.

The term "gift" does not include an award given for merit, excellence in a certain field of expertise, or a particular accomplishment.

The President or delegate may grant a categorical exception, in writing, where the recipients of gifts are not in a position to take action on behalf of the University that could benefit the commercial interests of the business entity offering the gifts.

2. **Meals and Entertainment:** Covered individuals, unless authorized by a chancellor, dean or administrative unit head in advance, may not accept meals, or entertainment, or similar benefits from a business entity either on or off-site, with the exception of modest meals offered to all attendees at large professional conferences.

- When permitted, payment for or reimbursement by the business entity for meals should be consistent with the standards set forth in administrative policy: *Traveling on University Business*, unless a chancellor, dean, or administrative unit head approves a different standard.
- The restrictions of this provision do not apply to student recruiting events sponsored by business entities unless the event has a commercial marketing purpose.
- Meals provided or reimbursed by a business entity in the context of a consulting relationship that meets the requirements of Section II.A do not require prior approval but must otherwise meet the requirements of this section.

F. Sponsored Research Involving Sub-Grantees, Contractors, or Collaborators

When individuals outside the University participate as a sub-grantee, contractor, or collaborator in sponsored research with covered individuals, the University, at least to the extent required by the research sponsor, will take reasonable steps to ensure that sub-grantees, contractors, or collaborators are adequately informed of their obligation to comply with all applicable conflict of interest reporting, review, and disclosure requirements as required by federal and state law, as well as all conflict of interest policies of research sponsors. This requirement is satisfied if the University's contract or other agreement with the sub-grantee, contractor, or collaborator includes a provision setting forth these obligations.

G. Prohibited External Relationships or Activities **Covered individuals may not:**

1. **Accept Payment for Promotion of Products or Services.** Covered individuals may not accept payment for promoting the products or services or other commercial interests of a business entity. In a clinical setting, the incentive for making these payments may be to improperly 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.

This provision does not prevent a covered individual, with the approval of a chancellor, dean or administrative unit head, from selecting for educational, research, clinical care or outreach purposes, a product the covered individual developed.

2. **Accept Payment for the Recruitment of Patients for Clinical Research Studies.** Covered individuals may not accept payment, gifts or other benefits solely for the purpose of recruiting patients for clinical research activities unless it is in the form of a payment made as part of a global fee for performing or overseeing a clinical trial.
3. **Accept Payment for Completing Evaluations or Surveys Developed by a Business Entity.** Covered individuals may not accept payment, gifts or other benefits in return for completing evaluations or surveys developed by a business entity unless this activity is conducted in the context of a written consulting agreement which meets the requirements of Section II of this policy and/or the activity has been approved in advance by a chancellor, dean, administrative unit head or designee.

4. **Receive Personal Gain from Use of Instructional Materials They Developed.** Covered individuals may not personally profit from the assignment of materials, or the assignment of the venue for the purchase of materials, to students in classes or any other instructional setting at the University without proper administrative approval by the appropriate collegiate department.
5. **Engage in Ghostwriting.** Covered individuals may not have 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 meaningful authorship in the publication or article.
 - Authorship must be restricted to those individuals who made a significant intellectual contribution to the work, including: conception, design, and performance; analysis and interpretation; and manuscript preparation and critical editing for intellectual content.
6. **Make Endorsements. Covered individuals may not endorse a product** or service developed or sold by a particular business unless: (a) a contract entered into by the University permits the endorsement; or (b) the endorsement is based on the covered individual's scholarly activity and research. This provision applies to both written and oral endorsements when the product or service relates to the covered individual's University-related expertise or responsibilities, whether or not the covered individual uses his or her University title in making the endorsement. This provision is not intended to restrict: (1) classroom discussion or other educational activities that involve comparative analysis; or (2) the covered individual from providing an opinion based on scholarly activity or research.

H. Sponsorship of Fellowships and Scholarships by Business Entities

Chancellors, deans, and administrative unit heads may accept the sponsorship of fellowships and scholarships by business entities under the following conditions:

The sponsorship must be:

- in the form of a gift given to either the University of Minnesota Foundation or the Minnesota Medical Foundation, or
- in the form of a grant given to the University through the Office of Sponsored Projects Administration; and
- given without any expectation of reciprocity.

Once received, these funds must be used to support educational programs and activities for students, residents and fellows.

While it is within the purview of the donor to select a particular area of interest, the business entity is not permitted to select the recipient of a scholarship or fellowship.

When opportunities for fellowships and scholarships arise, campuses, departments and units should work in collaboration with the foundations to obtain gifts from business entities in support of scholarships and fellowships.

SECTION VI. Disclosing Business Interests and Significant Financial Interests

A. Generally

Whether or not required by the terms of a conflict management plan, covered individuals must make the following disclosures:

1. **In the context of clinical health care.** Covered individuals, who provide clinical care and who also have a business interest or a significant financial interest in a business which manufactures or distributes pharmaceuticals, medical devices, or other health care products, must provide a written disclosure of that business or financial interest to all patients for whom the individual prescribes a branded product of that business. The same disclosure must be made when the business interest or significant financial interest is held by a family member.

The written disclosure may be made in the form of a letter addressed to the individual patient or, alternatively, in the form of a declaration which adequately discloses the financial interest but may not be individually addressed to each patient. In either case, documentation of the disclosure must be made in the health record.

2. **To research sponsors.** Covered individuals must disclose relevant business or significant financial interests to sponsors of research as required by the sponsor.
3. **To professional journals and other publications.** When submitting a paper for publication, a covered individual must disclose to the editor any business or significant financial interest that may be affected by publication. This provision also applies to the release of information to news media.
4. **In the context of a public appearance.** Covered individuals must disclose relevant business or significant financial interests when making an appearance, either in person or by way of a written communication, before any public body, commission, group, or individual, to present facts or to give an opinion respecting any issue or matter up for consideration, discussion, or action.
5. **When serving on vendor selection committees.** Covered individuals who serve on vendor selection committees must disclose relevant business or financial interests when participating in vendor selection decisions on behalf of the University, University of Minnesota Physicians, or Fairview. The term “relevant business or financial interests” means financial and business interests held by the individual or a member of the individual’s family as well as financial interests associated with monetary contributions made by a business entity to that individual’s University department.

B. When Required by a Conflict Management Plan

When required by the terms of a conflict management plan, covered individuals must make the following disclosures:

1. Once the Committee determines that a conflict of interest exists, covered individuals must disclose the existence of the conflict as required by the terms of the covered individual’s conflict management plan. In the context of human subjects research, the disclosure will be made on the Consent Form and the substance of the disclosure will be subject to the discretion of the IRB.
2. **Retaining Documentation of the Disclosures Made.** Covered individuals must retain documentation of the disclosures made for the period of time the conflict management plan is in effect.

C. Public Disclosure of Financial and Business Interests

Disclosure to the Public. The AHC will maintain a public website on which covered individuals may voluntarily disclose:

- compensation received from a business entity for consulting activities that relate to the covered individual's University expertise or responsibilities;
- royalty income; and
- any equity interest held in a business entity where the products or services of the entity relate to the covered individual's University expertise or responsibilities.

NOTE: The University will amend its public disclosure rules to conform to federal Health and Human Services (HHS) regulations requiring public disclosure of financial interest information when such regulations are final and implemented. Proposed HHS regulations call for mandatory public disclosure of the following information via a publicly accessible Web site, before expenditure of any funds under a Public Health Services (PHS)-funded research project is made, when it is determined that a financial conflict of interest exists that is related to PHS-funded research:

- the covered individual's name;
- the covered individual's position with respect to the particular research project;
- the nature of the significant financial interest; and
- the approximate dollar value of the significant financial interest in specified ranges.

SECTION VII. Educational Requirements

Covered individuals who are required to report business and financial interests on a REPA will be required to complete training on the University's policies and procedures on individual conflicts of interest and any applicable state and federal laws at least every three years.

SECTION VIII. Compliance

Covered individuals must comply with all University policies and procedures related to conflicts of interest and applicable federal and state law.

REASON FOR POLICY

To implement Board of Regents Policy: *Individual Conflicts of Interest* and to comply with federal and state law. This policy is intended to ensure that covered individuals report and fully disclose financial and business interests that relate to their University expertise and responsibilities so that potential conflicts of interest can be reviewed and, where conflicts of interest are found to exist, 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 external interests and relationships.

PROCEDURES

- *Reporting External Relationships and Business and Financial Interests*
- *Evaluating Reports of Business and Financial Interests 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)	Lynn Zentner	612-626-7852	lzentner@umn.edu
Technical problems	EGMS helpline	612-624-1600	repa@egms.umn.edu
Policy Questions	Policy Helpline	612-626-1462	repamail@umn.edu

DEFINITIONS**Academic Employees**

Appointment categories which include Faculty (regular, term and adjunct; probationary and tenure track; temporary and visiting) and Academic Professional and Administrative Staff.

Associated Entity

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

Business Entity

Any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other nongovernmental legal entity organized for profit, nonprofit, or charitable purposes. This definition does not include organizations and entities that are organized solely for educational, religious, philanthropic, or research purposes.

Business Interest

Holding any executive position (e.g., Chief Executive Officer, Chief Operating Officer, Chief Scientific or Technical Officer) in a business or membership on a board of a business entity, whether or not such activities are compensated. The term "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.

Clinical Health Care

The provision of medical, dental, nursing, or other health-related care to humans or animals for the treatment of disease or injury. In the context of animals, this definition includes those owned by the University and those brought to the University by their owners specifically for the purpose of health care.

Conflict of Interest (Individual)

A relationship between a covered individual's private business or financial interests, or those of the covered individual's family members, and the covered individual's expertise and responsibilities such that an independent observer might reasonably question whether the individual's objectivity in the performance of University responsibilities could be compromised by considerations of personal gain.

In the context of research, a *financial conflict of interest* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the research.

In the context of clinical care, a conflict of interest exists when a secondary financial interest creates the risk that the primary duty to the patient and the delivery of optimal care will be improperly influenced by personal financial interests of the care provider.

Conflict Management Plan

A formal document approved by the applicable conflict review committee that directs the covered individual's management of the conflict of interest.

Conflict Review Committee

University committees 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 reduced, 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, Human Research Protection Program, Office of Research Integrity and Oversight Programs, and the Office of the General Counsel.

Consulting

A commitment engaged in by a covered individual outside the University related to that individual's University-related expertise or which overlaps with the covered individual's University responsibilities. The outside commitment involves the provision of paid professional services intended to further the interests of an outside party, irrespective of whether such services are provided as an employee of the outside party, an independent contractor, a business owner, or as a director or manager. An outside consulting activity involves the provision of services that are outside the scope of the covered individual's University 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 or technologies, speaking engagements, scientific, technical or other professional advisory board membership, position paper preparation, or serving as an expert witness in legal proceedings. 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 (P&A) Staff*.

Covered Individual

Includes the following: (a) faculty and staff; (b) individuals with responsibility for the design, conduct, or reporting of University research; and (c) other individuals authorized to act on behalf of the University to fulfill its research and discovery, teaching and learning, and outreach and public service missions.

Departmental Approver

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

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>).

Endorsement

A promotional statement made to further the commercial interests of a business entity.

Equity Interest

Any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Fair Market Value

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

- a. reflects the expertise and credentials of the covered individual;
- b. is comparable to the compensation paid to the covered individual's peers;
- c. is reasonable in the context of the services provided; and
- d. does not include an enhancement in exchange for an agreement to improperly:
 - i. Make or induce others to make referrals to a business entity;
 - ii. Make or induce others to endorse the products or services of a business entity;
or
 - iii. Improperly influence research results to benefit the interests of a business entity.

Family Member

The covered individual's spouse or domestic partner, dependent children, and any other family member whom the covered individual reasonably knows may benefit personally from actions taken by the covered individual on behalf of the University.

Financial Interest and Significant Financial Interest**Financial Interest:**

Anything of monetary value, including, but not limited to:

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

Significant Financial Interest:

Anything of monetary value where the value equals or exceeds:

- a. an aggregated equity interest in a business representing ownership of 5% (regardless of worth) or a value of \$5,000 or more as determined through reference to public prices or other reasonable measures of fair market value;
- b. an aggregated equity interest in a non-publicly traded business entity in any amount;
- c. an aggregated annual income of all types from a business of \$5,000 or more; or
- d. the receipt of or commitment for future royalties from a business entity that are expected to be \$5,000 or more in aggregated annual income.

Non-compliance

Non-compliance with the provisions 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 eliminating, reducing, or managing a potential conflict.

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 a 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 also applies to teaching, engaging in outreach activities, and/or providing administrative services. 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.

Remuneration

Includes salary and any payment of services not otherwise identified as salary (e.g., consulting fees, honoraria, and paid authorship).

REPA (Report of External Professional Activities) Form

The form in the Electronic Grants Management System (EGMS) used by covered individuals to report external professional activities at least annually.

Reporting Obligations

A requirement to report means that, at least annually, covered individuals must provide information regarding external financial and business relationships that relate to their University responsibilities using an established reporting process internal to the University. Covered individuals must also report substantial changes in financial or business interests within 30 days of the time that the change occurs. With respect to a financial interest, a "substantial change" includes, but is not limited to (1) an increase in the value of an existing financial interest to a value that qualifies it as a significant financial interest; (2) a covered individual's acquisition of a new significant financial interest (e.g., through purchase, marriage, or inheritance); (3) assuming an executive or other fiduciary role with a business entity; or (4) a change in a covered individual's responsibilities that relates to an existing business or financial interest.

Sales and Marketing Event

An event sponsored by a business entity primarily for the purpose of promoting its commercial interests.

Sponsored Project

Research, training, and instructional projects involving funds, materials, or other compensation from outside sources under agreements that involve any of the following:

- a. the agreement binds the University or an affiliated institution to a line of scholarly or scientific inquiry specified to a substantial level of detail;
- b. a line-item budget is involved; financial reports are required;
- c. the award is subject to external audit;
- d. unexpended funds must be returned to the sponsor at the conclusion of the project; or
- e. the agreement provides for the disposition of either tangible or intangible properties that may result from the activity.

RESPONSIBILITIES**Collegiate Approver**

Reviews REPAs. Follows up with the covered individual if they have questions or if they have reason to believe the information reported on the REPA may not be accurate or complete.

Approves REPAs where permitted by University conflict of interest procedures (under development). Refers REPAs for review by the Conflict of Interest Program as required by University conflict of interest procedures. The collegiate approver is the senior administrative officer for the college or administrative unit (typically a dean or vice president) or that officer's designee.

Conflict Review Committee

Reviews REPAs and other related information to determine if a conflict of interest exists, and, if it is determined that a conflict of interest exists, takes action to eliminate, reduce, or manage the conflict and defines the elements of a conflict management plan.

Covered Individual

Reports external professional activities at least annually, and, where a conflict management plan has been issued to the individual by a Conflict Review Committee, complies with management mechanisms specified in the plan and, at least annually, confirms his or her compliance with the plan.

Department Approver

Reviews REPAs completed by covered individuals in the approver's college, unit or department. Follows up with covered individuals if they have questions or if they have reason to believe the information reported on a REPA may not be accurate or complete.

Executive Conflict Review Committee

A subgroup of a conflict review committee that reviews and evaluates potential conflict of interest matters and prepares them for consideration and action by the appropriate conflict review committee. Members include the chair of the associated Conflict Review Committee, representatives from the Office of Institutional Compliance, and a representative from the Office of the General Counsel.

Office of Institutional Compliance

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

Unit Approver

Reviews REPAs completed by covered individuals in the approver's administrative unit. Follows up with covered individuals if they have questions or if they have reason to believe the information reported on a REPA may not be accurate or complete.

APPENDICES

- *Clarification of Reporting Requirements for Particular Appointment Situations*
- *Conflicts of Interest Categories*
- *Implementation Timeline: Individual Conflicts of Interest: Clinical Health Care - Patient Contact in the Academic Health Center*
- *Individuals Required to, or Who are Exempt from, Completing a Report of External Activities (REPA)*

FAQ

- Individual Conflict of Interest FAQ

RELATED INFORMATION

Board of Regents Policies:

- Code of Conduct
- Individual Conflicts 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
- Educational Materials Conflict of Interest: Twin Cities, Crookston, Morris, Rochester

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

Amended:

October 2010 - The policy: a) expanded reporting requirements to reflect the change in the definition of family members, b) differentiates operationally the ethical standards that apply to those individuals whose University responsibilities involve higher risk activities; c) adds standards to govern relationships with business entities, e.g., the acceptance of gifts, the presence of business representatives on campus, and the use of products developed and provided by business entities; and d) incorporates a separate appendix covering those individuals involved in the provision of clinical health care. Title changed to Individual Conflicts of Interest.

Amended:

February 2010 - Updated Administrative Procedure: *Evaluating and Managing Individual Conflict of Interest Disclosures* with additional language about IRB involvement in evaluation and management of conflicts.

Amended:

October 2009 - Added Frequently Asked Questions.

Effective:

September 2005

Supersedes:

September 2005 - Administrative Policy: *Purchasing Conflict of Interest*, issued 1/1993, revised 9/2003. See Board of Regents Policy: *Individual Business or Financial Conflict of Interest* for more details on the history of this policy.

COMMENT:

The proposed policy was reviewed carefully by the Senate Committee on Faculty Affairs, the Senate Research Committee, and the Senate Consultative Committee. All three committees endorse it.

**KATHRYN VANDENBOSCH, CHAIR
SENATE CONSULTATIVE COMMITTEE**

2. UNIVERSITY BUDGET
Discussion by the University Senate
(30 minutes)

3. BENEFITS ADVISORY COMMITTEE
FACULTY AFFAIRS COMMITTEE
Health Insurance Issues
Discussion by the University Senate
(30 minutes)

4. UPDATE ON LIGHT RAIL TRANSIT
Discussion by the University Senate
(30 minutes)

5. UNIVERSITY SENATE OLD BUSINESS

6. UNIVERSITY SENATE NEW BUSINESS

7. UNIVERSITY SENATE ADJOURNMENT

THIS CONCLUDES THE UNIVERSITY SENATE BUSINESS.
THE SUBSEQUENT ITEMS ARE FACULTY SENATE BUSINESS ONLY.

MEETING OF THE FACULTY SENATE

**8. FACULTY AFFAIRS COMMITTEE
FACULTY CONSULTATIVE COMMITTEE
Faculty Retirement Plan Changes
Discussion by the Faculty Senate
(45 minutes)**

9. FACULTY SENATE OLD BUSINESS

10. FACULTY SENATE NEW BUSINESS

11. FACULTY SENATE ADJOURNMENT

Faculty Retirement Plan Peer Comparisons
Faculty Senate - April 14, 2011

	Employee Contributions	University Contributions	Replacement Ratio (Estimated)	Notations
The Ohio State University*	10%	14%	91%	Choice of plan – defined contribution listed
University of California - Berkeley	2%	4%	85%	Defined benefit – (normal cost 17.6%)
University of California – Los Angeles	2%	4%	85%	Defined benefit – (normal cost 17.6%)
Penn State	6.25%	4.11%	85%	Choice of plan – Defined benefit listed
University of Texas	6.4%	6.4%	76%	Choice of plan – Defined benefit listed
University of Illinois*	8%	9.1%	74%	Choice of plan – Defined benefit listed
University of Washington-Seattle	5%-10%	5%-10%	63%	Defined Contribution
University of Minnesota	2.5%	13%	61%	Defined Contribution
University of Michigan	5%	10%	59%	Defined Contribution
University of Wisconsin	0%	11%-11.9%	57%	Defined Benefit
University of Florida	0%	8.74%	56%	Choice of plan – Defined benefit listed

*Does not participate in Social Security

STATEMENT ON ACCESS TO HEALTHPARTNERS CLINICS

FOR INFORMATION:

The Senate Committee on Faculty Affairs (SCFA), a standing committee of the University of Minnesota Faculty Senate, urges: That HealthPartners negotiate in good faith to make its clinics available through Medica at the best possible price, keeping in mind the long term devotion of many University members to their HealthPartners clinics; that Medica negotiate in good faith to achieve the best possible outcome for the University and its employees; and that Employee Benefits closely monitor these negotiations, giving particular consideration to the effect the outcome will have on current HealthPartners members, while exercising all necessary due diligence in looking out for the University's economic best interests.

COMMENT:

Given the current University budget situation, SCFA reluctantly recognizes the necessity of finding all reasonable cost savings in the UPlan. SCFA appreciates the value of savings available by going from two administrators to one for the UPlan Medical Program and also recognizes that moving to Medica as the UPlan's sole administrator for 2012 and beyond does not necessarily imply a loss of access to HealthPartners clinics.

At the same time, SCFA is deeply concerned for the third of University faculty and staff who currently obtain their health care through the HealthPartners Classic plan offering.

SCFA therefore expresses its strong desire that the expressed goal of retaining continued access to HealthPartners clinics, through Medica as the UPlan administrator, be achieved at the most affordable cost possible.

Adopted April 12, 2011

**GEORGE SHEETS, CHAIR
FACULTY AFFAIRS COMMITTEE**

STATEMENT ON THE FACULTY RETIREMENT PLAN

FOR INFORMATION:

The Retirement Subcommittee recommends to the President that the total contributions (employer and employee) to the FRP shall not go below 15.5%. The employer/employee contribution rate to the plan for existing employees will remain at 13%/2.5%, and the contribution rate for new employees hired after the implementation date will be 10%/5.5%, respectively.

COMMENT:

Keeping the total contribution whole for the newly-hired FRP-eligible participants at 15.5% (employer contribution 10% and employee contribution 5.5%) is intended to help plan participants build a portfolio that will allow them to retire.

The Faculty Consultative Committee voted to endorse this motion from the Retirement Subcommittee.