3.3.15.1 – Policy on Financial Conflict of Interest in Externally-Funded Research

I. Statement of Policy

This Financial Conflict of Interest Policy is designed to protect the integrity and credibility of faculty and staff in the University’s research, teaching, education and public service activities. In accordance with Federal regulations, the University has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator. Financial Conflict of Interest (FCOI) means a Significant Financial Interest that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of U.S Public Health Service (PHS) funded research, which includes the National Institutes of Health (NIH) and all government-sponsored grants.

The University requires that investigators disclose any significant financial interest that may present an actual or potential conflict of interest in relationship with a sponsored project. The University also requires disclosure of any family relationships between investigators and persons working with them on sponsored projects. The policy applies to all Investigators at Stetson University who apply to or receive external research support; therefore, the policy requires that Investigators disclose any significant financial interest that may reasonably appear to be affected by sponsored projects.

The Department of Health and Human Services amended its regulations related to financial disclosure on 8/25/2011. All institutions applying for U.S. Public Health Service (PHS) funding for research are required to have a policy that complies with these amended regulations; this PHS/NIH Financial Conflict of Interest Policy is designed to comply with the federal regulations and hereby incorporates by reference 42 CFR, Part 0, Subpart F.

II. Applicability of Policy

This policy is the basis for specific certifications that the National Science Foundation (NSF), the Public Health Service (PHS) and other government agencies require from those seeking grant support.

A significant financial conflict of interest exists when the University, through procedures described below, reasonably determines that a potential conflict of interest could directly and significantly affect the design, conduct or reporting of externally sponsored projects. The University 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 University and managed appropriately.

III. Definitions

Investigator means the principal investigator/project director, co-principal investigators, and any other person who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor. The Investigator is also responsible for reporting personal financial interests for any member of the Investigator’s immediate family, specifically, any dependent children, spouse, domestic partner or significant other.

Significant Financial Interest means anything of monetary value, including, but not limited to:
• Salary or other payments for services (e.g., consulting fees or honoraria) received by the investigator exceeding $5,000 in the prior or next 12-month period.
• Equity interests (e.g., stocks, stock options or other ownership interests) of the investigator exceeding $5,000 in fair market value.
• Intellectual property rights (e.g., patents, copyrights and royalties from such rights) assigned to the investigator in excess of $5,000 during a 12-month period.
• Reimbursed or sponsored travel related to their institutional responsibilities. This does not apply to travel that is reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute affiliated with an institution of higher education.

   Note: If any compensation is conditioned upon a particular outcome in a sponsored research project, then it may be considered a conflict of interest and should be disclosed.

   The term does not include:
• Salary, royalties, or other remuneration from the applicant institution,
• 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,
• Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research (SBIR) program or the Small Business Technology Transfer (STTR) program; however, a University employee may not conduct research or administrative activities in conjunction with an STTR project on behalf of both the University and the grantee or sub-grantee company,
• An equity interest that when aggregated for the investigator and the investigator’s spouse or domestic partner and dependent children does not exceed $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, or
• Salary, royalties or other payments that when aggregated for the investigator or domestic partner and dependent children over the next twelve months, are not expected to exceed $5,000.

IV. Responsible Office

The Provost, acting as the Institutional Official, is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional Officer is implemented.

Stetson University’s Research Integrity Officer (RIO), who is appointed by the Provost, will ensure procedural compliance.

V. Policy Details

A. Disclosure

   When is disclosure required?

   A disclosure shall be submitted:
   • before a proposal is submitted;
   • annually, during the grant period in conjunction with filing the required annual progress and/or final report;

• within 30 days after new or significant financial interests are required.

_How do I submit a disclosure?_
Financial Conflict of Interest disclosure forms must be submitted to the Office of Grants, Sponsored Research and Strategic Initiatives. The form is available on the Office of the Provost’s web site under the link to Policies and Guidelines:

[https://www.stetson.edu/administration/provost/policies-and-guidelines/index.php](https://www.stetson.edu/administration/provost/policies-and-guidelines/index.php)

_What Happens When I Disclose a Potential Significant Financial Interest?_
If your disclosure indicates that there is a significant financial interest related to a sponsored research project, you will be required to submit additional information that will be reviewed by the Research Integrity Officer (RIO). If it is determined that the interest has the potential to directly and significantly affect the design, conduct, or reporting of research, then the following conditions or restrictions may be used to manage, reduce or eliminate the conflict of interest.

The following list is illustrative, and is not intended to include all possible conditions or restrictions that might be used:

• Public disclosure of the significant financial interest on publications and in presentations, to your research team, and to the public via a publicly accessible site at [http://www.stetson.edu/administration/grants/](http://www.stetson.edu/administration/grants/) or upon a request, within 5 business days
• Monitoring of research or other activities by independent reviewers
• Modification of a research plan
• Disqualification from participation in all or a portion of the proposed project
• Divestiture of Significant Financial Interest
• Severance of relationships that create actual or potential crisis

_What Information about a Conflict of Interest is Conveyed to the Research Sponsor?_
The following is information about a conflict of interest that will be conveyed to the research sponsor:

• The PHS and agencies that have adopted the PHS rule require notification that a conflict has been identified and is being managed.
• NSF requires notification only of conflicts that cannot be resolved.
• The University will comply with the conflict of interest disclosure rules of other research sponsors.

_B. Collaborative Projects/Sub-agreements_
Collaborators/subrecipients/subcontractors from other organizations must either comply with this policy or provide a certification 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
C. Record Retention

The Office of Grants, Sponsored Research and Strategic Initiatives will maintain all records of Investigator disclosures of financial interest for three years from the date of submission of the final expenditures report. The RIO will maintain all records of Stetson’s review of, or response to, such disclosures (whether or not a disclosure resulted in Stetson’s determination of a Financial Conflict of Interest), and all actions under Stetson’s policy or retrospective review which will be maintained by the RIO for three years from the date of submission of the final expenditures report.

D. What Training and Support Will Be Provided?

- Training: Each Investigator must complete training on this Policy prior to engaging in research, including any funded by PHS. Investigators must also complete training within 60 days: (1) if this Policy is substantively amended in a manner that affects the requirements of Investigators, or (2) if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

VI. Related Policies

Related policies include:

- Department of Human Resources, 4.1.5 Conflict of Interest Policy:
  [http://www.stetson.edu/administration/human-resources/media/hotline/conflict-of-interest-policy.pdf](http://www.stetson.edu/administration/human-resources/media/hotline/conflict-of-interest-policy.pdf)
- Stetson College of Law Conflict of Interest Policy:

VII. Supporting Information and Resources

Additional information on this topic can be found at the following websites: