## KEY POLICY CHANGES

- 1. Expanded the title to cover contents of the policy.
- 2. Incorporates content from Individual Conflicts of Interest: Standards that Govern those that are Engaged in Clinical Health Care. That policy will be retired.
- 3. Provides new "no income" standard for human participant study investigators.
- 4. Clarifies standards governing relations with business entities to include prohibited activities, gifts, and consulting agreements.
- 5. Revises language to align with Board of Regents Policies and Public Health Service COI regulations.



### ADMINISTRATIVE POLICY

# Individual Conflicts of Interest and Standards Governing Relationships with Business Entities

#### **Policy Contents**

- Policy Statement
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Effective Date: September 2005 Last Updated: August 2012

**Responsible University Officer:** University President

Policy Owner: Director, Office of Institutional Compliance

**Policy Contact:** Lynn Zentner

#### POLICY STATEMENT

The University encourages its faculty and staff to engage in relationships with business entities to further the University's mission while acknowledging that inherent in these relationships is the risk that professional judgment may be improperly influenced by the existence of such relationships. All faculty and staff are held to a shared ethical standard of ensuring that their relationships with business entities are transparent, grounded in objectivity, and do not improperly influence their professional judgment, exercise of University responsibilities, or performance of University-related activities.

Some relationships with business entities require greater vigilance than others. For example, when a relationship with a business entity could influence decisions made in the provision of clinical health care or conduct of research involving human participants, ensuring the safety of patients and research participants is paramount.

This policy, which applies to all University faculty and staff, provides the framework to effectively identify and manage conflicts of interest, and establishes standards that enable faculty and staff to collaborate with business entities while ensuring that students, faculty and staff of the University, as well as the general public have

confidence in the integrity and objectivity of the University's research and discovery, teaching and learning, and outreach and public service activities.

Campuses, colleges, departments, and administrative units may adopt standards that are more, but not less, restrictive than those set forth in this policy.

#### SECTION I. REPORTING, REVIEW & MANAGEMENT OF RELATIONSHIPS WITH BUSINESS ENTITIES

**Report of External Professional Activities (REPA).** All paid faculty, Professional and Academic Administrative employees (P&A), and other individuals designated by a senior leader or their designate, or the Conflict of Interest (COI) Program staff, must comply with the following requirements to report significant financial interests and business interests they or their family members hold that relate to the covered individual's University expertise and responsibilities:

- Annual reporting. Covered individuals must complete an annual Report of External Professional Activities (REPA), even if they have no reportable external activities, significant financial interests, or business interests.
- **Change in circumstances reporting.** In addition to the annual reporting requirement, covered individuals must file a REPA within 30 days of:
  - Acquiring a significant financial interest or acquiring a business interest that relates to their University expertise and responsibilities;
  - Assuming a new University responsibility that relates to an existing business or significant financial interest; or
  - For Public Health Service (PHS) funded investigators, travel not previously reported that is related to one's University responsibilities, valued in excess of \$5000, and paid for or reimbursed by a business entity.
    - Travel paid for or reimbursed by a governmental agency, an institution of higher education, an
      academic teaching hospital, a medical center, or a research institute that is affiliated with an
      institution of higher education does not need to be reported.
    - The covered individual must disclose the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

Supervisors or designees within the covered individual's department, administrative unit, college, or campus are responsible for reviewing the REPA.

Conflict of Interest (COI) Program staff review REPAs that reflect a significant financial or business interest, and refer potential conflict of interest matters to a Conflict Review Panel (CRP). A Conflict Review Panel determines whether a conflict of interest exists and, if so, whether the conflict can be managed under the terms of a conflict management plan.

When a conflict management plan is established, the Conflict of Interest Program will conduct a compliance review 90 days after the plan is executed, and then annually until the conflict no longer exists and the management plan is retired by Conflict of Interest Program Staff. Compliance review results are reported to the Conflict Review Panel.

**Institutional Review Board (IRB) Applications.** Investigators, and individuals who enroll or consent participants, must disclose relevant financial interests and business interests when completing IRB applications for human participant studies.

#### **Educational Requirements**

Covered individuals must complete the University's conflict of interest course (add Link) when filing the REPA for the first time, and every four years thereafter.

In addition, investigators engaged in PHS-funded research, to include sub-recipient investigators, must complete a conflict of interest course prior to engaging in research related to any PHS-funded grant, and must take the course immediately when:

- the University revises this conflict of interest policy or procedures in any manner that affects the requirements imposed on investigators;
- an Investigator is new to the University; or

• the University finds that an Investigator is not in compliance with this policy or a conflict management plan.

#### **Disclosing Business and Significant Financial Interests**

All employees must disclose relevant business and significant financial interests in the following situations (see also **Appendix:** *Required Disclosures*):

- To patients (in the context of clinical health care) for whom the employee is prescribing or using a branded product;
- To sponsors of research;
- To professional journals and other publications;
- In the context of a public appearance;
- To students or trainees;
- When determined to be non-compliant with PHS regulations;
- When serving on supplier selection committees; and
- When required by the terms of a conflict management plan.

University disclosure in response to external requests for financial conflict of interest information associated with PHS-funded research. The Conflict of Interest Program will provide the following information in a written response within five business days of the request:

- the investigator's name, title, and role on the research;
- the name of the business entity in which the significant financial interest is held;
- the nature of the significant financial interest; and
- the approximate value of the significant financial interest in dollar ranges or a statement that the value cannot be readily determined.

For at least three years from the date on which the information was most recently updated, information concerning the significant financial interests of an investigator will remain available in order to respond to written requests for this information.

#### SECTION II. STANDARDS GOVERNING RELATIONSHIPS WITH BUSINESS ENTITIES A. Prohibited Activities.

Employees are prohibited from engaging in the following activities with business entities (see Appendix: *Prohibited Activities with Business Entities* for more details.)

- Having a financial or personal beneficial interest in a University contract or purchase order (see Minnesota Statute, Section 15.43)
- Receiving personal gain from the use of instructional materials without proper administrative approval
- Ghostwriting
- Endorsing a product or service related to one's University responsibilities and expertise
- Accepting payment for the selection, use or promotion of products or services for University purposes.
- Accepting payment for the referral of students to prospective employers
- · Accepting payment for the recruitment of patients for clinical research studies
- Accepting payment for participating in surveys intended to promote, market or sell a drug or medical device directly to the practitioner
- Using or disclosing nonpublic research information in violation of insider trading laws
- Making professional referrals to a business entity in which they have a business or financial interest.

## B. Receiving Personal Remuneration from a Company While Participating in a Human Participant Study Sponsored by that Company.

Investigators who participate in an open human participant research study requiring IRB approval and oversight that is sponsored by a company, or involves the development or evaluation of a company's product, device, or other technology, may provide consulting or speaking services ("services") for the company during the period of the research study under the following conditions:

1. Any payments made in exchange for the services are directed to the University under the

terms of a University External Sales Agreement;

- 2. The funds are not used to support the salary of the investigator.
- 3. The arrangement is approved by a Conflict Review Panel.

For purposes of this provision, a human participant research study is open from the time the study is approved by the IRB until participant enrollment is closed and the primary outcome from the study has been published.

Investigators may receive study-related expenses as approved in the University budget for the study, including salary support and travel expenses.

An investigator may request that the Conflict Review Panel approve an exception to this provision in order to receive personal remuneration or equity from the company while participating in the study. Compelling circumstances must be present to warrant approval of the exception.

C. **Gifts**. Employees are expected to exercise good judgment and should decline a gift that would compromise, or have the appearance of compromising, the employee's decision making in University matters.

A gift is any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, service, training, transportation, lodging, meals, or other item that constitutes a personal benefit to the recipient. It does not include an award given for merit, excellence in a certain field of expertise, or a particular accomplishment. It also does not include a gift made to the University or its Foundation for University purposes.

- 1. Allowable gifts. Employees may accept the following:
  - modestly priced meals or other items (e.g., tote bags or door prizes) offered to all attendees at a widely-attended educational event or professional conference;
  - meals approved in advance by the employee's chancellor, dean, or administrative unit head after determining that the meal is being offered in a context that supports the education, research, or outreach mission of the University. The value of the meal should be consistent with the standards set forth in Administrative Policy: *Traveling on University Business*
  - a gift made in an international context; and
  - items provided to employees pursuant to a University contract approved by the Office of General Counsel.

#### 2. Gift Acceptance Limits.

- a. "University Officials" are subject to the provisions of Board of Regents Policy: *Gifts Received and Given by Regents and University Officials.*
- b. Employees involved in clinical health care may not accept gifts from any healthcare related business entity (e.g., pharmaceutical, biotechnology, medical device, or medical diagnostics) irrespective of the nature or value of the gift, including items of nominal value such as coffee mugs, pens, free services, or items with the name or logo of a business entity. Modest refreshments, such as coffee, donuts, and soft drinks may be accepted.
- c. Employees in direct contact with suppliers or potential suppliers to the University, or who may directly or indirectly influence a purchasing decision or contract by establishing specification, testing purchased products, evaluating contracted services, or otherwise have official involvement in the purchasing or contracting process, may not accept a gift directly or indirectly from a person, firm, or corporation to which a contract or purchase order has been or may be awarded, unless the value of the gift meets the "nominal gift" standard set forth in Administrative Policy: *Purchasing Goods and Services*.
- 3. **Disposition of Prohibited Gifts**. If an employee has received a gift that cannot be accepted, the employee may:
  - return the gift;
  - pay its market value;
  - transfer the gift to charity; or

 share a perishable gift (e.g. a fruit basket or flowers) with the office if it is not practical to return the gift.

#### D. Consulting with Business Entities.

- 1. Written Agreement. Employees who plan to provide compensated consulting services for one year or longer relating to their University expertise and responsibilities should enter into a signed, written agreement with the business entity prior to providing the consulting services. The written agreement should:
  - state the timeframe covered by the agreement;
  - describe the services and any deliverables to be provided by the employee;
  - state the amount of compensation and expenses to be paid; and
  - make clear that the employee is acting solely in his or her individual capacity and not on behalf of the University.
  - Compensation should fall within fair market value parameters for the services provided.
  - Payment of travel, food, and lodging expenses should be consistent with the standards set forth in Administrative Policy: <u>Traveling on University Business</u>.

#### 2. Additional Compliance Obligations.

- a. Unless an exception is approved by a Conflict Review Panel, employees may not receive personal remuneration or equity from a company while serving as an investigator on a human participant study requiring IRB approval and oversight that is sponsored by that company, or involves the development or evaluation of that company's product, device, or other technology. See Section II B.
- b. Employees must also comply with the requirements of Board of Regents Policy: <u>Outside Consulting</u> <u>and Other Commitments</u>, Administrative Policy: <u>Outside Consulting and Other Commitments</u>, and related administrative procedures.

#### E. Attending or Participating in Events Sponsored by Companies

#### 1. Education and Training Events (non-accredited).

- a. Employees may attend on-site and off-site education and training events sponsored by companies. Employees may not accept compensation (e.g., an honorarium or consulting fees) simply for attending an education or training event sponsored by a company.
- b. An on-site educational or training event that does not qualify as a "continuing education event" must receive prior approval from a chancellor, dean or administrative unit head, and must meet these criteria:
  - (1) the funding is in the form of a grant to the unit;
  - (2) the grant is unrestricted as to content and format of the activities for which it will be used; and
  - (3) the University co-sponsor retains ultimate control with respect to the final selection of speakers, the order of presentations, and their content.
- c. Chancellors, deans, or administrative unit heads will determine whether to accept a company's offer to pay some or all of an employee's expenses to attend an off-site education or training event. Factors to consider include the University need for the employee's education or training, the substance of the agenda, the frequency of the training, and the venue.
- 2. **Continuing Education Events (accredited).** Companies may fund on-site continuing education events if the following criteria are met:
  - a. the funding is in the form of a grant to the unit;
  - b. the grant is unrestricted as to content and format of the activities for which it will be used;
  - c. the University co-sponsor retains ultimate control with respect to the final selection of speakers, the order of presentations, and their content; and
  - d. the event meets applicable continuing education requirements.

Chancellors, deans, and administrative unit heads should develop guidance to govern these circumstances.

- 3. **Presentations at Events Sponsored by Business Entities.** Employees may give presentations in their individual capacities at events sponsored by companies where the subject matter of the event relates to the individual's University expertise and responsibilities if:
  - a. the information presented is evidence-based;
  - b. the employee represents that the lecture materials fairly reflect his/her independent views and not solely the views of the business entity; and
  - c. the following information is disclosed to the audience:
    - (1) the employee's business or financial relationship with the business entity, if any; and
      - (2) a representation that the employee is speaking and acting solely in his or her individual capacity and not on behalf of the University.

#### F. Using Products Developed and Provided by Business Entities

1. Educational Materials. In connection with their University responsibilities, employees may use educational materials developed or provided by business entities, but may not disseminate to students or require students to 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, employees must disclose the name of the business entity, 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 an employee, 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 University employees to review for potential course adoption, or (b) laboratory supplies, reagents or pharmaceutical products and medical devices, provided in limited quantity for evaluation purposes.

In the clinical health care context, for demonstration and educational purposes, employees are permitted to use a product or information found in a product branded with the name of a particular business entity with a patient for whom the product has been prescribed.

Chancellors, deans, and administrative unit heads may exempt certain arrangements from the requirements of this provision if they determine that the free sample or demonstration item would not influence any action an employee may take that could benefit the commercial interests of the business entity offering the free or discounted item.

#### G. Presence of Business Entity Representatives on Campus.

- 1. Academic Health Center. Representatives of business entities are not permitted in:
  - a. AHC college or school research, clinical or teaching areas unless invited by faculty or staff;
  - b. Clinical areas in colleges and departments outside the AHC unless invited by faculty or staff.
- 2. Other campuses, colleges, and administrative units. Chancellors, deans, and administrative unit heads are responsible for ensuring that the presence of representatives of business entities on campus supports the educational, research, and outreach missions of the University.
- H. **Business Entity Sponsorship of Fellowships and Scholarships** Chancellors, deans, and administrative unit heads may accept the sponsorship of fellowships and scholarships by business entities under the following conditions:
  - 1. the sponsorship must be in the form of a gift given to the University of Minnesota Foundation, or in the form of a grant given to the University through the Office of Sponsored Projects Administration;
  - 2. the gift or grant must be made without any expectation of reciprocity;

- 3. the funds must be used to support educational programs and activities for students, residents, or fellows; and
- 4. the business entity is not permitted to select the recipient of a scholarship or fellowship.

#### I. Sponsored Research Involving Sub-Grantees, Contractors, or Collaborators

When individuals outside the University participate as a sub-grantee, contractor, or collaborator in sponsored research, 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.

For PHS-sponsored research, the University will specify in the written agreement whether the University's or the sub-recipient's conflict of interest policy applies, and will specify time frames for the sub-recipient to act to enable the University to meet its reporting obligations to the PHS. Where the agreement specifies that the University's conflict of interest policy applies, only those provisions relating to reporting of financial interests, conflict of interest determinations and management, and conflict of interest training, are applicable.

#### SECTION III. NON-COMPLIANCE

Non-compliance with the provisions of this policy includes, but is not limited to, failing to timely disclose a significant financial or business interest, failing to complete educational requirements, 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 conflict of interest.

Non-compliance with this policy may result in disciplinary action, up to and including termination of employment, as well as ineligibility of employees to submit grant applications, seek approval from the Human Research Protection Program, or supervise graduate students.

Failure to timely disclose a significant financial interest may result in a retrospective review to determine whether any PHS-funded research or portion of the research conducted during the period of noncompliance was biased. The retrospective review, reporting, and submission of a mitigation report if bias is found, will be conducted in accordance with PHS procedures established in 42 CFR 50.605(a)(3). See Administrative Procedure: *Retrospective Reviews and Mitigation Plans*.

#### REASON FOR POLICY

To implement Board of Regents Policy: <u>Individual Conflicts of Interest</u>, 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

- <u>Reporting External Relationships and Business and Financial Interests</u>
- Evaluating Reports of Business and Financial Interests and Managing Individual Conflicts of Interest
- Retrospective Reviews and Mitigation Plans

#### FORMS/INSTRUCTIONS

• Report of External Activities (REPA)

#### APPENDICES

- Conflict of Interest Categories
- Prohibited Activities
- Required Disclosures
- Public Health Service (PHS) Agencies

#### FAQ

• <u>REPA FAQ</u>

#### ADDITIONAL CONTACTS

Subject	Contact	Phone	Fax/Email
Primary Contact(s)	Lynn Zentner	612-626-7852	lzentner@umn.edu
Policy or REPA questions	REPA Helpline	612-626-1462	REPAmail@umn.edu

#### DEFINITIONS

#### Accredited

An educational or training event that meets the requirements for continuing education credits established by a recognized continuing education organization or body.

#### **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.

#### **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.

#### Change in Circumstance

The occurrence of one of the following events that triggers the obligation of an employee to file a REPA within 30 days:

- an increase in the value of an existing financial interest, or the acquisition of a new financial interest, that qualifies as a significant finance interest related to an employee's University expertise and responsibilities;
- the assumption of a paid or unpaid executive or board position in a business entity that is related to an employee's University expertise and responsibilities;
- a change in University responsibilities (e.g., a new research project) that relates to an existing business or significant financial interest;
- (for PHS sponsored researchers only) travel related to one's University responsibilities valued in excess of \$5000 paid for or reimbursed by an entity that is related to your University responsibilities (does not include travel paid for or reimbursed by a governmental agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education).

#### **Clinical Health Care**

The provision of medical, nursing, or other health-related care to humans or animals for the treatment of disease or injury.

#### Company

An organization that produces or sells goods or services in order to make a profit.

#### **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 conflict of interest exists when a significant financial interest or business interest could directly and significantly affect the design, conduct, or reporting of the research.

#### **Conflict Management Plan (CMP)**

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

#### **Conflict Review Panel (CRP)**

The entity with the authority to make conflict of interest determinations and develop conflict management plans. The panel consists of voting and nonvoting (ex-officio) members. Voting members may include faculty, professional academic and administrative staff, and community members whose appointments to the panel have been approved by the University's Senior Vice Presidents. Nonvoting members may include representatives from the Office of Institutional Compliance, Office for Technology Commercialization, Sponsored Projects Administration, Human Research Protection Program, Office of Research Education & Oversight, and the Office of the General Counsel.

#### Consulting

An outside commitment that is paid professional service intended to further the interests of an outside party, regardless 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.

#### **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 mission.

#### Employee

An individual employed by the University of Minnesota under any of the Employee Groups and Classifications defined in Board of Regents Policy: *Employee Group Definitions*.

#### Endorsement

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

#### **Equity Interest**

Any stock, stock option, or other ownership interest in a business entity, 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:

- reflects the expertise and credentials of the covered individual;
- is comparable to the compensation paid to the covered individual's peers;
- is reasonable in the context of the services provided; and

- does not include an enhancement in exchange for an agreement to improperly:
  - make or induce others to make referrals to a business entity;
  - o make or induce others to endorse the products or services of a business entity; or
  - o 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**

#### a. Financial Interest

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

- 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
- 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.

#### b. Significant Financial Interest

For covered individuals involved in clinical health care, or who are responsible for the design, conduct, or reporting of research funded by, or applied for from, the Public Health Service (PHS), where the aggregated value of the financial interest in a business entity held by the covered individual and family members exceeds:

- \$5,000 in annual remuneration received plus the value of any equity interest held in a publicly traded business entity;
- \$5,000 in royalty income received;
- \$5,000 in annual remuneration received from a non-publicly traded business entity; or
- any equity interest held in a non-publicly traded company.
- For PHS sponsored researchers only: travel valued in excess of \$5000 annually paid for or reimbursed by an entity unless the travel was paid for or reimbursed by a governmental agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The covered individual must disclose the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

For all other covered individuals, where the aggregated value of the financial interest in a business entity held by the covered individual and family members exceeds:

- \$10,000 equity interest or an ownership share of 5% (regardless of worth) in a business entity as determined through reference to public prices or other reasonable measures of fair market value;
- \$10,000 in annual remuneration and royalties.

#### Institution of Higher Education

A public or nonprofit educational institution in the United States that is accredited or pre-accredited by a nationally recognized accrediting agency or association, and provides a post-secondary program of education for which the institution awards a bachelor's degree or provides not less than a 2-year program that is acceptable for full credit toward a bachelor's degree.

#### Investigator

The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include, for example, collaborators or consultants.

#### Non-compliance

Non-compliance with the provisions of this policy includes, but is not limited to, failing to timely disclose a significant financial or business interest, failing to complete educational requirements, 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.

#### Practitioner

A licensed doctor of medicine, licensed doctor of osteopathy duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian, licensed advanced practice registered nurse, a physician assistant authorized to prescribe, dispense, and administer under Minnesota Statute chapter 147A, and a dental therapist authorized to dispense and administer under Minnesota Statute chapter 150A.

#### **Public Health Service Agencies**

Federal funding source for research. See Appendix: Public Health Service Agencies.

#### Remuneration

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

#### **Report of External Professional Activities (REPA)**

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

#### **Sponsored Project**

An externally funded activity that is governed by specific terms and conditions. Sponsored projects must be separately budgeted and accounted for subject to terms of the sponsoring organization. Sponsored projects may include grants, contracts (including fixed price agreements), and cooperative agreements for research, training, and other public service activities.

#### **Travel Expenses**

Costs of transportation, lodging, meals and incidentals.

#### Unit Head

The department, unit, or division head, as appropriate.

#### **University Responsibilities**

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

#### Widely attended educational event or professional conference

An event or conference that is attended by either a large number of people throughout an industry or profession, or by those representing a wide range of interests.

#### RESPONSIBILITIES

#### **Collegiate Approver/Reviewer**

The senior administrative officer for the college or administrative unit (typically a dean or vice president) or that officer's designee. Reviews REPA. Follows up with the employee if there are questions regarding the information reported. Approves REPA where the employee has no reportable interests.

#### Conflict of Interest Program

Administers the REPA reporting and conflict of interest review and management process.

#### **Conflict Review Panel (CRP)**

Reviews matters referred by the Executive CRP to determine if a conflict of interest exists and, if a conflict of interest exists, takes action to manage, reduce, or eliminate the conflict.

#### **Covered Individual**

Reports external professional activities and financial and business interests as required by University policy. Must disclose significant financial and business interests no later than the time of application for sponsored research. Complies with terms of conflict management plans (CMP), and confirms CMP compliance with the COI Program as required

#### **Department Approver/Reviewer**

The employee's immediate administrator; typically the department head, department chair, or department/division director. Follows up with the employee if there are questions regarding the information reported, and approves the REPA for further review by the Collegiate Approver.

#### Employee

Complies with Standards Governing Relationships with Business Entities.

#### **Executive Conflict Review Panel**

A subset of a full conflict review panel consisting of the chair, vice chair, representatives from the Office of Institutional Compliance, and a representative from the Office of the General Counsel. Reviews matters presented by COI Program staff to determine whether to refer to the full panel for review. Can make "no conflict of interest" determinations.

#### Office for Technology Commercialization

Refer employees who plan to hold a business interest and/or equity in a University startup to the Conflict of Interest Program.

#### RELATED INFORMATION

#### **Board of Regents Policies:**

- <u>Code of Conduct</u>
- Individual Conflicts of Interest
- Institutional Conflict of Interest
- Purchasing

#### Administrative Policies:

- Outside Consulting and Other Commitments
- Institutional Conflict of Interest
- 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:

- <u>Conflict of Interest On-Line Course</u>
- Minnesota Statute, Section 15.43, "Acceptance of advantage by state employee; penalty"
- Federal Acquisition Regulations

#### HISTORY

#### Amended:

August 2012 - The policy clarifies a) periodic reporting requirements and b) application of the conflict of interest policy to certain sub-recipients of PHS-sponsored research.

#### 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

#### Supercedes:

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.