Financial Conflict of Interest (FCOI) in Research and Educational Activities

Keene State College Policies and Procedures

Financial Conflict of Interest (FCOI) in Research and Educational Activities

Section Menu

Approved by Cabinet 08/06/2012

1. Statement of Need & Purpose

Externally sponsored research and educational activities are a vital part of the Keene State College (KSC) mission. As these activities grow in sophistication and complexity they may intersect increasingly with industrial explorations and entrepreneurial ventures, creating for Investigators the potential for conflicting interests.

A financial 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 or educational activities.

The purpose of this policy is to promote objectivity in research and educational activities by establishing standards and processes that provide a reasonable expectation that the design, conduct, and reporting of externally sponsored research and educational activities will be free from bias resulting from Investigator financial conflicts of interest.

Keene State College is compelled by both its mission and federal regulations to uphold these standards.

2. Investigator Requirements

Any Investigator responsible for the design, conduct, or reporting of research

or educational activities funded or proposed for funding by external sources is required to:

1. Disclose, prior to applying for external funding, all “significant financial interests” (and those of his/her spouse/domestic partner, or dependent child) related to the Investigator’s institutional responsibilities. If an Investigator has no significant financial interests to disclose, he or she must still complete the disclosure documentation indicating this to be the case.
2. Update the disclosure at the following points: a. Prior to initial award activation (i.e., prior to the release of funds by Keene State College) b. Within 30 days of acquiring a new significant financial interest c. At least annually throughout the life of a sponsored agreement
3. Comply with FCOI management plans instituted by the Keene State College FCOI Review Officer.
4. Complete FCOI training via the method/curriculum approved by the College as described on the OSPR webpage:
    - prior to engaging in the externally sponsored research or educational activity.
    - at least every 4 years
    - any time an investigator is new to the institution and plans to participate in externally funded research or educational activities
    - in the event an investigator has been found to be non-compliant with this policy or a management plan instituted by the Keene State College FCOI Review Officer.
    - if the institution makes substantive changes to this policy which affect Investigator requirements.

Project directors are responsible for ensuring that all individuals who are responsible for the design, conduct, or reporting of externally funded research and educational activities disclose all significant financial interests related to that individual’s institutional responsibilities. This includes individuals who come to work on an established project through reallocation of effort, hiring, transfer, promotion, etc., and who thereby take on a responsible position in a project.

3. Applicability

3.1 General Applicability

This policy applies to each Investigator who is planning to participate in, or is participating in, externally sponsored research and/or educational activities, regardless of sponsor or sponsor type (e.g., state, federal, private).

The policy also includes the Investigator’s immediate family, which is defined as his/her spouse or domestic partner and dependent children.

This policy does not apply to SBIR (Small Business Innovation Research) applications.

This policy does not apply to instances where external funding is paid directly to the individual Investigator, rather than to Keene State College. For example, individual fellowships paid directly to the Investigator rather than to the College on his/her behalf are not covered by this policy.

3.2 Subrecipients

The responsibility to identify, manage, and report FCOIs to sponsoring agencies extends to collaborating Investigators under any subrecipient agreements. Subrecipient agreements issued by Keene State College shall contain language documenting whether the subrecipient Organization will be subject to the Keene State College FCOI policy (this policy) or the FCOI policy of the subrecipient’s own institution.

- When the subrecipient will be following its own institutional FCOI policy, Keene State College will obtain a written certification from the subrecipient organization that its FCOI policy complies with the applicable sponsoring agency regulations regarding the identification, management, and reporting of FCOIs. Additionally, the subrecipient agreement will require the subrecipient organization to report identified FCOIs for its investigators to Keene State College, and will specify an acceptable time-frame for this reporting that will allow Keene State College to in turn report these FCOIs to the sponsoring agency as required.

- If a subrecipient cannot certify that their FCOI policy and procedures meet sponsoring agency regulations, then the subrecipient agreement shall require the subrecipient organization to adhere to the Keene State College policy and procedures, and to submit subrecipient Investigator disclosures to Keene State College. The timeframe for submitting disclosures will be specified so as to allow Keene State College to comply timely with its review, management, and reporting obligations under this policy.

3.3 Policy Implementation Schedule

This policy will be implemented according to the following schedule.

- For active/existing awards emanating from PHS funds, this policy becomes effective as of August 24, 2012.
- For active/existing awards emanating from non-PHS funds, Investigators will continue to follow the College Financial Conflict of Interest in Research policy dated 10/1/1996 until such time as the project is approaching a new award budget cycle (either competitive or non-competitive). At that time, each award will migrate to this August 24, 2012 policy.
- ◦ For all proposals submitted prior to August 24, 2012 and for which an award is received after August 24, 2012, Investigators will migrate immediately to the August 24, 2012 policy by submitting the disclosure form for this policy and completing the required training prior to expenditure of funds.
- As of August 24, 2012, all Investigators submitting new proposals for externally sponsored projects (regardless of sponsor) are subject to this policy in relation to those proposals and any future awards emanating from them.

4. What is a Significant Financial Interest (SFI)?

While many types of financial interests are excluded from this policy (see section 5. Exclusions), a financial interest consisting of one or more of the

following interests of the Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities is considered a "significant financial interest" (SFI) and must be disclosed:

4.1 Interests in Publicly Traded Entities

With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, and any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this policy, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). Equity interest includes stock, stock option, or other ownership interest, as determined by public prices or other reasonable measures of fair market value.

4.2 Interests in Non-publicly Traded Entities

With regard to any non-publicly traded entity, a significant financial interest exists if the value of any **remuneration** received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse/domestic partner or dependent children) holds *any* **equity interest** (e.g., stock, stock option, or other ownership interest), regardless of dollar value associated with that equity interest.

4.3 Intellectual property rights and interests

(e.g., patents, copyrights), upon receipt of income related to such rights and interests once an aggregated value of $5,000 from a particular source is reached.

4.4 Reimbursed or Sponsored Travel

Investigators also must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities (regardless of dollar value). Reimbursed travel includes instances where travel expenses incurred by the individual are ultimately covered by an outside entity through a reimbursement (pay back) process. Sponsored travel includes instances where the expenses are paid by the outside entity on behalf of the individual, rather than reimbursed to him or her. In the case of sponsored travel, the exact monetary value may not be readily known to the individual.

4.5 Other

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.

5. Exclusions

Financial interests that are excluded from this policy and which need not be disclosed include:

- Salary, royalties, remuneration paid by Keene State College (as your current employer)
- Income from seminars, lectures, or teaching engagements sponsored by:
  - A Federal, State, or Local government agency
  - An Institution of Higher Education
  - Academic Teaching Hospital
  - A Medical Center
  - A Research Institute that is affiliated with an Institution of Higher Education
- Income from service on advisory committees or review panels sponsored by:

    - A Federal, State, or Local government agency
    - An Institution of Higher Education
    - Academic Teaching Hospital
    - A Medical Center
    - A Research Institute that is affiliated with an Institution of Higher Education
- Travel reimbursed or sponsored by:
    - A Federal, State, or Local government agency
    - An Institution of Higher Education
    - Academic Teaching Hospital
    - A Medical Center
    - A Research Institute that is affiliated with an Institution of Higher Education
    - Intellectual property rights that you have assigned to Keene State College or in instances where an agreement exists to share royalties to such property rights.
- Income from investment vehicles or retirement accounts unless you directly control the investment decisions made in these vehicles.

6. Disclosure Process

Each Investigator applying for external funding for research and/or educational activities must disclose all significant financial interests (and those of his/her spouse, domestic partner, and dependent children) by completing a Keene State College FCOI Screening and Disclosure Form, in keeping with the following disclosure requirements:

- All significant financial interests must be disclosed prior to the time a proposal for external funding is submitted. The initial disclosure process will coincide with the normal proposal routing/approval process used by the Office of Sponsored Projects and Research. No proposal will be submitted without FCOI Screening and Disclosure Forms being complete and up-to-date for each Investigator (e.g., any individual responsible for

the design, conduct, or reporting of the proposed project, regardless of title). If an Investigator has no significant financial interests to disclose, he or she must still complete the disclosure documentation indicating this to be the case.

- In the event of a new incoming award, Investigators must review and update their Disclosure Forms to ensure they are complete and accurate prior to expenditure of funds.
- During the period of the sponsored agreement, all financial disclosures must be updated by Investigators within 30 days of discovering or acquiring a new significant financial interest.
- All financial disclosures must be updated by Investigators at least annually during the life of the sponsored agreement.
- Investigators newly hired or otherwise advancing to a role of responsibility in the design, conduct, and reporting of externally sponsored research or educational activities must contact the post-award grant/contract administrator assigned to the award to disclose SFIs and complete the required training.
- Individuals should contact the post-award grant/contract administrator assigned to the award to update disclosures for ongoing sponsored projects.

Disclosures made to the Office of Sponsored Projects and Research or to Post Award Administration (Business Office) will be forwarded to the FCOI Review Officer in a timely manner to support the review process.

7. Review Process

The FCOI Review Officer is the Keene State College Provost or his/her designee chosen from the Keene State College administration. The designee option is available at the Provost’s discretion in order to facilitate the review process in a timely and appropriate manner. A designee may be appointed in instances including, but not limited to: situations where compelling reasons exist to have another individual conduct the review in order to provide an appropriate, informed review; to avoid known conflicting interests between parties involved in the review; and/or the unavailability of the Provost to

conduct a timely review.

The FCOI Review Officer is responsible for reviewing FCOI Screening and Disclosure forms in which significant financial interests have been disclosed in order to determine whether the interests could reasonably be expected to directly and significantly affect the design, conduct, or reporting of the activities funded or proposed for funding. The FCOI Review Officer may request additional clarifying information from the Investigator as necessary to complete the review.

In the case of initial awards, the FCOI Review Officer will conduct a review of disclosures, including the development of a management plan if necessary, prior to the expenditure of funds. In the case of disclosures of new financial interests throughout the life of an on-going project, the FCOI Review Officer will conduct his/her review of disclosures, including the development of a management plan if necessary, within 60 days of receiving the disclosure.

8. Management/Monitoring Process for Identified Conflicts of Interest

The FCOI Review Officer is responsible for developing a management plan for any identified conflicts of interest to ensure that any conflict is managed, reduced, or eliminated. The FCOI Review Officer may include the Investigator in the development of this plan. 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.

8.1 Management Plan Conditions/Restrictions:

Management plans may include conditions or restrictions such as, but 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;
- Reduction or elimination of the significant financial interests (e.g., sale of an equity interest);
- Severance of relationships creating financial conflict.

8.2 Management Plan Required Elements:

Management plans will include at a minimum a description of the following elements:

- Role and principal duties of the conflicted investigator in the research project.
- Conditions of the management plan.
- How the management plan is designed to safeguard the objectivity in the research project.
- Confirmation of the Investigator’s agreement to the management plan.
- How the management plan will be monitored to ensure investigator compliance.
- Other information as needed.

As part of the FCOI Screening and Disclosure form each Investigator must certify that if the FCOI Review Officer 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 throughout the life of the funded project.

9. Retrospective Review Process and Remedies

In instances where any of the following has occurred, the FCOI Review Officer will complete within 120 days a retrospective review of the research project to

determine whether bias has occurred in the research:

- Whenever a financial conflict of interest is not identified or managed in a timely manner, including instances where an investigator failed to disclose a significant interest that is determined by the FCOI Review Officer to be a financial conflict of interest;
- Whenever the institution has failed to review or manage a financial conflict of interest;
- Whenever an Investigator fails to comply with the conflict of interest management plan proscribed by the FCOI Review Officer.

If it is determined through retrospective review that the research has been biased by the Investigator's financial interests, then the FCOI Review Officer will decide upon an appropriate set of remedies to eliminate or mitigate the bias.

Depending on the nature of the financial conflict of interest, the FCOI Review Officer may determine that additional measures are necessary with regard to the Investigator's participation in the funded research project during the period of the retrospective review.

10. Maintenance of Records

The Business Office and the Office of Sponsored Projects & Research will jointly maintain records of all disclosures, reviews, and associated FCOI Review Officer actions. 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.

All FCOI Screening and Disclosure forms and related documents are considered sensitive information and only those persons involved in the implementation of this policy will routinely have access to such records. However, all FCOI and SFI information (including institutional reviews and determinations) will be made available to the sponsoring agency upon request, or as required by this policy's reporting requirements. Additionally, there may be circumstances in which FCOI related information is made public in accordance with sponsor regulations and the public accessibility

requirements of this policy (*see 11. Reporting Process and 12. Public Accessibility sections below*).

11. Reporting Process

Keene State College recognizes its obligation to report information emanating from the College's FCOI process to sponsoring agencies, and will provide the necessary information to those agencies in a manner, format, and level of detail consistent with the sponsor's requirements for such reporting. The post-award grant/contract administrator assigned to the award is the individual designated to submit reports to the sponsoring agency, and he/she will review the sponsoring agency's reporting requirements to ensure the appropriate information is submitted.

11.1 Reporting to PHS Awarding Components:

Management plan reports to PHS awarding components will include at a minimum the following elements:

- Sponsor Project Number or identifier
- PD/PI or contact PD/PI
- Name of Investigator with the financial conflict of interest
- Name of Entity with which the Investigator has a financial conflict of interest
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
- Value of the financial interest (dollar ranges are permissible):
  $0-4,999
  $5,000 - $9,999
  $10,000 - $19,999
  $20,000 - $39,999
  $40,000 - $59,999
  $60,000 - $79,999

$80,000 - $100,000
Over $100,000 (document in increments of $50K)
$___
_ Value cannot be readily determined

- A description of how the financial interest relates to the funded research, and the basis for the institution’s determination that the financial interest conflicts with such research
- A description of the key elements of the management plan, including:
  - Role and principal duties of the conflicted investigator in the research project.
  - Conditions of the management plan.
  - How the management plan is designed to safeguard the objectivity in the research project.
  - Confirmation of the Investigator’s agreement to the management plan.
  - How the management plan will be monitored to ensure investigator compliance.
  - Other information as needed.

11.2 Retrospective Review and Mitigation Reports to PHS Awarding Components:

In the event that the failure of an Investigator to comply with this policy or with a financial conflict of interest management plan appears to have biased the research/educational activity, the post-award grant/contract administrator assigned to the award, on behalf of the FCOI Review Officer, will notify the sponsoring agency of the corrective action taken, including the outcome of the retrospective review, and the mitigation plan (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

Retrospective Review and Mitigation Reports to PHS awarding components will include, at minimum, the following elements:

- Project Number; • Project Title; • PD/PI or Contact PD/PI if a multiple PD/PI model is used; • Name of Investigator with the FCOI; • Name of the entity with which the Investigator has a financial conflict of interest; • Reason(s) for the retrospective review; • Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); • Findings of the review; • Conclusions of the review; and • Description of the impact of the bias on the research project and the Institution’s plan of action or actions taken to eliminate or mitigate the effect of the bias.

12. Public Accessibility

Keene State College recognizes the importance of transparency, and that some sponsors require information about FCOIs to be made accessible to the public. The College maintains an FCOI Public Accessibility webpage to fulfill this obligation. In instances where a financial conflict of interest of *senior/key personnel* has been managed (rather than eliminated) the following information will be made available to the public prior to expenditure of funds:

Name of Investigator with the financial conflict of interest, title, role on the research project. Name of Entity with which the Investigator has a financial conflict of interest *Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)* Approximate value of the financial interest (in dollar ranges described in section 11.1)

Additionally, this information will be updated annually throughout the life of the funded project, and within 60 days of any new disclosure determined to be a financial conflict of interests. The information will remain available for 3 years from the date of the most recent update of the information.

13. Enforcement Mechanisms, Remedies, and Noncompliance

Failure to properly disclose relevant financial interests or to adhere to conditions or restrictions imposed by the FCOI Review Officer will be considered a violation of this policy.

Alleged violations of this policy will be investigated by the FCOI Review Officer, 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 FCOI Review Officer.

If the President determines that this policy has been violated; he/she may impose a range of sanctions including but not limited to: notification of sponsor and possible termination of award; formal admonition; a letter to the Investigator's personnel file; suspension of the privilege to apply for external funding and/or to seek IRB/IACUC approval; and other remedies necessary to eliminate or mitigate the impact of any potential bias.

If the allegations and review suggest a possible violation of the USNH Board of Trustees policy prohibiting fraud, a concurrent report to USNH Internal Audit will be made.

14. Appendix

14.1 Definitions

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of externally funded research or educational activities.

FCOI report means an Institution's report of a financial conflict of interest to the external sponsor.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities means your professional responsibilities on behalf of Keene State College, which include: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as IRB, IACUC, or other monitoring boards.

Investigator means any 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 and/or educational activities, which may include collaborators or consultants.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal investigator of a funded research project and/or educational activity; the PD/PI is included in the definitions of senior/key personnel and Investigator.

PHS means the Public Health Service of the US Department of Health and Human Services and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS awarding component means an organizational unit within PHS that funds research.

Research and/or Educational Activities means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book or book chapter), product development (e.g., a diagnostic test or drug), and artistic or creative works. As used in this policy, the term includes any such activity for which funding is available for research and/or educational activities through a grant (sponsored project) or cooperative agreement.

Significant Financial Interest (see section “What is a Significant Financial Interest?”)

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted by the Institution to the external sponsoring agency.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the

Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this policy, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-56

14.2 Keene State College Institutional Responsibilities

As an institution that receives external funding for research and sponsored programs, Keene State College has the following responsibilities under this policy:

- To establishing standards that provide a reasonable expectation that the design, conduct, and reporting of funded research and educational activities will be free from bias resulting from Investigator financial conflicts of interest.* To maintain an up to date, written, enforced policy that complies with federal FCOI regulations and to make this policy available via a publicly accessible website.
- To inform each Investigator of this policy and their responsibilities regarding disclosure.
- Require each Investigator to complete training regarding this policy prior to engaging in externally funded research, and at least every 4 years, and immediately when any of the following circumstances apply:
    - If the policy revised in a substantive way that affects investigator requirements.
    - If the Investigator is new to Keene State College.
    - We find that an Investigator is not in compliance with the policy or an FCOI management plan.
- To take reasonable steps to ensure any subrecipient complies with either this policy or their own institutional policy which must meet the external sponsor’s FCOI requirements.
- To designate an institutional official or officials to solicit and review disclosures of significant financial interests from each Investigator who is

planning to participate in, or is participating in, funded research.

- To require that each Investigator disclose to the designated official(s) the Investigator’s significant financial interests, and those of the Investigator’s spouse/domestic partner and dependent children prior to submission of a proposal for external funding for research or educational activities.
- To require that the Investigator involved in the funded research submit an updated disclosure of significant financial interest at least annually.
- To require that the Investigator involved in the funded research submit an updated disclosure of significant financial interest within 30 days of discovering or acquiring (through purchase, marriage, or inheritance) a new significant financial interest.
- To provide guidelines for the designated officials to determine whether the significant financial interest is related to funded research, and if so related, whether it is a financial conflict of interest.
- To take such actions as necessary to manage the financial conflict of interest, including any financial conflict of interest of a subrecipient Investigator. Management of an identified FCOI requires development and implementation of a management plan, and, if necessary, a retrospective review and a mitigation report.
- To provide initial and ongoing reports as required by the sponsoring agency.
- To maintain records of all Investigator disclosures of Investigator financial interests and the institution’s review of and response to such disclosures (whether or not a disclosure resulted in the institution’s determination of FCOI) and all actions under the institution’s policy or retrospective review if applicable. These records shall be aintained for at least 3 years from the date of submission of the final expenditures report, or as specified by the funding agency.
- To establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance, as appropriate.
- To provide certifications regarding our FCOI process in each application for funding when such certifications are required by the sponsor.
- Disclose information about FCOIs currently being managed in relation to

the institution’s sponsored agreements via a publicly accessible website.

14.3 Informing the Campus Community of this Policy

As a matter of process, Investigators will be informed of these requirements through several means and at several key time-points, including (but not limited to) some or all of the methods listed below. This list is not meant to be exhaustive or proscriptive, but rather is meant to convey the institution’s commitment to establishing a culture of compliance with this policy by utilizing multiple and varied communication strategies.

- Campus-wide communications/reminders regarding Keene State College sponsored projects and research policies.
- Publication of this policy on the College website.
- The Keene State College proposal routing process.
- New award communications sent to the principal Investigator during the award set-up phase, and prior to expenditure of funds.

14.4 Policy History

- 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
- Revised policy approved by Interim President Jay V. Kahn on 08/06/2012. (Policy updated in response to PHS final rule issued August 25, 2011 in the Federal Register)