



Keene State College Office of Sponsored Projects and Research

Policy Statement

Financial Conflict of Interest in Research

Statement of Need and Purpose

Externally sponsored research is a vital part of the Keene State College mission. As this activity grows in sophistication and complexity it may intersect increasingly with industrial explorations and entrepreneurial ventures, creating for investigators the potential for conflicting interests.

A conflict of interest exists when it can be reasonably determined that an investigator's personal financial concerns could directly and significantly influence the design, conduct, or reporting of sponsored research activities. Faculty and staff of the College have an obligation to scrupulously maintain the objectivity of their research, avoiding any conflict of interest.

Keene State College has developed this policy to protect the integrity of sponsored research and to comply with federal regulations. It is the intent and policy of KSC, as an institution of higher education in receipt of federal research support, to comply with present and future regulations. To that end, this policy is subject to further refinements as other rules are published.

Specifically, the intent of this policy is to identify and eliminate or manage any possible threat to research objectivity at KSC. The main components are disclosure of investigators' financial interests that might be affected by the research, and application of methods to minimize or eliminate the risks associated with such connections. It is not meant to discourage, but rather to safeguard the pursuit and dissemination of knowledge.

Applicability

This policy becomes effective October 1, 1995 and applies to any employee of KSC who is responsible for the design, conduct, or reporting of research activities funded or proposed for funding by external sources. The policy also includes the investigator's immediate family, which is defined as his/her spouse or domestic partner and dependent children.

Project directors are responsible for ensuring that all participants in a project who are responsible for the design, conduct, or reporting of the research disclose any significant financial interests that would reasonably appear to be affected by the research. Individuals who come to work on an established project through reallocation of effort, hiring, transfer, promotion, etc., and thereby take on a responsible position in a project, must also disclose any such significant financial interests.

Collaborators, subcontractors, subrecipients, and visiting scientists must either comply with this policy or provide a certification to the KSC Grant/Contract Administrator that their institutions are in compliance with pertinent federal policies and that they in turn are in compliance with their own institutional policies. Subcontractors from commercial firms need make a certification only when the prime award is from the Public Health Service.

Significant Financial Interests

Any KSC employee responsible for the design, conduct, or reporting of research activities funded or proposed for funding by external sources must reveal all current significant financial interests that would reasonably appear to be affected by the research.

Significant financial interest is defined as any current financial interest of the investigator and his/her immediate family that could reasonably appear to be affected by the activities proposed for funding; or any interest held by the investigator and his/her immediate family in a business entity (company, corporation, or other enterprise) whose financial interests might reasonably appear to be affected by such activities.

Specifically, significant financial interests might include, but are not limited to, any of the following:

- Anything of significant monetary value, including salary or other payments for services, such as consulting fees or honoraria;
- Direct equity interests, such as stock, stock options, or ownership interests;
- Intellectual property rights owned by the investigator, such as patents, copyrights, and royalties from such rights.

The term does not include:

- Financial interests in business enterprises or entities that when aggregated for the investigator and his/her immediate family meet both of the following tests:
 1. the financial interest does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and
 2. the financial interest does not represent more than a five percent ownership interest in any single entity;
- Salary, royalties, or other remuneration from KSC;
- Salary, royalties, or other payments that when aggregated for the investigator and his/her immediate family, are not expected to exceed \$10,000 during the next twelve month period;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or non-profit entities.

An investigator may choose to disclose any other financial or related interest that might present an actual, potential, or perceived conflict of interest. Disclosure can be a key factor in protecting an individual's reputation and career from potentially harmful allegations of misconduct.

Disclosure Process

All Disclosure Statements and related documents are considered sensitive information and only those persons involved in the implementation of this policy will have access to such records.

Each investigator who has significant financial interests possibly affected by the research must complete a [Keene State College Financial Disclosure Statement](#) and attach all required supporting documentation. In addition, the investigator must submit a proposed conflict of

interest management plan that details steps that could be taken to manage, reduce, or eliminate any conflict of interest. The form, documentation, and plan should be submitted in a sealed envelope marked confidential to the Grants/Contracts Administrator.

All significant financial interests must be disclosed prior to the time a proposal is submitted. All financial disclosures must be updated by investigators during the period of the award as new reportable significant financial interests are obtained.

Review of Disclosures

A Disclosure Review Committee (DRC) will review all disclosure statements. The committee will be chaired by the Vice President for Academic Affairs. The President will appoint three additional faculty members representing the diverse colleges, schools, and programs of KSC. Members will serve three year staggered terms.

The Committee will be responsible for determining whether the significant financial interests of the investigator could reasonably be expected to affect the design, schedule, conduct, or reporting of the activities funded or proposed for funding. The Committee may request additional clarifying information from the individual which will be treated as non-public information to the extent allowed by law.

Management Plans for Conflict

The Committee will review the proposed conflict management plan and approve it or add conditions or restrictions to ensure that any conflict is managed, reduced, or eliminated. Such conditions or restrictions may include, but are not limited to, the following:

- Public disclosure of significant financial interests;
- Monitoring of the research by independent reviewers;
- Modification of the planned activities (possibly subject to sponsor approval);
- Disqualification from participation in all or part of the project;
- Divestiture of significant financial interests;
- Severance of relationships creating conflict.

In all cases, resolution of the conflict or establishment of an acceptable conflict management plan must be achieved before expenditure of any funds under an award.

Appeals

Appeal of the Disclosure Review Committee's decision may be made to the College President, who will consult with the investigator and the Committee and make a final determination.

Compliance

As part of the Financial Disclosure Statement each investigator must certify that if the Disclosure Review Committee determines a conflict exists, the investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully with the individual(s) assigned to monitor compliance.

Enforcement

Failure to properly disclose relevant financial interests or to adhere to conditions or restriction imposed by the Disclosure Review Committee will be considered a deviation from accepted standards of conducting research at KSC.

Alleged violations of this policy will be investigated by the Disclosure Review Committee which will make recommendations for action to the President. Breaches of policy include failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous, or misleading disclosure forms; or failure to comply with procedures prescribed by the Committee. If the President determines that the policy has been violated, he/she may impose sanctions including notification of sponsor and termination of award; formal admonition; a letter to the investigator's personnel file; and suspension of the privilege to apply for external funding and/or to seek IRB approval.

Records

The Business Office will maintain records of all disclosures and associated activities securely and confidentially.

All records will be maintained for three years following the letter of termination or completion of the project or resolution of any government action involving the records.

Records will not be routinely provided to sponsors unless such is an agency requirement, the agency submits a written request, or KSC is unable to satisfactorily manage an actual or potential conflict of interest. The Grant/Contract Administrator will be responsible for communications with sponsors. Disclosure statements and associated information will not be released without notifying the investigator.

Federal Regulations References

Department of Health and Human Services. Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought. July 11, 1995. 60 Fr 35810, Part III.

National Science Foundation. Investigator Financial Disclosure Policy. July 11, 1995. 60 FR 35810, Part III.

UNH First draft completed 2/7/95.

Policy approved by Interim President Thomas Fairchild 6/29/1995.

Policy updated September 25, 1995, to comply with final regulations promulgated by the Public Health Service (PHS) in the July 11, 1995, issue of the Federal Register; and by the National Science Foundation (NSF) in the June 28, 1994, Federal Register as modified by the July 11, 1995, Federal Register.

Revised policy approved by President Joan Leitzel 8/14/96.

KSC Revised Policy approved by President Stanley J. Yarosewick 10/1/96.