Policy: Interim 2-30 Rev. 8

Date: July 15, 2003

Policy 2-30R7

Subject: Conflict of Interest Policy: INTERIM

I. PURPOSE & SCOPE*

In carrying out its primary missions of teaching, research and community service, the University must implement a diverse set of principles: maintaining academic freedom and an atmosphere that promotes free and open scholarly inquiry without bias; facilitating the transfer of technology and other developments for the benefit of the public; and serving as the steward of public and private resources entrusted to it. There are several general categories of Conflict of Interest that this policy will address: Research and Other Sponsored Projects, Use of University Resources, Technology Transfer and Commercial Endeavors, and Institutional Conflict of Interest.

Conflicts also arise in procurement situations when an Employee has the option of purchasing goods or services from entities in which the Employee has a substantial financial or other interest. Procurement conflicts are treated specifically in <u>Policy 4-8</u> of the Policy and Procedure Manual and are not within the scope of this policy. However, because conflicts situations covered by this policy may also involve procurement issues, the Conflicts of Interest Committee will, from time to time, need to coordinate their efforts with the Director of Purchasing.

The University recognizes the value of transferring technology and other activities to enhance public access to University research and to further the economic development of the State and the Nation. Additionally, participation by academic staff in external activities that enhance their professional skills or constitute public service may be beneficial to the University as well as the individual.

It is critical that business transactions and the design, conduct or reporting of research will not be biased or compromised by any conflicting financial interest or other potential or actual personal gain of an Investigator or the University or one of its units. Failure to comply may jeopardize existing or future funding, and erode public trust.

The University recognizes that many potential conflicts of interest do not constitute actual conflicts or may be acceptable with proper oversight and safeguards. The complexity and diversity of professional relationships has grown increasingly intertwined with outside entities in research and other University activities. Increased research support from private entities, changes in federal law and regulations encouraging technology transfer and the need for the University and its Employees to demonstrate public accountability mandate new approaches in the discovery and management of potential conflict of interest situations. This may require reevaluation of previously acceptable activities. The most effective way to address conflict of interest is to establish a process by which Employees disclose and obtain evaluation of potential conflict on a case by case basis.

To implement this process, this policy prescribes procedures for disclosure, review, and for the exercise of ongoing oversight where necessary. It also provides for review of decisions at higher levels of University

administration. Lastly, it indicates the sanctions that may be applied when the policy is violated.

This policy applies to all University Employees. As appropriate, subcontractors and other external collaborators must also comply with this policy unless their institution/company provides adequate assurances that they are in compliance with the federal regulations referenced above. This policy applies to any research, education or service activity regardless of whether or not support is provided to the University or Employee. Support may be in the form of sponsorship, incentive, equipment or gift.

* This policy overlaps with but does not supplant University Employees' responsibilities under the Utah Public Officers' and Employees' Ethics Act, Utah Code Annotated § 67-16-1 et seq. (the Ethics Act), which in some instances may include additional reporting responsibilities. In many instances, this policy is broader than the Ethics Act in the situations covered. Also, incorporated by reference are the National Science Foundation Policy; Grant Policy Manual 510, Investigator Disclosure Policy, 60 F.R. 132, pp. 35810-823 (July 11, 1995) and U.S. Department of Health and Human Services, Objectivity in Research Subpart F-Responsibility of Applicants for Prompting Objectivity in Research for Which Funding is Sought, 42 CFR Part 50, Subpart F. As additional external federal policies are imposed, this policy will incorporate such new policies by reference.

II. REFERENCES

- Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-1 et seq.
- Utah Criminal Code, Utah Code Ann. § 76-8-105(1)
- National Science Foundation Policy; Grant Policy Manual 510, Investigator Disclosure Policy, 60 F.R.132, pp. 35810-823 (July 11, 1995)
- U.S. Department of Health and Human Services, Objectivity in Research Subpart F-Responsibility of Applicants for Promoting Objectivity in Research for Which Funding is Sought, 42 CFR Part 50, Subpart F
- Anti-Kickback Act of 1986 (41 U.S.C. 51-58) and OMB A-110
- Policy and Procedures No. 2-9, Disciplinary Actions and Dismissal of Staff Employees
- Policy and Procedures No. 2-26, Remunerative Consultation and Other Employment Activities
- Policy and Procedures No. 2-67, Additional Compensation and Overload Policy
- Policy and Procedures No. 2-70, Use and Security of Property
- Policy and Procedures No. 4-4, Restricted Purchases and Special Procurement
- Policy and Procedures No. 4-8, Procurement from Vendor- University Employee with Interest
- Policy and Procedures No. 6-1.1, Interim Policy for Research Misconduct
- Policy and Procedures No. 6-7, Copyright Policy: Ownership Purpose and Scope
- Policy and Procedures No. 8-12.4 & 8-12.5, Code of Faculty Rights and Responsibilities

III. DEFINITIONS

- (1) "Business entity" means a sole proprietorship, partnership, association, joint venture, corporation, firm, trust, foundation, or other organization or entity used in carrying on a trade or business, including parent organizations of such entities or any other arrangement in which an entity operates through a subsidiary.
- (2) "Conflict of interest" means any outside activity or interest that may adversely affect, compromise, or be incompatible with the obligations of an Employee to the University or to widely recognized professional norms. A significant conflict of interest includes, but is not limited to, situations where consideration of a significant financial or other interests will likely affect the approval, design, conduct, or reporting of

research or other projects or the objectivity of decision making.

- (3) "Conflict of commitment" may occur when external activities demand excessive time, conflicting with a faculty/Employee's responsibilities to the University.
- (4) "Designated Official" is the person responsible for reviewing all financial disclosures and will review situation information and advise the Conflict of Interest Committee as to whether a conflict of interest exists. The designated official at the University of Utah is the Director of Sponsored Projects.
- (5) "Employee" means any person who is employed by the University of Utah, whether full or part time, and includes but is not limited to staff, faculty, postdoctoral appointees, residents and students. It also includes investigators as defined by the federal policies referenced above and individuals who are not paid on a project i.e. "volunteers".
- (6) "Family," for the purpose of this policy, means spouse/domestic partner and/or dependent children.
- (7) "Intellectual property" means any ideas, inventions, technology, creative expression and embodiments thereof, in which a proprietary interest may be claimed, including "but not limited to", "without limitation", patents, copyrights, trademarks, know-how, and biological materials. This policy is intended to affect only that Intellectual Property owned by the University. It does not alter other University policies that determine ownership of Intellectual Property.
- (8) "Investigator" includes any faculty, staff, post-doc, resident or student who is responsible for the design, conduct or reporting of research or scholarly activities conducted in whole or in part at the University of Utah.
- (9) "Significant financial or other interest" includes anything of significant monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights). "Significant financial or other interest" also includes the holding of a position as an officer, director, agent, consultant or employee of a business entity. "Significant financial and other interest" includes such interests held by the Employee and by the Employee's immediate family members.

The term does NOT include:

- (a) salary, royalties, or other remuneration from the University;
- (b) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities:
- (c) income from service on advisory committees or review panels for public or nonprofit entities;
- (d) an equity interest that when aggregated for the Employee and the Employee's immediate family meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measure of fair market value, and does not represent more than a five percent (5%) ownership interest in any single entity;
- (e) annual salary, royalties or other payments from sources other than those referenced in

subparagraphs (a) and (b) above that individually do not exceed \$10,000 or, when aggregated for the Employee and the Employee's family over twelve months, are not expected to exceed \$10,000.

- (f) income from mutual funds and /or pension funds.
- (g) a percentage of income received from the Veteran's Administration Medical Center as part of physician reimbursement for University faculty.
- (10) "Research agreements" may include "testing agreements", service agreements, collaborative agreements, clinical investigation agreements, purchase orders, material transfer agreements, confidentiality agreements and any other written agreement between the university and an external entity that has been duly signed and agreed upon by authorized officials of the cooperating entities.
- (11) "Technology transfer" includes any option, license, assignment, or conveyance of any other legal or equitable interest in Intellectual Property owned by the University, including but not limited to the right to make, market, copy, sell, or use such property in any way.
- (12) "Personal gain" includes gifts and other incentives to investigators, their University departments or other University entity, or family members.
- (13) "Clinical investigations" include any research project dealing with humans, including medical industry corporation or other private business entity sponsored trials, departmental sponsored research, studies utilizing human tissues, social science research, and medical chart reviews.
- (14) "Conflict of Interest Officer" refers to the person designated by the Vice President for Research to receive conflict of interest disclosure information. This individual will review the Conflict of Interest Evaluation disclosures and other materials in consultation with the Designated Official, and present the case to the Conflict of Interest Committee for review.
- (15) "Institutional conflict of interest" refers to situations where the University's beneficial relationship with corporate entities may place it in conflict with it's responsibilities as a public institution of higher education. The conflict may involve equity interest in companies, certain licensing situations and Board and other leadership positions held by University faculty or administrators.

IV. CONFLICT OF INTEREST SITUATIONS

The issues addressed in this section include situations that constitute a conflict of interest and require full disclosure. Approved conflicts of interest require oversight by the University and may require modification to reduce or eliminate the conflict. Certain activities present an unacceptable conflict of interest that the University will not allow under any circumstances (See Section VI below).

a. Use of University Name, Property or Facilities *

Employees may only use the University's name, its property, or its facilities for pecuniary gain, or for personal advantage if the use of such property or facilities has a legitimate relationship to the faculty member's academic service AND such use causes no more than trivial cost to the University and a minor commitment of time. No disclosure is required where the conditions of such limited use are met. For purposes of this section, professional activities, which serve to

maintain or improve an Employee's skills, and which do not violate University restrictions on outside activities have a legitimate relationship to the Employee's service. Consultation involving service to individual patients or clients may take place in an Employee's office or laboratory on a limited basis without approval.

Except as otherwise approved pursuant to this or other University policy or agreement, use of University facilities and equipment resulting in clearly identifiable additional cost to the University REQUIRES APPROVAL. Usually, approval of such situations will be granted in exceptional circumstances conditioned upon reimbursement of costs. Exceptions to the requirement for reimbursement may be approved by the line Vice President upon recommendation of the Dean or Director, subject to any conditions imposed by the Vice President.

* The first part of this provision is a restatement of the language of University Policy and Procedures Manual, "Code of Faculty Responsibility," No. 8-12.4, C.1, extended to staff. The existing policy has the effect of permitting nonreimbursed use of University property and facilities only when both of the stated conditions are satisfied. The latter part of this section, which deals with private consultation activities, is a restatement in substance of the applicable section of the "Remunerative Consultation and Other Employment Activities Policy," No. 2-26(IV)(E)(4).

b. Conflict of Interest Involving Students

Research agreements with external sponsors, especially entities in which an Investigator has a financial, managerial or executive relationship, must maintain basic academic values and promote open dissemination of knowledge. Student participation in such activities is of particular concern. It is important that the educational experience of students and postdoctoral fellows not be influenced detrimentally by faculty special interests or relationships with external funding entities. Consistent with these policies and concerns, the following research projects require APPROVAL before they are commenced and MONITORING throughout:

- i. Projects of a confidential nature that include restrictions of student publication or communication rights with respect to research or other work that will be the basis of evaluation of the student or fulfillment of degree requirements. Such projects will only be permitted if the publication restrictions are reasonably necessary to protect intellectual property rights and do not prevent the publication of student research in a timely manner. Publication in a timely manner shall usually be the earlier of six months from the completion of the project or the completion of the student's degree requirements.
- ii. Sponsored research projects involving students that have the potential to benefit substantially a business entity in which a faculty member has a significant financial or other interest. Approval shall be granted only where there is a demonstration that students will receive some academic benefit from their efforts without risk to academic freedom, integrity and objectivity. Approval shall not be granted where such research is motivated primarily by commercial concerns and will be the basis of evaluation of the student or fulfillment of degree requirements.

- iii. Sponsored research projects where a student is both working on a project for a faculty member at the University and working at a company in which the faculty member has a financial or other interest.
- iv. Sponsored research where the research is driven primarily by commercial considerations and the sponsor is involved in the direction of the research.
- * This section is not intended to preclude the involvement of research assistants or research associates who are primarily University Employees in support of commercial activities or work that will not be used for evaluation of a student or fulfillment of degree requirements, under arrangements otherwise consistent with this and other University policies.

c. Interactions with Private Enterprise*

All of the examples described in this section have the potential for appearance of, and actual, misallocation of resources. Each situation requires APPROVAL AND MONITORING. Approval should normally be based on the proponent's demonstrating that the activity significantly benefits the University and does not involve an unacceptable risk of misallocation of funds and other resources or breech of the University's integrity. Approvals will be conditioned on technical and financial oversight of the project and any related activities, as well as reimbursement of all costs for uses of University resources that primarily benefit private entities.

- i. Research projects where an Employee also has direct or indirect authority over expenditure of funds and where the research is sponsored by a business entity in which the Employee or his/her immediate family have a significant financial or other interest.
- ii. Reimbursed use of faculty, students, research associates, technicians or other staff supported by public funds for work motivated primarily by commercial concerns or intended to benefit a business entity in which an involved Employee or his/her immediate family have a significant financial or other interest.
- iii. Participation by an Employee in a University decision that has the potential to benefit significantly or injure, directly or indirectly, a business entity in which the Employee or his/her immediate family have a significant financial or other interest. The preferred procedure will normally be for the Employee to withdraw from participation in the decision. In no event should the Employee be the final decision-maker.[RP1]
- iv. Use of University or other public or private funds for expenditures that have the potential to benefit a business entity significantly in which an Employee or his/her immediate family have a significant financial or other interest. One example of this situation is the purchase of equipment that may be useful to a business for which the Employee consults, or in which an Employee has an ownership interest. Another example of this situation is a project involving testing of a product in which an Employee has a significant financial or other interest, or a product that is

- a competitor of a product in which the Employee has a significant financial or other interest.
- v. Transfer of University technology or other Intellectual Property to a business entity in which the University Employee inventor or his/her immediate family have a significant financial or other interest.
- vi. Clinician referrals to a business entity in which the clinician/Employee or his/her immediate family have a significant financial or other interest.
- vii. Submission of proposals and acceptance of awards for grants or contracts by, to or from a business entity in which an involved Employee or his/her immediate family have a significant financial or other interest, where the subject matter of grant proposal is substantially related to the Employee's University research and where the University is qualified and eligible to apply.
- * The procurement of general goods and services from private enterprises can create significant potential conflicts of interest. Procurement conflicts are specifically addressed in <u>Policy 4-8</u> of the Policy and Procedure manual and are not within the purpose and scope of this policy. However, because conflict situations covered by this policy may also involve procurement issues, this policy and <u>Policy 4-8</u> may both apply.

V. CLINICAL RESEARCH

It is critically important for the University to manage conflicts in the area of Clinical Investigations due to the ethical requirement for protection of patients and the general public. Financial or other personal gain interests of the investigators, their families, the University or units of the University must not influence, or appear to influence, the approval, design, conduct or reporting of research or any clinical trials involving the evaluation of products such as drugs or medical devices or procedures. It is of the utmost importance that personal gain by any member of the clinical research team not influence the consent process such that participation is encouraged by even subtle minimization of the risks and exaggeration of the benefits to the potential subject. Additionally, arrangements with corporate sponsors which include recruitment bonuses, time designated accrual incentives, or finder-fees may influence the consent process, the reporting of adverse events or the analysis of the data, thereby creating conflicts which must be disclosed and reviewed. For these reasons, the following policies apply to all Clinical Research projects at the University:

- i. Prior to each study involving human subjects, all aspects of financial relationships between members of the investigative team, their immediate families, the University and its entities, and the corporate sponsor must be DISCLOSED. These include commitments of financial support unrelated to the current study, financial incentives, payments as a consultant, and non-monetary rewards and incentives to investigators and their families, including travel, entertainment and gifts.
- ii. Clinical research projects sponsored by business entities where investigators, other Employees, or their immediate families, or University units, have significant financial or other interests require APPROVAL and MONITORING. Employees with significant conflicts may participate as a Principal Investigator or Co-Principal Investigator only under exceptional circumstances. Under no circumstances shall a conflicted Employee consent subjects for

participation in a research project.

- iii. All studies of human subjects REQUIRE APPROVAL from the IRB with additional assurance from the investigators that there are no personal conflicts that may threaten the safety and privacy interests of the patient/research subject and public trust of the University's integrity and credibility.
- iv. Any financial or other interest that an investigator, his/her immediate family, or a unit of the University, have in a business entity sponsoring a clinical investigation must be DISCLOSED to the subjects recruited into the study.
- v. Sponsors of human research may provide payments or incentives related to a specific study by depositing into a departmental account. Employees with a financial or other interest in the sponsoring entity should not have signatory privileges on this account for disbursement of funds. Individual Employees involved in a study may not themselves or to their immediate families, accept payments, incentives or gifts from sponsors of clinical research.

VI. ACTIVITIES THAT ARE NOT ALLOWED

The following activities present conflicts of interest that cannot properly or effectively be approved and monitored and, therefore, are NOT ALLOWED.

a. Solicitation or Receipt of Gifts*

Solicitation or receipt by a University Employee or his/her department of a gift (including money, non-pecuniary gifts, excessive compensation or non-commercial loans) where (1) the purpose or effect of the gift is likely to influence the Employee in the discharge of his/her University responsibilities (i.e. vendor selection); (2) the gift is given to reward the Employee for official action taken; or (3) the gift is given in close proximity to recent past, present or future transactions between the University and the giver of the gift. This section is not intended to apply to the regular or ordinary compensation an Employee receives from a business entity in situations covered above by section IV(c), where approvals have been granted. This section also does not apply to occasional non-pecuniary gifts that have an insignificant monetary value and would not tend to influence an Employee in the discharge of his/her dutites.

* This section is intended to reiterate the requirements of the Utah Public Officers and Employees Ethics Act, Utah Code Ann. § 67-16-1 et seq. (the "Utah Act') and the federal Anti-Kickback Act of 1986, 41 U.S.C. 51-58 (the "Federal Act"). As of May 2002, Utah Act prohibits acceptance of non-pecuniary gifts in excess of \$50. The Federal Act does not specify a dollar amount and prohibits the acceptance of "anything of value" that could influence a decision.

b. Academic Freedom

i. Secrecy or confidentiality requirements beyond the scope of section IV(b) on projects that will be the basis of evaluation of a student or fulfillment of degree requirements, or evaluation of junior faculty or other Employees.

- ii. Arrangements that permit sponsor interference with the scientific analysis or publication of research results or conclusions.
- iii. Evaluation of junior faculty, postdocs, staff, or students based on participation in (or refusal to participate in) outside activities involving business entities in which the evaluating Employee or his/her immediate family have a significant financial or other interest. The involved Employee should not participate in such evaluations.
- c. Conflicts Associated with University Employees and Private Enterprise
 - i. Non-reimbursed involvement of faculty, students, research associates, technicians, or other staff supported by public funds, on University time, for work motivated primarily by commercial concerns or intended to benefit a business entity.
 - ii. Physician consultation for the purpose of marketing a product for a medical product company when the physician/researcher is in receipt of a grant or contract from the same company.
 - iii. Consenting of subjects by Employees who themselves, or whose immediate family members, have financial or other interests in an entity sponsoring clinical research.
 - iv. Conflicts between an Employee's obligations to the University and his/her commitments to an outside entity, including a sponsor of University-based research. For example, an Employee may not have an agreement with a sponsor regarding transfer of technology or Intellectual Property in conflict with the University policy governing ownership of Intellectual Property.
 - v. Transfer of University technology or other Intellectual Property without following the University's patent and copyright policies.
 - vi. Use of the University's name in connection with private activities in a manner that inappropriately suggests that the University endorses, sponsors or approves of such activities or views of the employee.

NOTE: A University Employee advising a government agency on matters in which the Employee has a significant financial or other interest, evaluating commercial competitors for a government agency, or consulting for a federal agency while conducting research sponsored by the agency, may be subject to agency conflicts of interest policies and disclosure requirements. Employees should remember that such requirements exist separate from and in addition to University requirements.

VII. CONFLICT OF COMMITMENT

Conflict of commitment may occur when external activities, including consulting and other professional or personal activities, demand excessive time conflicting with an Employee's responsibilities to the University

and detracting from its mission. Conflict of Commitment situations are governed by the University's Remunerative Consultation and other Employment Activities policy, Policy and Procedures Manual No. 2-26.

VIII. INSTITUTIONAL CONFLICT

The University must also avoid conflict of interest positions where its beneficial relationship with corporate entities may place it in conflict with its responsibilities as a public institution.

a. General Principals

- i. The University will deal legally and ethically with external sponsors of research and sponsored programs in ways that avoid institutional conflicts of interest.
- ii. The University will not enter into agreements contrary to its mission.
- iii. The University will not accept an award for a project that is unacceptable to the principal investigator. Once an award is accepted by the University, all parties are expected to fulfill their obligations under that agreement.
- iv. The University will not enter into activities or agreements which could jeopardize its eligibility to receive federal or state funds.
- b. Equity Interest in Corporations: Investment in Research Of particular concern are research situations where the University has equity in a business or receives donations from a business sponsoring research. These situations may create conflicts, or the appearance of conflict, that compete with those of research investigators or in the case of clinical research, of the research subject. Any financial relationship with a corporate sponsor should be documented, and include the following: equity interest or ownership, payments to the University or a unit of the University beyond payments directly associated with costs to carry out a particular protocol, any funds or other items of value given to the University or a unit thereof, any percent ownership of patents, royalties, or licenses granted to the commercial sponsor by the University, and whether or not the University stands to gain financially if the study shows a positive outcome.

Upon entering into business agreements that may place the institution in a conflict of interest situation, the University shall ask the Conflict of Interest Committee to review and recommend strategies for management of the conflict. Similar reviews shall be made of all active previous business arrangements, and where conflicts are found, referred to the Conflict of Interest Committee for review. The process to reduce, manage or eliminate such research conflicts that the institution may have, will be handled by the Conflict of Interest Committee and managed similarly to an individual conflict of interest situation. Possible solutions may include special management to protect the scientific integrity of the study and in the case of clinical research management to assure the safety of research participants, or alternatively, having a clinical study performed at other sites.

IX. CONFLICT OF INTEREST COMMITTEE AND DECISION MAKING

a. Conflicts of Interest Committee

The Conflicts of Interest Committee shall be a standing committee appointed by the President (the "Committee"). The Committee shall be comprised of 12 faculty members and staff from the campus at large representing the diversity of academic and research disciplines and administrative functions of the University. The Committee shall include Ex-Officio members including the Director of Sponsored Projects, the Director of Technology Transfer, the Director of the Institutional Review Board, the Conflict of Interest Officer, the Director of Purchasing, and a representative from the University's Office of General Counsel. All faculty and staff members have voting rights. A quorum consists of over half of all voting members. The Committee shall serve as an advisory body to the University administration on conflicts of interest issues, as provided in this policy.

The Committee will review information provided by the Conflict of Interest Officer and will make determinations as to the proper level of management of conflicts.

b. Conflicts of Interest in Decision Making

A committee member shall be recused from discussion of a particular case if: 1) The Committee member has a personal interest because of inter-departmental relationships, such as collaboration with the faculty member whose case is under consideration; or 2) The Committee member has a fiscal interest in the case under discussion.

All University Employees participating in decision making should be aware and comply with conflict of interest principals, including those outlined above, when serving on committees, in personnel decisions, purchasing, and other issues.

X. PROCEDURES

Any instance of conflict of interest must be disclosed, and reduced, managed or eliminated depending on the type and degree of conflict. It is the responsibility of each Employee to disclose possible individual conflicts for review. It is the responsibility of the University to evaluate and recommend that the Employee manage, reduce or eliminate the conflicts. A monitoring plan will be established for every instance of conflict of interest using federal funds and private/corporate funds from a business entity as determined by the Conflict of Interest Committee.

a. Disclosure

This policy uses disclosure as the key mechanism to bring potential conflicts of interest to light for further evaluation, and for oversight, where necessary.

i. Annual Disclosure: All faculty and Employees* shall fill out an Annual Financial Disclosure Form. The Annual Disclosure Form shall be submitted to department chairs or directors who will then forward all disclosures in their unit to the Conflict of Interest Officer. *The chair/director of each University department may identify Employees whose positions do not require the completion of an Annual Disclosure Form.

- ii. Project Based Disclosure—Conflict Evaluation Form: Conflict Evaluation Forms from the Principal Investigator must be submitted directly to the Conflict of Interest Officer on a project by project basis. The Principal Investigator shall ensure that all appropriate faculty and other Employees who are part of an investigative team submit Conflict Evaluation Forms. If a new conflict of interest arises during the life of a project, a new Conflict Evaluation Form should promptly be submitted to the Conflict of Interest Officer.
- iii. Confidentiality All records and information provided by an Employee for the purpose of disclosure and management and all official records of disclosure and management shall be considered confidential. Any information disclosed by an Employee as required by this policy shall be used solely for the purpose of administering this policy and may not be used for any other purpose unless required by law. Unauthorized disclosure of any such information by an Employee shall be deemed to be unethical behavior and shall be punishable under PPM 2-9(IV)(F) & (V) or <a href="PPM 8-12.4(A)(1), (3) & PPM 8-12.5.

b. Review

Annual disclosures submitted to Department chairs and directors and project based disclosures will be forwarded to the Conflict of Interest Officer who, together with the Designated Official, will review the cases, gather more details if necessary and forward the information for consideration to the Conflict of Interest Committee. To the extent that disclosures include procurement issues, the Conflict of Interest Officer shall also forward the disclosures to the Director of Purchasing. The Committee will review the file and recommend a strategy for management and oversight.

c. Management and Oversight

The Conflict of Interest Committee will consider potential conflicts of interest and determine whether to Manage, Reduce or Eliminate the conflict. The Committee, in consultation with the University Employee ultimately responsible for the proposed research or activity, will develop a Management, Monitoring and Implementation Plan (the "Plan"). The Plan will be approved by the Designated Official. The Department Chair or Director will be responsible for providing process and oversight for implementation of the Plan.

A conflict can be MANAGED if the conflict does not seem to be of such a degree that the research or activity as proposed would be compromised in regards to academic freedom, integrity or objectivity.

The conflict must be/may be REDUCED if there is a serious possibility that the research or other activity as proposed would be compromised or a serious concern that there could be a conflict with university policy. The conflict must be ELIMINATED if the research or activity as proposed would be compromised by the conflict. If the conflict cannot be eliminated, the Employee shall not proceed with the research or activity.

d. Appeals

Appeals to any determination made by the Conflict of Interest Officer and/or the Conflict of Interest Committee shall be made to the Vice President for Research (for research matters) or to an appropriate line Vice President (for non-research matters). Except in matters involving a Vice President, the decision of the cognizant Vice President on the appeal is final. In conflict matters involving a Vice President, appeals shall be made to the President and his/her decision on the appeal shall be final.

- e. Reporting Procedures for internal and external reporting will be implemented by the Conflict of Interest Officer and the Designated Official.
 - i. Internal Reporting Annual Monitoring Plan reports, and any violations, will be submitted by the Department Chair and Directors to the Conflict of Interest Officer, who will present them to the Conflict of Interest Committee, the Designated Official and to the cognizant Vice Presidents as appropriate.

For proposals that may restrict disclosure or publication of students' work that constitutes a degree requirement or that will be the basis of evaluation of a student (see Section IV.B.1), initial disclosure shall also be routed to the Graduate School, who will make an initial recommendation to the Conflict of Interest Committee, and the Dean of Students or other appropriate officials.

ii. External Reporting

The Public Health Service ("PHS") requires that the University certify to the PHS awarding component that action has been taken, prior to the institution's expenditure of any funds, to manage, reduce or eliminate any conflict of interest.* The University must specify the process that it will undertake to manage, reduce or eliminate the conflict of interest. The National Science Foundation requires that the University report any conflicts of interest that cannot, or have not been, satisfactorily managed, reduced or eliminated. It is anticipated that other Federal agencies shall require similar practices in the future. These requirements will be incorporated into this policy as requirements are imposed upon the University.

* PHS requires the University to certify that it will manage, reduce, or eliminate any new conflict of interest, at least on an interim measure, within 60 days from the time that the conflict is identified.

XI. VIOLATIONS AND SANCTIONS

a. Reporting and Investigating

The Conflict of Interest Officer and the Designated Official will forward any reports of violations to the Conflict of Interest Committee and to the Sponsoring Agency when specified by the agency policy. The Committee will then forward a recommendation to the Vice President for Research or other appropriate line Vice President. The cognizant Vice President shall coordinate the investigation of any violation with any sponsor who requires such investigation.

The cognizant Vice President shall have the authority as appropriate to determine resolution and

penalties of reported violations. The Vice President for Research shall coordinate the investigation of any violation with any sponsor who requires such investigation.

b. Discipline

- i. Violation of this University policy may result in discipline, including suspension and dismissal as provided under any of the following University policies: (1) "Code of Faculty Responsibility," Part V, <u>Policy No. 8-12.5</u>; and (2) "Termination of Nonacademic Staff Employees and Disciplinary Sanctions," <u>Policy IRP2 No. 2-9</u>.
- ii. Compliance with this policy may also be enforced through the exercise of administrative responsibility for oversight of funded research and management of University facilities and other University property. Such enforcement measures shall include, but shall not be limited to:
 - 1. Freezing research funds or accounts;
 - 2. Rescinding contracts entered in violation of this policy or state law;
 - 3. Bringing legal action to recover the amount of financial benefit received by an Employee as a result of the Employee's violation of this policy.
- iii. Violations of this Policy may also result in civil and criminal penalties pursuant to the Utah Public Officers' and Employees' Ethics Act, Utah Code Ann. § 67-16-1, et seq.
- iv. The remedies provided or referenced above are cumulative and shall be deemed to include any other remedies required or provided by applicable state or federal law.

XII. FORCE OF LAW

This policy shall be deemed to include all requirements relating to conflicts of interest to which the University and University Employees are subject under state or federal law.

^{*} Editorially revised 7/15/2003