

# Financial Conflict of Interest for Externally Funded Research Reporting Process (July 1, 2017)

## **Introduction**

This process governing financial conflicts of interest (FCOI) applies to all Centenary Investigators who apply to or receive external research support from the following federal agencies: the National Science Foundation (NSF) and Public Health Service (PHS) agencies, including but not limited to the National Institutes of Health (NIH). The Institutional Official is responsible for ensuring implementation of this reporting process and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the VPFA is implemented.

## **Reporting Statement**

Federal regulations governing grants from certain federal agencies (e.g., NSF and PHS agencies including NIH) require that the College adopt, monitor, and enforce a Financial Conflict of Interest Reporting Process covering financial conflicts that may arise as a result of research funded by such agencies. (See regulations at 42 CFR 50.601 and following.) The College recognizes that these conflicts may arise due to interests and investments that faculty and their families may have. The existence of a significant financial interest and any resulting financial conflict(s) is not prohibited in and of itself, but such conflicts must be disclosed to the College and managed appropriately. For these reasons, Centenary College adopts the following Financial conflict of Interest Reporting Process.

## **Procedures**

All Investigators who apply for or receive grants from the Federal agencies identified above are required to follow the procedures set forth below.

### ***Disclosures of Significant Financial Interests***

Using the College's FCOI Disclosure Form, each investigator shall disclose to the Institutional Official all significant financial interests

- (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by the grant source; or
- (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

The disclosure form can be downloaded here: [Financial Conflict of Interest Form](#)

Principal Investigators must ensure that required disclosures have been submitted by all other co-Investigators and Senior/Key Personnel on their projects.

### ***Disclosures of Travel***

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined below in the definition of Financial Interest. Travel reimbursed or sponsored by U.S. federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical

centers need not be disclosed. Disclosures for qualifying travel must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

### ***Timing of Disclosures***

Investigators and designated personnel are required to submit required FCOI disclosures as follows:

- Prior to submission of a proposal to one of the designated agencies.
- Annually in September of each year during the performance period of a funded proposal., Investigators and Senior/Key Personnel shall complete an FCOI Annual Disclosure Form and submit it to the VPFA.
- Within 30 days of acquiring or discovering any new reportable significant financial interests.
- Investigators who join the College and are conducting research sponsored by the agencies to which this reporting process applies will provide all necessary disclosures within 30 days.

### ***Review of Disclosures***

The Institutional Official shall review financial disclosures prior to the expenditure of any funds and determine whether a financial conflict of interest exists. A financial conflict of interest will exist if the Institutional Official or designee determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of federally supported research.

### ***Management Plans***

Written plans will be developed to manage, reduce, or eliminate any financial conflict(s) of interest. Management plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, and protect the sensitivity of disclosed information. If the Institutional Official determines that there is a financial conflict of interest, he or she must approve a written management plan before any related research goes forward. The affected Investigator is responsible for developing in consultation with and submitting to the Institutional Official a proposed management plan. One or more of the following elements may be found in a management plan:

- monitoring of the sponsored program by independent researchers or reviewers, the Institutional Official, an FCOI committee, or a designee;
- modifications to the research or program plan;
- appointment of an oversight panel or person to review research/scholarship;
- limitations on the employee's involvement in personnel or other decisions on behalf of the College;
- divestiture of significant financial interests; and/or
- other arrangements that manage, reduce, or eliminate a potential financial conflict of interest.

### **Reporting to a Federal Agency**

If any identified conflict or non-compliance requires reporting to the sponsoring agency, the Institutional Official will produce such a report in accordance with applicable regulations.

## **Investigator Non-Compliance**

### ***Disciplinary Action***

If an Investigator fails to comply with this reporting process, the Institutional Official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented. The decision to impose sanctions on an Investigator because of failure to comply with this process or the decision of the Institutional Official will be described in writing to the Investigator and will include notification of the Investigator's right to appeal the decision to the President.

### ***Retrospective Review***

In some cases the Institutional Official may determine that a financial conflict of interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a significant financial interest that is determined to be a financial conflict of interest. In such cases, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct, or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of the Investigator with the financial conflict of interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to the funding agency, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias by the investigator is found, the report will include a mitigation report in accordance with the applicable regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

## **Training**

Each Investigator must complete training on this process prior to engaging in research funded by the above-referenced federal agencies, and at least every four years thereafter. Investigators must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this reporting process is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this process or with a management plan related to their activities.

## **Record Retention**

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the funding agency.

### **Confidentiality**

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be kept confidential. However, the College may make such information available to the agency funding the research or to a requestor of information concerning financial conflict of interest related to relevant federal funding, if requested or required. If the College is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

### **Public Accessibility**

The information to be made available shall be consistent with the requirements of the applicable federal regulation or official funding agency policy. The College will respond to any requestor within five business days of the request, with information concerning any significant financial interest that meets the following criteria:

1. The significant financial interest was disclosed and is still held by the senior/key personnel;
2. A determination has been made that the significant financial interest is related to the federally funded research; and
3. A determination has been made that the significant financial interest is a financial conflict of interest.

### **Regulatory Authority**

This reporting process implements the requirements of 42 CFR 50 and 45 CFR 94; these requirements take precedence over any substantive difference that may exist between this reporting process and the requirements.

### **Subrecipients and Subawardees**

When the College works with subrecipients and subawardees of grant funds from federal agencies to which the reporting process applies, it will enter into written agreements specifying whether the subrecipient institution will follow Centenary’s FCOI Reporting Process or its own. Subrecipients and subawardees will be required to comply with any applicable federal regulations.

### **Definitions**

Term	Definition
Family	Any member of an Investigator’s immediate family, specifically, any dependent children, spouse, or domestic partner.
Financial Conflict of Interest	A significant financial interest that Centenary College (College) reasonably determines could directly and significantly affect the design, conduct, or reporting of the externally sponsored project

<p>Financial interest</p>	<ul style="list-style-type: none"> <li>• Anything of monetary value received or held by an Investigator or an Investigator’s family, whether or not the value is readily ascertainable, including, but not limited to salary payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) upon receipt of royalties or other income related to such intellectual property rights and interests.</li> <li>• Includes any reimbursed or sponsored travel undertaken by an Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of an Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state, or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education; academic teaching hospitals; and medical centers.</li> <li>• <b>DOES NOT INCLUDE</b> <ul style="list-style-type: none"> <li>➤ Salary, royalties, or other remuneration received from the College;</li> <li>➤ Income from the authorship of academic or scholarly works;</li> <li>➤ Income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state, or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or</li> <li>➤ Equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control</li> </ul> </li> </ul>
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	the investment decisions made in these vehicles.
Institutional Official	The individual within the College who is responsible for the solicitation and review of disclosures of significant financial interests including those of an Investigator's family related to the Investigator's institutional responsibilities. For the purposes of this process, the Institutional Official is designated as the Vice President for Finance and Administration (VPFA) or other official appointed by the President.
Institutional responsibilities	An Investigator's responsibilities associated with his or her College appointment or position, including but not limited to research, teaching, clinical activities, administration, and institutional internal and external professional committee service.
Investigator	Any individual who is responsible for the design, conduct, or reporting of research sponsored by the federal agencies specified above or proposals for such funding that result in agency funding flowing through the College for management and distribution.
NSF	The National Science Foundation
Public Health Services or PHS	The Public Health Service of the U.S. Department of Health and Human Services and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.
Research	A systematic investigation, study, or experiment designed to contribute to generalizable knowledge, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a publishable article, book, or book chapter) and product development (e.g., a diagnostic test or drug).

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<p>Senior/key personnel</p>	<p>The Project Director or the Investigator and any other person identified by the Investigator in a grant application, progress report, or any other report submitted to the funding agency by the College as independently responsible for the design, conduct, or reporting of the research. All of the following may be considered senior/key personnel, to the extent they are independently responsible for the design, conduct, or reporting of the research: professorial faculty, research associates, emeritus faculty, subrecipient personnel, postdoctoral research associates, research collaborators, visiting scientists, and individuals with courtesy appointments, as well as undergraduate, graduate, and post-doctoral students. The term does not usually apply to departmental research administrators or research administrative professionals.</p>
<p>Significant financial interest</p>	<p>A financial interest that reasonably appears to be related to an Investigator’s institutional responsibilities, and</p> <ul style="list-style-type: none"> <li>• If a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure and the value of any equity interest during that 12-month period or as of the date of disclosure exceeds \$5,000; or</li> <li>• If with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure exceeds \$5,000; or</li> <li>• If with a non-publicly traded entity, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or</li> <li>• Is income related to intellectual property rights and interests not reimbursed through the College.</li> </ul>