**Western Carolina University**

**Office of Research Administration**

**Supplemental Process to University Policy 54**

**Conflicts of Interest; External Activities for Pay; Conflicts of Commitment**

***This process applies to applicants to and recipients of PHS funded projects. This includes NIH and HRSA***

University policy 54 provides faculty and EPA non-faculty employees with direction regarding reporting and management of conflicts of interest. The U.S. Department of Health and Human Services (DHHS) has provided further regulations which are applicable to all investigators who apply for and receive Public Health Service (PHS) funding. National Institutes of Health (NIH) and Health Resources and Services Administration (HRSA) are both PHS funded agencies.

Revised in 2011, the updated regulations *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (*42 CFR Part 50 Subpart F) provides broader and more encompassing reporting requirements than University Policy 54. The application of and compliance with the revised regulations by PHS funded investigators is imperative to receiving and maintaining funding from the federal agency.

This supplemental process will provide an outline of the expectations under the 2011 Final Regulation.

**Who is Subject to the DHHS regulations?**

This regulation is applicable to each Institution that is applying for, or that receives, PHS funding by means of a grant or cooperative agreement. Phase I Small Business Innovation Research (SBIR) is exempt from the regulation.

Each investigator participating on the research team is required to submit a Conflict of Interest Disclosure at the time of application, and throughout the life of the funded project. PHS defines *investigator* as the Project Director/Principle Investigator, and any other person who is responsible for the design, conduct, and reporting of funded research, regardless of position or title. This may include faculty, EPA non-faculty, staff, and students.

**What is a Significant Financial Interest?**

University Policy 54 and the 2011 revised regulation are almost parallel in their definitions of “Significant Financial interests.” **“Significant Financial Interest”** in the context of PHS and NSF funded research, means a financial interest consisting of one or more of the following interests of the Covered Employee *(and those of the employee’s spouse and dependent children)* that reasonably appears to be related to the Covered Employee’s Employment Responsibilities:

1. 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; or
2. 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
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

The term *significant financial interest* does not include the following types of financial interests:

1. Salary, royalties, or other remuneration paid by the University to the Covered Employee if the employee 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;
2. Any ownership interest in the University held by the University, if the University is a commercial or for-profit organization;
3. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Employee does not directly control the investment decisions made in these vehicles;
4. 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
5. 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.

***Reimbursed and Sponsored Travel***

The PHS regulation goes a step further to include sponsored and reimbursed travel as a source of conflict which must be reported.

Investigators 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.

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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

A reimbursed or sponsored travel disclosure will include the following information:

* The purpose of the trip;
* The identity of the sponsor/organizer;
* The destination; and
* The duration

**When must I report my Significant Financial Interests?**

1. At the time of application for PHS funding, the Office of Research Administration will confirm that you have a current COI form on file.
2. Annually. Once funded you will need to submit forms annually to the Office of Research Administration.
3. Within 30 day of acquiring or discovering a new significant financial conflict of interest.

**What happens if my significant financial interest is considered to be a financial conflict of interest?**

If, upon review by the Office of Research Administration the significant financial interest is determined to be a financial conflict of interest related to PHS-funded research, a management plan must be implemented. Per University policy 54 this policy will be drafted as a coordinated effort between the investigator and the department head or director. The WCU COI panel will be available for consultation throughout the development, implementation, and oversight of the plan.

The management plan must include the following elements:

* The role and principle duties of the conflicted Investigator in the research project;
* Conditions of the management plan
* How the management plan is designed to safeguard objectivity in the research project;
* Confirmation of the Investigator’s agreement to the management plan;
* How the management plan will be monitored to ensure Investigator compliance; and
* Other information as needed

Updated or annual FCOI reports must include the status of the management plan and a description of any changes to the management plan since the last FCOI report.

The management plan will be retained in the employees project file and submitted to the funding agency.

**What happens if I fail to disclose a Financial Conflict of Interest?**

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

* Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
* Failure by the Institution to review or manage such a Financial Conflict of Interest;
* Failure by the Investigators to comply with a Financial Conflict of Interest management plan;

the Institution shall, within 120 days of the Institution’s determination of noncompliance, complete a “retrospective review” of the Investigator’s activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the non-compliance was biased in the design, conduct, or reporting of such research.

If a bias is found, the Institution must notify NIH promptly and submit a mitigation report to the NIH. The mitigation report will include a summary of the retrospective review, a description of the impact on the research project and the Intuition’s plan of action to eliminate or mitigate the effect of the bias.

Additionally, the PHS regulation requires re-training for the non-compliant investigator to ensure future compliance.

**Public Disclosure**

Under the new regulation, it is the responsibility of Western Carolina University to make all disclosed conflicts of interest publically available. WCU will adhere to this requirement by responding to any written request submitted to the Research Compliance Officer, within 5 calendar days of receiving the request.

The response to the requesting party will include the following information:

* Investigator’s name
* Investigator’s title and role with respect to the research project
* Name of the entity in which the Significant Financial Interest
* Nature of the Significant Financial Interest; and
* Approximate dollar value of the Significant Financial Interest (incremental dollar ranges will be provided)

**Will I Receive Training**

Each investigator (as defined by the regulation) must complete training prior to engaging in PHS sponsored research and at least every four years thereafter. Additionally, investigators will receive training under any of the following circumstance:

* Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
* An investigator is new to an institution
* An Institution finds that an investigator is not in compliance with the Institution’s Financial Conflict of Interest policy or management plan.