

FINANCIAL CONFLICT OF INTEREST (FCOI)

Promoting Objectivity in Research for
U.S. Department of Health and Human Services (HHS)
Public Health Services (PHS)
Sponsored Funding

I. POLICY STATEMENT

D'Youville College is committed to ensuring Institutional and Investigator compliance in accordance with the U.S. Department of Health and Human Services, Public Health Service Regulations (42 CFR Parts 50 and 94) regarding the “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors.” As per the Final Rule, this regulation is commonly referred to as the Financial Conflict of Interest (FCOI) regulation.

The “Purpose” of this regulation, as stated in 42 CFR § 50.601 and §94.1, “promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded (or performed under) Public Health Service (PHS) grants or cooperative agreements (or contracts) will be free from bias resulting from Investigator financial conflicts of interest.” Defined by the regulation, this policy applies to Institutions and Investigators, that plan to apply for, participate in, or that receives research funding through a Public Health Service (PHS) Agency grant, cooperative agreement or contract. The policy provides for the procedures for Investigator’s disclosure of Significant Financial Interests, Institutional management and reporting of any identified Financial Conflicts of Interest including public accessibility, Institutional compliance with PHS Agency requirements, and Investigator training requirements. This policy becomes effective on August 24, 2012.¹

Public Health Service (PHS) Agencies to which this Policy Applies:

- Agency for Healthcare Research and Quality (AHRQ)
 - Agency for Toxic Substances and Disease Registry (ATSDR)
 - Centers for Disease Control and Prevention (CDC)
 - Food and Drug Administration (FDA)
 - Health Resources and Services Administration (HRSA)
 - Indian Health Services (IHS)
 - National Institutes of Health (NIH), including all NIH centers, institutes and programs
 - Office of the Inspector General (OIG)
 - Substance Abuse and Mental Health Services Administration (SAMHSA)
- (This regulation does not apply to Phase I Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) Programs.)

¹ PHS: 76 FR 53283-53293 (August 25, 2011)

II. KEY DEFINITIONS

For the purpose of this policy, and as stated in 42 CFR § 50.603²:

- A. **Financial conflict of interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- B. **Institutional responsibilities** means an Investigator's professional responsibilities on behalf of the Institution, which may include: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- C. **Investigator** means the project director or principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include collaborators or consultants.
- D. **Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- E. **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 to the PHS by the Institution under this subpart.
- F. **Significant Financial Interest** means:
 - (1) A financial interest consisting of one or more of the following **interests of the Investigator (and those of the Investigator's spouse and dependent children)** that reasonably appears to be related to the Investigator's institutional responsibilities:
 - (i) 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 disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes 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

² PHS: 76 FR 53283-53284 (August 25, 2011)

- ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- (ii) 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 or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - (iii) **Intellectual property rights and interests** (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (2) Investigators also must disclose the **occurrence of any reimbursed or sponsored travel** (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The disclosure of reimbursed or sponsored travel must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The designated institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.
- (3) The term *significant financial interest* **does not include the following types of financial interests**: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

III. PROCEDURES AND PROCESSES

- A. Public Accessibility:** In accordance with the Financial Conflict of Interest (FCOI) regulations, the D'Youville College FCOI policy shall be made available on a publicly accessible page via the College's Web site effective August 24, 2012. Prior to the expenditure of funds under a PHS-funded research project, the College shall make available via a publicly accessible Web page or within five business days of a written request, information concerning any identified financial conflict of interest disclosed and still held by the senior/key personnel, as defined by the regulation.
- (1) The information made available shall include: the Investigator's name, title, and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (permissible dollar ranges are: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
 - (2) The information the College posts via the publicly accessible Web page shall be updated at least annually; within sixty (60) days of a newly identified financial conflict of interest; and shall remain available for at least three years from the date that the information was most recently updated.
- B. Training Requirements:** D'Youville College shall require each Investigator on a Public Health Service (PHS) funded grant, cooperative agreement, and/or contract to complete training with respect to the applicable PHS financial conflict of interest (FCOI) regulations, the College's policy on financial conflicts of interest, and the responsibilities of Investigators to disclose significant financial interests:
- (1) Prior to engaging in any PHS-funded grant, as of and following the effective date of this policy;
 - (2) At least every four (4) years;
 - (3) Immediately, if and/or when:
 - (i) The College revises its FCOI policy in any manner that affects the requirements of Investigators;
 - (ii) An Investigator is new to the College; or
 - (iii) The College identifies that an Investigator is not in compliance with the FCOI policy or management plan.

Additionally, upon notice of award of a PHS-funded grant, cooperative agreement, and/or contract, the College shall inform the Investigator(s) of the College's FCOI policy and the responsibilities for Investigator's disclosure of significant financial interests. The College shall provide the Investigators copies of the PHS FCOI regulations, the College's FCOI policy, Disclosure of Financial Interest Forms, and access to the required training materials.

- C. Subrecipient Requirements:** Under any Public Health Service (PHS) funded grant, cooperative agreement, and/or contract, whether carried out through a subrecipient or with the College as subrecipient, D'Youville College shall ensure the incorporation of provisions, via a written agreement, establishing whether the subrecipient will follow the financial conflict of interest (FCOI) policy of the awardee Institution or the FCOI policy of the subrecipient, where applicable.
- (1) If applicable, the College shall obtain certification that the subrecipient's FCOI policy complies with the PHS FCOI regulation. In the event that certification to such cannot be provided, Investigators will be subject to the FCOI policy of the awardee Institution.
 - (2) If applicable, the written subrecipient agreement shall include the requirements for the subrecipient to report identified financial conflicts of interest for its Investigator(s) in a time frame that allows the awardee Institution to report identified financial conflicts of interest to the PHS Agency as required by the regulation.
 - (3) Alternatively, if applicable, the written agreement shall specify the time frame and requirements to solicit and review subrecipient Investigator disclosures of significant financial interests in a manner sufficient to enable the awardee Institution to identify, manage and report identified financial conflicts of interest to the PHS Awarding Component.
 - (4) Consistent with the PHS FCOI regulation, provisions for the FCOI reporting to the PHS Awarding Component, all financial conflicts of interest of all subrecipient Investigators shall be reported prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
- D. Disclosure, Review and Monitoring Requirements:** The D'Youville College President's Council, and the Vice President for Financial Affairs, are the designated institutional officials responsible for making any and all required certifications and determinations with respect to Federal regulations compliance, disclosure, review and monitoring applicable to financial conflicts of interest. The solicitation and review of disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in Public Health Service (PHS) funded research will be managed by the designated institutional official(s) as required pursuant to 42 CFR § 50.604 and § 50.605.
- (1) The College shall require each Investigator to disclose all significant financial interests (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities, pursuant to 42 CFR § 50.604(e)(1)-(3). Each Investigator must complete the College's Disclosure of Financial Interests Forms:
 - (i) No later than the time of application for PHS-funded research;
 - (ii) At least annually during the period of the award;
 - (iii) Within 30 days of discovering or acquiring any new significant financial interest
 - (2) Disclosure of the occurrence of any travel reimbursements or sponsored travel related to the Investigator's Institutional responsibilities must include the purpose of the trip, the identity of the sponsor/organizer, the destination and duration, and description of the monetary value of travel expenses upon request by the designated institutional official(s).

- (3) Disclosure of Financial Interests Forms shall be returned to the Investigator, in the event that they are not complete, and will require resubmission, as per the request and directions of the designated institutional official(s).
- (4) The designated institutional official(s) shall notify any and all Investigators who have failed to provide the annual updated Disclosure of Financial Interests Forms. Investigators shall not be permitted to engage in any PHS-funded research until the required annual updated Disclosure of Financial Interests Forms have been received and/or certified by the designated institutional official(s).
- (5) Prior to the expenditure of funds, the designated institutional official(s) shall review all Investigator disclosures of significant financial interest(s), including any Investigator who is new to participating in the PHS-funded research or for any existing Investigator who discloses a new significant financial interest. Upon review of disclosures, the designated institutional official(s) shall determine whether any Investigator's significant financial interest is related to PHS-funded research, and if so, whether the significant financial interest is a financial conflict of interest (FCOI) consistent with and pursuant to the regulation, 42 CFR § 50.603, § 50.604(f)-(h), § 50.605(a)(1)-(3) and (i)-(iii):
 - (i) An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research.
 - (ii) The designated institutional official(s) may consult with the Investigator, and other College officials and or representatives as appropriate in making determinations, including but not limited to, the Vice President for Academic Affairs, the College Controller, the College Legal Counsel, the Deans of the Colleges and/or Department Chairs, the Director of Government Grants, the Director of Sponsored Programs, the Director of Human Resources, and the Research Standards Officer.
 - (iii) When the designated institutional official(s) determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research, then a financial conflict of interest exists.
 - (iv) If a conflict of interest is determined to exist, the designated institutional official(s) shall develop and implement a management plan to manage, reduce or eliminate any financial conflicts of interest, as needed.
 - (v) In the unlikely event that the College identifies a significant financial interest that was not disclosed timely by an Investigator or not previously reviewed by the College, the designated institutional official(s) shall review, develop and implement a management plan within sixty days.
 - (vi) The College shall manage financial conflicts of interest, including any of a subrecipient Investigator pursuant to 42 CFR § 50.604(c) and (g). The designated institutional official(s) and the College shall develop and implement a management plan as needed and, if necessary, a retrospective review and mitigation report pursuant to 42 CFR § 50.605(a).

(vii) The College shall provide initial and ongoing FCOI reports to the PHS as required pursuant to 42 CFR § 50.605(b).

- E. **Maintenance of Records:** The College's Office of Financial Affairs and responsible parties shall maintain all compliance documentation and records, including but not limited to, disclosures of financial interests, the College's review, correspondence, determinations and actions, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations, pursuant to 42 CFR § 50.604(i).
- F. **Management and Reporting Requirements:** In accordance with 42 CFR § 50.605(a)-(b), the D'Youville College designated institutional official(s) shall review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest prior to the College's expenditure of any funds under a PHS-funded research project.
- (1) The management plan shall be developed and implemented with the intention to manage, reduce, or eliminate identified financial conflicts of interest. Conditions or restrictions that might be imposed to manage a financial conflict of interest might include, but not necessarily be limited to, the following:
- (i) Public disclosure of financial conflicts of interest when presenting or publishing the research, on the College's Web site, and in other locations or venues as necessary;
 - (ii) Disclosure of financial conflicts of interest directly to participants for research projects involving human subjects research, as part of informed consents or otherwise;
 - (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
 - (iv) Modification of the research plan;
 - (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - (vi) Reduction or elimination of the significant financial interest; or
 - (vii) Severance of relationships that create financial conflicts.
- (2) Whenever the College identifies, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest, or whenever the College identifies a significant financial interest that was not disclosed timely by an Investigator, or was not previously reviewed by the College during an on-going PHS-funded research project, the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and if so:

- (i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
 - (ii) The College may determine that additional measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the review, depending on the nature of the significant financial interest.
- (3) The College and the designated institutional official(s) shall review the proposed management plan and shall, within sixty days of Investigator(s) submission of the D'Youville College Disclosure of Financial Interests Forms, approve a management plan and communicate the approved management plan to any and all affected Investigators. After the development and approval of the management plan, the College may require, though not necessarily in all cases, that affected Investigators shall cease participation in all, or in a portion thereof, the PHS-funded research project.
- (4) Pursuant to 42 CFR § 50.605 (a)(4), whenever the College implements a management plan, the College shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.
- (5) Additionally, whenever a financial conflict of interest is not identified or managed in a timely manner, including Investigator failure to disclose a significant financial interest that is determined to be a financial conflict of interest; failure by the College to review or manage such a conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the College shall within 120 days of determination of the noncompliance, complete a retrospective review and mitigation report in accordance with 42 CFR § 50.605(a)(3)(ii)-(iii).
- (6) In accordance with and pursuant to 42 CFR § 50.605(b)(1)-(4): Prior to the College's expenditure of any funds under a PHS-funded research project, the College shall provide the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found to be conflicting, and the College shall ensure that a management plan has been implemented in accordance with the PHS FCOI reporting regulations. The College shall not be required to submit an FCOI report to the PHS Awarding Component in cases in which the College identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, pursuant to 42 CFR § 50.605(b)(1). Subsequent to the initial FCOI report, the College shall provide the PHS Awarding Component, within sixty days, an updated FCOI report, pursuant to 42 CFR § 50.605(b)(2). The College shall ensure that any FCOI report required under this section shall include sufficient information and the necessary elements to enable the PHS Awarding Component to understand the nature and extent of the financial conflict of interest and assess the management plan, pursuant to 42 CFR § 50.605(b)(3). Additionally, the College shall provide to the PHS Awarding Component an annual FCOI report for any financial conflict of interest previously reported by the College with regard to an ongoing PHS-funded research project for the duration of the project period (including extensions with or without funds) in the

time and manner specified by the PHS Awarding Component and in accordance with and pursuant to 42 CFR § 50.605(b)(4).

- G. Enforcement Mechanisms and Remedies:** The College, President's Council, and the Vice President for Financial Affairs shall have the authority to suspend or to terminate any and all research, educational, or service activities under any and all PHS-funded grants, cooperative agreements, or contracts individually or together, to the extent the College, President's Council and/or the Vice President for Financial Affairs determines that such action is necessary to ensure compliance by Investigators with the requirements of the D'Youville College Financial Conflicts of Interest (FCOI) policy, and any and all applicable Federal regulations.

An Investigator's failure to comply with the D'Youville College FCOI policy, including but not necessarily limited to, failure to file timely and complete Disclosure of Financial Interests Forms, or failure to comply with any conditions or restrictions imposed in any management plan shall constitute grounds for disciplinary action by the College, up to and including termination of employment.

Pursuant to 42 CFR § 50.606 (a)-(c):

The College shall promptly notify the PHS Awarding Component of corrective action taken or to be taken, if an Investigator's failure to comply with the College's FCOI policy or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research. The College shall fully comply with the PHS Awarding Component and/or U.S. Department of Health and Human Services' (HHS) determinations, conditions, corrective actions, remedies, and/or requirements as necessary until the matter is resolved.

In any case in which the HHS determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an Investigator with a financial conflict of interest that was not managed or reported by the College as required by the regulation, the College shall require the Investigator(s) involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

- H. Additional HHS Regulations:** Please refer to 42 CFR § 50.607 for the other HHS regulations and policies that apply to this regulation.