

**University Policy Number 1000.1:  
FEDERAL FINANCIAL CONFLICT OF INTEREST**

**Responsible Administrator:** Provost – the Chief Academic Officer

**Responsible Office:** Sponsored Programs

**Authority:** Office of the President

**Policy Statement**

It is the policy of Claflin University to ensure compliance with federal guidelines regarding financial conflict of interest.

**Statement of Purpose**

This statement of purpose establishes guidelines for that part of ethical research conduct at Claflin University (CU) which deals with potential or actual financial conflicts of interests (FCOIs) in research (see definitions, page 2). It is the intent and policy of CU, as an institution of higher education in receipt of federal research support, to comply with present and future regulations, and to that end, this policy is subject to further refinements as other rules are established and published. All investigators are required to comply with the University policy and federal regulations on financial conflict of interest in research that promote objectivity in research. All CU faculty and professional staff must read, sign, and submit the CU Federal Financial Disclosure form (see Appendix I).

Ultimately, the intent is to identify, eliminate, and manage possible threats to research at CU. It is not meant to discourage, but rather to safeguard the pursuit and dissemination of knowledge. Every effort will be made to determine whether or not a situation involves a conflict of interest and if so, to suggest reasonable and realistic alternatives to managing the conflict. This CU FCOI policy will be an up-to-date and enforced policy on financial conflicts of interest that complies with federal regulation and available via a CU publicly accessible Website ([www.claflin.edu](http://www.claflin.edu)).

A FCOI occurs when there is a relationship between an investigator's private interests and professional obligations such that an independent observer might reasonably question whether the investigator's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual FCOI depends on the situation and not on the character or actions of the investigator. This policy seeks to maintain a reasonable balance between competing interests and gives the University the ability to identify and manage FCOIs that may bias the research.

## DEFINITIONS

*Financial Conflict of Interest (FCOI)* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

*Significant Financial Interest (SFI)* mean a significant financial interest (SFI) is defined as a financial interest consisting of one or more of the following interests of the Investigator (or those of his/her spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities. An SFI exists as defined in the following scenarios:

- Publicly traded entity: If the value of any remuneration received from the entity in the 12 months preceding the disclosure \_ the value of any equity interest<sup>2</sup> in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. This includes:
  - Salary
  - Any payment for services not otherwise identified as salary
  - Consulting fees
  - Honoraria
  - Paid authorship
  - Equity interest (e.g., stock, stock option, or other ownership interest)
- Non-publicly traded entity: If the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated exceeds \$5,000, **or** when the Investigator holds **any** equity interest
- Intellectual property rights and interests **upon receipt of income** related to such rights and interests
  - Patents
  - Copyrights
- Reimbursed or Sponsored Travel: 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 Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the 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.

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 University, including intellectual property rights assigned to the University 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.
- 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

*Immediate family member* means a close relative, such as a dependent parent/step-parent, spouse, dependent child/step-child and members of an ‘employee’s family, spouse or anyone living in the same household as the employee whether or not a relative.

*Passive investment interest* is defined as a purely financial involvement in an organization for which the employee performs no managerial functions, provides no advice and has no ability to influence the policies, products or business of the outside organization.

*Investigator* means the project director (PD), principal investigator (PI), co-principal investigators, sub-recipients, collaborators, or consultants, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by a federal agency.

*Conflict Management Plan (CMP)* means a detailed plan to address a determined FCOI which can include reducing or eliminating the FCOI to ensure that the design, conduct, and reporting of the research will be free of bias.

*Business courtesy* means a gift or favor from persons or firms with whom CU maintains or could reasonably establish a business relationship and for which fair market value is not paid by the recipient. A business courtesy may be a tangible or intangible benefit, including, but not limited to, such items as nonmonetary gifts, meals, drinks, entertainment, hospitality, recreation, door prizes, transportation discounts, tickets, passes, promotional items, or use of a donor’s time, materials or equipment.

*Mitigation plan* means a detailed plan to address any bias found by a retrospective FCOI review and limit the impact and severity of any discovered bias.

## **APPLICABILITY**

### **A. Scope**

This policy applies to all faculty and staff at CU conducting projects or submitting proposals for:

- federally funded research
- federally funded research-training,
- federally funded research-related grant, contract, or cooperative agreement, and/or
- research funded by non-federal sponsors that have adopted the Public Health Services (PHS) or the NSF FCOI policy.

### **B. Eligibility**

1. This policy is applicable to any faculty, administrative or professional staff member of CU who is an investigator responsible for the design, conduct, or reporting of research activities in projects: (a) funded by NSF, PHS, or other federal agencies that require compliance with the PHS or NSF FCOI policies, or non-federal sponsors who have adopted PHS or NSF FCOI in research policy in research regulations with Notice of Award issue date on, or subsequent to, the effective date; or (b) proposed for funding by NSF, PHS, other federal agencies, or non-federal sponsors in applications submitted on or after the effective date. The policy also applies to the investigator's "immediate family" (See definitions, page 2).
2. Sub-recipients, off-campus collaborators, subcontractors, and visiting scientists must either: agree in writing to compliance with this policy; or provide a written certification to the Office of Human Resources that their institutions are in compliance with pertinent federal policies and that they in turn are in compliance with their own institutional policies prior to submission of the proposal.

### **C. Responsibilities**

- All investigators who are responsible for the design, conduct, or reporting of the research in a proposed or active federally funded research project, must disclose any Significant Financial Interest (SFI) (See definitions, page 2) that might benefit from that research.
- The Office of Sponsored Programs will maintain CITI training and retraining.

- The FCOI will be filed and maintained in the Office of Human Resources for bi-yearly review by the Financial Conflict of Interest Committee, see details regarding the Committee below.
- Individuals, who come to work on an established project through reallocation of effort, hiring, transfer, promotion, etc., and thereby take on a responsible position in a project, must also disclose any such SFIs.
- The University will make this FCOI Policy available to any applicable funding agency to whom a funding proposal is made within 5 business days upon written request.

### **Financial Conflict of Interest Committee (FCOIC)**

This committee is charged with protecting the integrity of federally sponsored research at CU by determining whether SFIs disclosed by investigators could reasonably be expected to affect the design, schedule, conduct, or reporting of the activities funded or proposed for funding, and, if so, whether the SFI represents a FCOI. They will also determine what conditions or restrictions, if any, should be imposed by CU to manage, reduce, or eliminate the FCOI.

The committee will also investigate alleged violations of this policy, and make recommendations for action to the Provost Office. Breaches of policy include, but are not limited to, failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous or misleading disclosure forms; or failure to comply with procedures prescribed by this policy.

The FCOIC will be a standing committee in the Provost Office that will meet twice per year and as needed. The committee will consist of the Vice President for Fiscal Affairs (chair), the Vice President of Institutional Advancement, the Associate Vice Provost for Research, Dean of the pertinent school, a faculty member, and a staff member. When a proposed project deals with human subjects and/or vertebrate animal welfare the chair of the University Institutional Review Board (IRB) will be an ex officio member.

## **GUIDELINES AND STANDARDS**

### **Compliance**

In response to federal regulations codified at 42 CFR 50.601 et. seq. (1), CU hereby establishes standards and procedures to be followed by investigators applying for both federal and non-federal funding to ensure that the design, conduct, reporting of such research or related educational activities, cooperative agreements, or contracts, will not be biased by any conflicting SFI.

Department of Health and Human Services. Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought. 42 CFR 50 Subpart F (revised August 25, 2011).

PHS and NSF policies are substantially the same regarding conflicts of interest (PHS, 1995; NSF, 1995). Under PHS policy: "...investigators are required to disclose to an official(s) designated by the institution a listing of Significant Financial Interests ... that would reasonably appear to be affected by the research proposed for funding by the PHS." The institutional official(s) are responsible to review "those disclosures and determine whether any of the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research and, if so, the institution must, prior to any expenditure of awarded funds, report the existence of such conflicting interests to the PHS Awarding Component and act to protect PHS-funded research from bias due to the conflict of interest."

The details of PHS/NSF FCOI requirements can be found at 60 Fed. Reg. 35820 of July 1995 and Notices No. 118 of July 1995 respectively. CFR-2007-title45-vol1-sec94-4 is also pertinent.

## **Procedures**

### **1. Disclosure Process**

a. Each investigator responsible for the design, conduct, or reporting of research activities funded or proposed for federal funding must disclose any SFIs and those of a spouse or domestic partner and dependent children related to research responsibilities no later than the time of application by CU. Such disclosure will be made on the CU Federal Financial Conflict Disclosure Form (See Appendix I) including all required supporting documentation prior to submission of the proposal. The form and supporting documentation should be submitted in a sealed envelope marked confidential to the Provost and Associate Vice Provost for Research. If the disclosure statement indicates involvement of human subjects or vertebrate animals in the research, the Associate Vice Provost for Research will notify the chairperson of the CU Institutional Review Board (IRB) so the situation may be considered, and if appropriate, addressed, by the IRB.

b. If CU determines that a FCOI exists, the University shall request that the investigator submit a proposed conflict management plan that details steps that could be taken to manage, reduce, or eliminate the FCOI. Resolution of the conflict or establishment of an acceptable conflict management plan must be achieved before any federal funds awarded are spent.

c. Each investigator who is participating in federally or non-federally funded research must submit to the Provost and Associate Vice Provost for Research an updated disclosure of SFIs annually (fiscal year July 1 – June 30) during the period of the award and within thirty (30) days of acquiring a new SFI. Such disclosure shall include any information that was not disclosed initially or in a subsequent disclosure of SFIs (e.g., any FCOI identified on a federally or non-federally funded project that was transferred from another institution), and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

d. Each investigator who is participating in federally or non-federally funded research must submit an updated disclosure of SFIs within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

e. All disclosure statements and related documents will be treated as confidential and will not be disclosed outside the FCOIC, Provost, or Sponsored Programs Office staff without the investigator's consent except in response to a request from a funding agency, or pursuant to a judicial order or lawfully issued subpoena. CU will make reasonable efforts to notify the investigator of any judicial order or lawfully issued subpoena in advance of disclosure of this information, unless the order is from a federal grand jury or is for law enforcement purposes and its terms prohibit CU from disclosing its existence or contents.

## 2. Review of Disclosure Process

a. Prior to expenditure of any funds under a federally or non-federally funded research project, the Associate Vice Provost for Research shall review all pertinent SFI disclosure statements and accompanying documentation, and shall determine whether an investigator's SFI is related to the federally or non-federally funded research and, if so related, whether the SFI represents a FCOI. An investigator's SFI is related to the federally or non-federally funded research when the SFI could affect the federally or non-federally funded research, or is in an entity whose financial interest could be affected by the research. (The University may involve the investigator in its determination of whether a SFI is related to federally or non-federally funded research.) A FCOI will be considered to exist when CU reasonably determines that the SFI could

directly and significantly affect the design, conduct, or reporting of the federally or non-federally funded research.

b. If a FCOI is deemed to exist, CU shall request that the investigator submit a proposed conflict management plan (CMP) that details steps that will be taken to manage, reduce, or eliminate the FCOI. The University shall review the proposed CMP and approve it or add conditions or restrictions to ensure that any conflict is effectively managed, reduced, or even eliminated. Such conditions or restrictions may include, but are not limited to, the following:

- Public disclosure of the FCOI (e.g., when presenting or publishing the research);
- Monitoring of the research by independent reviewers;
- Modification of the planned activities (possibly subject to federal sponsor approval);
- Disqualification from participation in all or part of the project;
- Divestiture of the significant financial interests;
- Severance of relationships creating the conflict;
- For research involving human subjects, disclosure of financial conflicts of interest directly related to the research subjects.

In all cases, resolution of the conflict or establishment of an acceptable CMP must be achieved before expenditure of any federal funds awarded. The University will make all FCOIs deemed to exist available to any federal and non-federal agency to which a funding proposal is made within 5 business days upon written request.

c. When an investigator who is new to participation in a federally or non-federally funded research project discloses a SFI or an existing investigator discloses a new SFI to CU, the University shall:

- review the disclosure of the SFI within thirty (30) days;
- determine whether it is related to the research;
- determine whether a FCOI exists; and, if so,
- implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage the FCOI.

d. Depending on the nature of the SFI, CU may determine that additional interim measures are necessary with regard to the investigator's participation in the federally or non-federally funded research project between the date of disclosure and the completion of its review.



CU will initially report the FCOIs to the pertinent sponsoring agency prior to expenditure of funds. CU shall also report FCOIs from a new investigator or any revised FCOIs within thirty (30) days. Reports on all FCOIs, including any CMP changes, will be submitted annually with a project's annual progress report until the completion of the project.

e. Whenever a SFI is identified that was not disclosed in a timely manner by an investigator or, for whatever reason was not previously reviewed by CU during an ongoing federally or non-federally funded research project, CU shall:

- review the SFI within thirty (30) days;
- determine whether it is related to the research;
- determine whether a FCOI exists; and, if so
- implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.

#### Retrospective reviews

a. Whenever a FCOI is not identified or managed in a timely manner (including failure by an investigator to disclose a SFI that is determined by CU to constitute a FCOI; or failure by CU to review or manage such a FCOI; or failure by the investigator to comply with a FCOI management plan within thirty 30 days of the determination of noncompliance), CU shall complete a retrospective review of the investigator's activities related to the federally funded research project within 120 days to determine whether research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.

b. CU's documentation of such a retrospective review should include, but not necessarily be limited to, the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the investigator with the FCOI;
- Name of the entity with which the investigator has a FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of any review panel, and documents reviewed);

- Findings of the review; and
- Conclusions of the review.

c. Based on the results of the retrospective review CU shall update the previously submitted FCOI report, if appropriate, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, CU shall notify the awarding agency promptly and submit a mitigation report and plan. The mitigation plan must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project, and CU's plan of action taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project, extent of harm done including any qualitative and/or quantitative data to support any claim of actual or future harm) and whether the research project is salvageable.

d. Thereafter, CU will submit FCOI reports on this specific grant annually. Depending on the nature of the FCI, CU may determine that additional interim measures are necessary with regard to the investigator's participation in the research project between the date that the FCOI or the investigator's noncompliance is determined and the completion of CU's retrospective review.

e. In any case in which the HHS determines that a PHS-funded 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 conflicting interest that was not disclosed or managed as required, the investigator(s) involved are required to disclose the conflicting interest in each public presentation of the results of the research and publish an addendum to all pertinent presentations and publications.

#### Disclosure Review Results Appeals Process

If an investigator disagrees with the final decision about conditions or restrictions, the investigator can appeal in writing to the Provost Office within ten (10) working days after receipt of the notification. The appeal should detail why such conditions and/or restrictions are inappropriate. The Associate Vice Provost for Research will consult with the investigator and the FCOIC and make a recommendation to the President or the President's designee for final determination.

#### Training of Investigators in Financial Conflict of Interest

Investigators must receive training from the University programs, the CITI Program, related to research-related FCOI prior to engaging in research at the University and at least every four years thereafter. In addition to reading of the various federal guidelines, such training on FCOI is one of nine segments of training in the “Responsible Conduct of Research” (RCR) required by federal agencies.

In addition, investigators must again receive training within thirty (30) days under the following circumstances:

- if CU revises its policy on FCOI in research for federally or non-federally funded projects or procedures related to this policy in any manner that affects the requirements of investigators;
- the investigator is new to CU; or
- CU finds that an investigator is not in compliance with this policy.

#### Records of Disclosure and Reviews

The Sponsored Programs Office will maintain records of all disclosures and associated activities securely and confidentially. All records will be maintained for three years following termination or completion of the project or resolution of any government action involving the records as detailed in 42 CFR 50.604, 605 48 CFR part 4, subpart 4.7, 45 CFR 74.53, 45 CFR 92.42, 45 CFR Part 94 and NSF AAG Chapter IV. A where applicable.

FCOI records will not be routinely provided to sponsoring agencies unless such is an agency requirement, the agency submits a written request, or CU is unable to satisfactorily manage an actual or potential conflict of interest. The Associate Vice Provost for Research will be responsible for communications with sponsoring agencies.

#### **EXPECTED RESULTS**

Establishment of this policy will comply with federal regulations and requirements relevant to proposals for federal or non-federal funding for various research projects and allow subsequent funding if granted.

Each investigator responsible for the design, conduct, or reporting of research activities proposed for federal funding shall be deemed to have accepted and agreed to this FCOI Policy and the procedures herein and must confirm receipt of a copy of this policy by signature on the attached signature page.

The Sponsored Programs Office considers violation of these rules of conduct a serious

matter and sanctions may be imposed including, but not limited to, notification of sponsor; formal warning via a letter to the investigator's grant file with a copy of the letter sent to the appropriate Dean. The FCOIC will review the violation and, based on the severity of the violation, make recommendations for disciplinary action to the President for final decision.

#### **REGULATORY COMPLIANCE**

This policy complies with federal regulations and requirements relevant to proposals for federal or non-federal funding for various research projects and allow subsequent funding if granted.