



DISCLOSURE & DESCRIPTION OF FINANCIAL INTERESTS

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

D'Youville College Financial Conflict of Interest (FCOI) Policy¹ Summary & Requirements

D'Youville College is committed to ensuring Institutional and Investigator* compliance in promoting objectivity in research in accordance with the new PHS 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.” The regulation applies to Institutions and Investigators, that plan to apply for, participate in, or that receives research funding through any of the PHS Agencies².

The D'Youville College Financial Conflict of Interest (FCOI) Policy requires each PHS-funded 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 the PHS-FCOI regulation. Each PHS-funded Investigator must complete the Disclosure & Description of Financial Interests Forms:

- No later than the time of application for PHS-funded research;
- At least annually during the period of the award;
- Within 30 days of discovering or acquiring any new significant financial interest(s).

The Disclosure & Description of Financial Interests Forms requires each PHS-funded Investigator to disclose, and, when necessary, describe whether any one or more of the following interests of the Investigator (and those of their spouse and dependent children) reasonably appears to be related to the Investigator’s Institutional Responsibilities:

- Publicly Traded Entity Interests
- Non-Publicly Traded Entity Interests
- Intellectual Property Rights and Interests
- Reimbursements and Sponsored Travel Occurrences

The completed Disclosure & Description of Financial Interests Forms, and any additional or supporting information, should be submitted to the Financial Affairs Office, KAB, Room 106 in a sealed envelope, marked CONFIDENTIAL.

Additionally the PHS-FCOI Regulations and DYC FCOI Policy require that any PHS-funded research, which involves human subjects, must also comply with the College’s IRB Policy requirements.

¹ The DYC FCOI Policy for PHS Sponsored Funding can be found via the Research page at www.dyc.edu, effective August, 24, 2012.

² The PHS Agencies to which the FCOI regulation applies can be found on page one of the DYC FCOI Policy.

*Terms are defined on page 4 of the Disclosure & Description of Financial Interest Forms, and in the DYC FCOI Policy, under Key Definitions.



DISCLOSURE OF FINANCIAL INTERESTS FORM

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

Investigator's Name: _____

Department: _____ Position: _____

PHS- Sponsor/Agency: _____

Project Title: _____

Position on Project: _____

Project Beginning Date: _____ Project End Date: _____

Significant Financial Interests

1. Entity/Organizational Interests:

Do you, your spouse or, any of your dependent children, to the best of your knowledge, hold any position as an employee, independent contractor, or consultant; director, trustee, partner, or officer with any company or organization that currently does or seeks to do business with D'Youville College, its subsidiaries and affiliates; or have any such positions been held in the last 12 months? Yes No

Please refer to the Instructions and Definitions for "Significant Financial Interests" as detailed on page 4:
With regards to the following:

- 2. Publicly Traded Entity Remuneration/Equity Interests: Yes No
- 3. Non-Publicly Traded Entity Remuneration/Equity Interest: Yes No
- 4. Intellectual Property Rights & Interests: Yes No
- 5. Reimbursements and Sponsored Travel Occurrences: Yes No

If you answered **No** to **Interests 1-5** above, your disclosure is complete. Please sign and date the certification below and forward this document to the Financial Affairs Office, KAB, Room 106.

If you answered **Yes** to any of the **Interests** above, please sign and date this document, and then complete a separate Description of Financial Interests Form for **each** Significant Financial Interest as applicable. Forward these and any additional documents to the Financial Affairs Office, KAB, Room 106 immediately upon completion.

Investigator Certification:

- I certify that the information that I have provided in the Disclosure & Description of Financial Interests Forms, is true and complete to the best of my knowledge.
- I understand, and agree to fully comply with, the PHS-FCOI Regulation and DYC FCOI Policy as stated.

Investigator Name (please type or print): _____

Investigator Signature: _____ Date: _____

Designated Institutional Official: _____ Date: _____

Signature



DESCRIPTION OF FINANCIAL INTERESTS FORM

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

Investigator's Name: _____

Entity/Organizational Interests:

Name of Entity: _____

Financial relationship(s) with the entity/organization (check all that apply):

- Consultant Employee Equity Interest Recipient of Honoraria Recipient of Royalties
- Other (describe) _____

Financial relationship(s) is between the entity/organization and (check all that apply):

- Self Spouse Dependent Child(ren)

Describe the relationship, if any, between the business, activities or services of the entity/organization and your current Institutional Responsibilities (if necessary, please attach additional documentation/ information):

Provide the dollar value of the financial interests in this entity/organization as applicable:

Publicly Traded Entity Remuneration/Equity Interests: Yes No N/A

- \$0-\$4,999 \$20,000-\$39,000 \$80,000-\$99,999 Greater than \$200,000
- \$5,000-\$9,999 \$40,000-\$59,999 \$100,000-\$150,000 (specify amount) \$ _____
- \$10,000-\$19,999 \$60,000-\$79,000 \$150,000-\$199,999

Describe as necessary: _____

Non-Publicly Traded Entity Remuneration/Equity Interests: Yes No N/A

- \$0-\$4,999 \$20,000-\$39,000 \$80,000-\$99,999 Greater than \$200,000
- \$5,000-\$9,999 \$40,000-\$59,999 \$100,000-\$150,000 (specify amount) \$ _____
- \$10,000-\$19,999 \$60,000-\$79,000 \$150,000-\$199,999

Describe as necessary: _____

Intellectual Property Rights & Interests: Yes No N/A

Describe as necessary: _____

Reimbursements and Sponsored Travel Occurrences: Yes No N/A

Describe the Purpose of the Trip: _____

Sponsor/Organizer Name: _____

Destination and Duration: _____

Monetary Value (if known): _____

Investigator Signature: _____ Date: _____

Designated Institutional Official: _____ Date: _____

Signature

D'Youville

PUBLIC HEALTH SERVICE (PHS)-FCOI

Definitions per 42 CFR § 50.603³

“**Institutional Responsibilities**” are 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.

“**Investigators**” include the 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 funded by the PHS, or proposed for such funding, which may include collaborators or consultants.

“**Significant Financial Interest**”

1. A financial interest consisting of one or more of the following **interests of the Investigator (and those of the Investigator's spouse/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 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.

³ PHS: 76 FR 53283-53284 (August 25, 2011)