

Conflict of Interest in Research Policy Promoting Objectivity in Research

Policy/Procedure

PURPOSE:

The purpose of this policy is to protect the credibility and integrity of the College's faculty and staff and to ensure public trust and confidence in the College's research and educational activities. These policies and procedures are designed to meet the requirements of Federal regulations covering conflicts of interest (42 CFR Part 50 Subpart F for grants and cooperative agreements and 45 CFR Part 94 for contracts). Dickinson College has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may arise because of the financial interests of an Investigator.

DEFINITIONS:

- A **conflict of interest exists** when the College determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the research sponsored by federal sources, or the conduct of the Investigator's institutional responsibilities. (42 CFR 50.605).
- **Investigator** means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the federal sources, or proposed for such funding. **Investigator** includes the Investigator's spouse and dependent children. (42 CFR 50.603).
- **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge. (42 CFR 50.603).
- **Significant Financial Interest (SFI)** means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests in publicly-traded or non-publicly traded entities); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:
 - Salary, royalties, or other remuneration from Dickinson College.
 - Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
 - Income from service on advisory committees or review panels for public or nonprofit entities;
 - Payments for services or equity interests received from a publicly traded entity, if the aggregate value received by the Investigator (including the Investigator's spouse and dependent children) in the preceding twelve months does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value; or
 - Payments for services received from a non-publicly traded entity, if the aggregate value received by the Investigator (including the Investigator's spouse and dependent children) in the preceding twelve months does not exceed \$5,000. NOTE: Any equity interest in a non-publicly traded company constitutes a **Significant financial interest**.

- 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.
- **Sponsored Travel** means any reimbursed or sponsored travel, (i.e. travel that is paid on behalf of the Investigator, including the Investigator's spouse and dependent children), and that relates to the Investigator's Institutional Responsibilities, in the preceding twelve months when aggregated with other significant financial interests, per entity, is greater than or equal to \$5,000 in value. This definition does not include travel that is paid for or reimbursed 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.
- **Institutional Responsibilities** means teaching, research, research consultation, and institutional committee memberships.

TRAINING:

1. Dickinson College Investigators must complete conflict of interest training prior to engaging in research related to any Federally-funded grant or contract and at least every four years, and immediately under the designated circumstances:
 - College conflict of interest policies change in a manner that affects Investigator requirements
 - an Investigator is new to the College, or
 - the College finds an Investigator noncompliant with College's conflict of interest policy or management plan.
2. To meet the training requirement, Investigators must review this policy and complete successfully the Conflict of Interest mini-course, a web-based curriculum provided by the Collaborative Institutional Training Initiative (CITI).
3. Dickinson College will notify each proposed Investigator seeking Federal funding of this policy, the investigator's disclosure responsibilities and the Federal regulation.

DISCLOSURE:

Disclosure of both perceived and actual conflict of interest protects one's reputation from embarrassing or harmful allegations of misconduct. A faculty or staff member may choose to disclose *any* financial or related interest, beyond those required by regulation or this policy that could present an actual or perceived conflict of interest.

1. Each Investigator shall complete a Financial Interests Disclosure Form. The completed disclosure form must be submitted to the Associate Provost's office along with a copy of the proposal for review.
2. All significant financial interests (SFI) must be disclosed prior to the time a proposal is submitted as required by Federal regulation. All financial disclosures must be updated by Investigators during the period of the award, annually and within thirty days of when a Significant Financial Interest or Sponsored Travel occurs or is discovered.

3. Each Investigator is required to disclose the following significant (greater than or equal to \$5,000, when aggregated per entity) financial interests:
 - a) Any significant financial interest of the Investigator that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor, including provision of Sponsored travel; or
 - b) Any significant financial interest of the Investigator in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.
- The College will determine if Sponsored travel requires further investigation.

REVIEW PROCESS:

1. Prior to submitting a proposal that involves a Significant financial interest, including Sponsored travel, the Investigator should discuss with appropriate College officials proposed measures that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by a significant financial interest. Such measures could include:
 - a) Public disclosure of significant financial interests;
 - b) Review of research protocol by independent reviewers; and
 - c) Monitoring of research by independent reviewers.
2. The Associate Provost or official designee, with the assistance, if necessary, of appropriate members from Financial Operations, shall review all financial disclosures to determine whether a conflict of interest exists. If the Associate Provost for Institutional Resources determines that there is a potential for conflict of interest covered by this policy, then the Associate Provost may impose additional conditions or restrictions other than those listed in #1 above, including the following:
 - a) Modification of the research plan;
 - b) Disqualification from participation in all or a portion of the research funded;
 - c) Divestiture of significant financial interests; or
 - d) Severance of relationships that create actual or potential conflicts.The Associate Provost may require that a plan for reducing or eliminating conflicts of interest be incorporated into a Memo of Understanding between the College and the Investigator.
3. The Associate Provost will notify the Provost and Dean of the College of the conditions or restrictions to be imposed. If the Provost determines that imposing the conditions or restrictions would be ineffective or inequitable, or that the detrimental effects that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Provost may decide that, to the extent permitted by Federal regulations, the research go forward without imposing such conditions or restrictions. In these cases, the Provost shall make the final decision regarding resolution.

MANAGING CONFLICTS OF INTEREST:

Actual or potential conflicts of interest will be satisfactorily managed, reduced, or eliminated in accordance with these guidelines and all required reports regarding the conflict of interest submitted to the sponsor prior to expenditure of any funds under an award.

Where any conflicts of interest exist with regard to a federally-funded research project, the College will develop and implement a management plan that specifies the actions taken, and/or to be taken to manage the conflict of interest, and the College will make any reports or disclosures of the conflict of interest that are required or that the College deems to be appropriate.

VIOLATIONS OF CONFLICT OF INTEREST POLICY:

Whenever an Investigator has violated this policy or the terms of any resolution plan required by the Associate Provost (including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms), the Associate Provost shall notify the Provost, who, in consultation with the Faculty Personnel Committee, will impose sanctions or institute disciplinary proceedings against the Investigator.

In addition, the College shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to 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.

ENFORCEMENT MECHANISMS AND REMEDIES AND NONCOMPLIANCE SPECIFIC TO NIH.

1. The College shall complete and document retrospective reviews within 120 days of the Institution's determination of noncompliance for SFIs: a) not disclosed timely or b) not previously reviewed or c) whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation. 42 CFR 50.605(a)(3)
2. The College shall ensure that in any case in which the Department of Health and Human Services 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 an FCOI that was not managed or reported by the Institution as required by the regulation, the College shall require the Investigator involved to:
 - Disclose the FCOI in each public presentation of the results of the research, and
 - To request an addendum to previously published presentations.

REPORTING REQUIREMENTS SPECIFIC TO NIH

1. The Associate Provost or her/his designee shall send initial, annual and revised FCOI reports including all reporting elements required by the regulation, to the NIH for the Institution and its subrecipients, if applicable, as required by the regulations in 42 CFR 50.604(h) and/or 42 CFR 50.605(b). This shall be performed:

- Prior to the expenditure of funds
 - Within 60 days of identification for an Investigator who is newly participating in the project
 - Within 60 days for new, or newly identified, FCOIs for existing Investigators
 - At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
 - Following a retrospective review to update a previously submitted report, if appropriate. 42 CFR 50.605(a)(3)(iii)
2. The Associate Provost or her/his designee shall notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and include the requirement to submit a Mitigation Report in accordance with the regulation.
- This notification will include all reporting elements as required by the regulation.
3. The Associate Provost or her/his designee shall notify NIH promptly if an investigator fails to comply with the Institution's FCOI policy or if an FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research. 42 CFR 50.606(a).
- This policy confirms the Institution's requirement to notify NIH promptly and take corrective action for non-compliance with the Institution's policy or the management plan.

RECORD MAINTENANCE:

Records of Investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by the Corporate, Foundation and Government Support office until three years after the later of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

COLLABORATIVE PROJECTS/SUB-AGREEMENTS:

Collaborators/sub-recipients/subcontractors from other organizations must either comply with this policy or provide a certification or written agreement that their organizations are in compliance with Federal policies regarding Investigator significant financial interest disclosure and that their portion of the project is in compliance with their institutional policies.

If applicable, Collaborators/sub-recipients/subcontractors from other organizations include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee Institution to identify, manage and report identified FCOIs to the NIH.

PUBLIC ACCESSIBILITY REQUIREMENTS

1. The College will make this FCOI publicly accessible on the following website: https://www.dickinson.edu/info/20276/corporate_foundation_and_government_support/1932/sponsored_projects_office_spo. 42 CFR 50.604(a) and NIH GPS 4.1.10

2. The College will make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), publicly accessible prior to the expenditure of funds. The information will:

- Include the minimum elements as provided in the regulation
- Be posted on a Public Website or made available within 5 calendar days of a written request
- Be updated, at least annually (Web site only but any response to a written request should include the updated information)
- Be updated, within 60 days of a newly identified FCOI (Web site only but any response to a written request should include the updated information)
- Remain available for three years from the date the information was most recently updated.

Related Information

History/Revision Information

Responsible Division/Office: Academic Affairs, Sponsored Projects Group

Effective Date: February 8, 2006

Last Amended Date: 10/27/2020

Next Review Date: 10/27/2023

Also Found In: