Assumption College Conflict of Interest Policy for Government Grant Recipients

August 21, 2012

Regulatory Authority
This policy implements the requirements of 42 CFR 50 and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.
Assumption College has an obligation to assure that the principles of objectivity in research are upheld to ensure that there is no reasonable risk that the design, conduct, or reporting of research will be biased by any conflicting financial interests of an Investigator. The federal government has established specific reporting and management requirements, effective August 24, 2012, with which this policy is intended to comply. There is some variation in requirements among federal agencies. This policy has been designed to comply with the requirements of the National Institutes of Health, which is the strictest case.

Disclosure of Financial Interests
Investigators engaged in externally sponsored activity must, in accordance with Federal and College policy, disclose to the Director of Grant Development on disclosure forms provided by the Director all Significant Financial Interests (including those of their spouse or domestic partner, parents and dependent children, including adopted or stepchildren) that would reasonably appear to affect or be affected by the sponsored activity. Investigators should choose to disclose any other financial or related interest that could present an actual or perceived conflict of interest. Any such disclosure should provide sufficient detail to permit an accurate and objective evaluation as to whether there may be a conflict. Such disclosure form must be completed and submitted before the contract or grant application is submitted, and the disclosure must be reviewed to determine if further action is required before the College expends any awarded funds or issues a purchase order or subcontracts for the acquisition of goods and services related to that project. Such disclosure forms must be updated at least annually or more frequently, if new reportable information is obtained during the period of an award.

What Must Be Disclosed
All Investigators are required to disclose their Significant Financial Interests. A Significant Financial Interest means one or more of the following interests, if it reasonably appears to be related to the Investigator’s institutional responsibilities, including all research, teaching and/or service to the College:
a) 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 the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds $5,000. Remuneration includes any salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

b) 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 spouse, partner, parents or dependent children, including adopted or stepchildren) owns any equity interest, regardless of dollar value.

c) Intellectual property rights and interests (e.g. patents and copyrights) upon receipt of income related to such rights and interests.

d) Any occurrence of reimbursed or sponsored travel related to your institutional responsibilities must also be disclosed, including instruction, research or service to Assumption College, with the exception of any travel reimbursed or sponsored by a federal, state or local government agency, an institution of higher education (including Assumption), an academic teaching hospital, a medical center, or a research center affiliated with an institution of higher education. Travel that is reimbursed by Assumption College from a sponsored fund account whose sponsor is an entity that is not one of those exempt entities shall be treated as a Significant Financial Interest. The Investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination and its duration. Additional information, including the estimated cost of travel, may be requested by the Director of Grant Development and must be furnished upon request.
Exclusions

The term “Significant Financial Interest” does not include: a) normal salary, royalties, or other remuneration from Assumption College; b) income from investment vehicles such as mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; c) income from seminars, lectures, or teaching engagements sponsored by government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education; d) income from service on advisory committees or review panels for government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.

Timing of Required Disclosures

1. Investigators must provide all required financial disclosures at the time a proposal is submitted.

2. In addition, Investigators must update those financial disclosures:
   - Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest; and
   - Annually within the period of the award, beginning with the anniversary date of the original disclosure.

Review and Decision of Institutional Official

If the Director of Grant Development determines, after reviewing the disclosure form and other available information, that financial or other interests may affect the design, conduct or reporting of research activities or teaching/mentoring activities, the Director shall consult with the Provost (or designee). If this review confirms a potential conflict the project may be referred to an ad hoc committee of three or four individuals named by the Provost. Following review of the matter, unless there is no further action needed, the committee will recommend in writing to the Provost one of the following actions:
   - Accept the proposed sponsored project; or
   - Do not accept the proposed sponsored project; or
• Accept the proposed sponsored project provided certain conditions or restrictions are imposed so that the conflict will be managed, reduced or eliminated.

Examples of possible conditions or restrictions are:

• Monitoring of research by independent reviewers
• Public disclosure of Significant Financial Interests
• Modification of the research plan
• Disqualification from participation in the portion of the sponsored funded research that would be affected by the Significant Financial Interest
• Divestiture of Significant Financial Interest
• Severance of relationships that create actual or potential conflicts

If the Investigator is dissatisfied with the committee’s recommendations, the Investigator may, within ten (10) calendar days of such recommendation, appeal to the Provost (designee) who will consult with the faculty member and the committee, as appropriate. After such review, the Provost (designee) will make the final decision.

Prior to the expenditure of funds under the award, the College will report to the appropriate Federal Agency the existence of a conflicting interest found by the College and assure that the interest has been managed, reduced, or eliminated and, for any interest that the College identifies as conflicting subsequent to the College's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification.

Collaborators/sub-recipients/subcontractors from other institutions involved in externally-sponsored research of the College must either comply with this policy or provide a certification from their institutions that they are in compliance with Federal policies regarding disclosure of conflicts of interest and that their portion of the project is in compliance with their institutional policies.

The College shall maintain records of all financial disclosures and of all actions taken to resolve Financial Conflicts of Interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any federal or state action involving those records, whichever is longer.
Investigator Compliance

All persons subject to this policy are expected to comply fully and promptly with it. Instances of deliberate breach of policy, including but not limited to failure to file disclosure forms or knowingly filing incomplete, erroneous, or misleading disclosure forms, will be reported to the Provost.

In the event of non-compliance by an Investigator, the Provost (designee) will determine possible sanctions to be imposed on an Investigator that may include, but are not limited to:

- Formal admonition,
- A letter from the Provost to the person’s file,
- Ineligibility for (i) grants, or (ii) IRB approval,
- Non-renewal of appointment,
- Dismissal (in accordance with the provisions of the Faculty Policy Document).

The Provost (designee) will then recommend an appropriate sanction to the President, who will make the final decision.

In addition, the College shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to materially comply with this policy. The sponsor may take its own action, as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

Training

- **Investigators on NIH/PHS-funded projects**: Each Investigator (including senior/key personnel) on projects funded by or proposed to NIH or other Public Health Service (PHS)-affiliated agencies must complete training in the College’s conflict of interest policy. For Investigators of current or pending NIH grants as of July 23, 2012, this training will consist of a scheduled meeting with the Director of Grant Development covering institutional policies, Investigator responsibilities under that policy, and the federal regulations that mandate the policy.

- **New or previously unfunded Investigators**: New and/or previously unfunded Investigators who notify the Director of Grant Development of their intent to submit a research proposal to NIH or another PHS-affiliated agency after August 24, 2012 will be required to complete training (and make the disclosures described above) prior to submission of their proposal. This
training will consist of a scheduled meeting with the Director of Grant Development and a review of an online module from the National Institutes of Health web site.

- **Investigators on non-NIH/PHS projects**: For Investigators sponsored by or seeking funding from NSF and/or other federal agencies, as well as any Investigators initiating research sponsored by a private, for-profit entity, the above training activities are optional but strongly recommended. Training will become mandatory if those agencies adopt mandatory training as part of their conflict of interest policies.

- **Repeat training**: Group training of active NIH/PHS-funded Investigators, consisting of the mandatory workshop, will be repeated (i) every four years and (ii) on any occasion when Assumption College revises its Financial Conflict of Interest policies and procedures in any manner that affects the requirements of Investigators.

**Confidentiality**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, Assumption College may make such information available to an agency funding research of the faculty member or to a requestor of information concerning Financial Conflict of Interest related to grant funding, if requested or required. This information will also be made available to any *ad hoc* committee charged by the Provost to determine if a conflict of interest exists. If Assumption College is requested to provide disclosure forms, conflict management plans, or related information to an outside entity, the Investigator will be informed of the disclosure.

**Public Accessibility**

Assumption College will respond to any requestor within five business days of the request for information concerning any Significant Financial Interest that meets the following criteria:

- The Significant Financial Interest was disclosed and is still held by the Investigator;
- A determination has been made that the Significant Financial Interest is related to the government-funded research;
- A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

Policy approved by Provost and General Counsel 8/21/12 LCJ