

## Financial Conflict of Interest (FCOI)

### Conducting Research Funded by Federal Grants

The federal government requires that the University establish and administer a financial disclosure policy for investigators and a program for training investigators in that policy. This is designed to ensure appropriate management of actual or potential conflicts of interest. The West Virginia State University policy fulfills the requirements of grantee institutions as put forth in the National Institutes of Health's guidelines (see <http://grants.nih.gov/grants/policy/coi/index.htm>) and the National Science Foundation's conflict of interest policies (see [http://www.nsf.gov/pubs/policydoc/pappguide/nsf08\\_1/aag\\_4.jsp#IVA](http://www.nsf.gov/pubs/policydoc/pappguide/nsf08_1/aag_4.jsp#IVA)).

**A. Disclosure of Significant Financial Interests.** The University Vice President for Research and Public Service will designate the University Research Integrity Officer. Using the online Form A – “Financial Conflict of Interest Disclosure Statement” located on this website, all University personnel responsible for the design, conduct or reporting of research under the terms of a federal grant or contract (each, an “Investigator”) are required to disclose to the University’s Research Integrity Officer (the “RIO”) all “Significant Financial Interests” of the Investigator and/or the Investigator’s spouse, partner, and dependent children.

### B. “Significant Financial Interest.”

1) Definition. A Significant Financial Interest means one or more of the following interests, if it reasonably appears to be related to the Investigator’s institutional responsibilities, including all research, teaching and and/or service to the University:

a) 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 the disclosure, when aggregated, exceeds \$5,000. Remuneration includes any 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.

b) 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 spouse, partner, or dependent children) owns *any* equity interest, regardless of dollar value.

c) Intellectual property rights and interests (e.g. patents and copyrights) upon receipt of income related to such rights and interests. This does not include any income received from West Virginia State University for intellectual property rights assigned to West Virginia State University based on agreements to share in the royalties related to such rights in conformity with the University’s Intellectual Property policy.

d) Any occurrence of reimbursed or sponsored travel related to your institutional responsibilities must also be disclosed, including instruction, research or service to West Virginia State University, with the exception of any travel 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 center affiliated with an institution of higher education. Travel reimbursed by West Virginia State University from a sponsored fund account whose sponsor is an entity that is *not* one of those exempt entities shall be treated as a Significant Financial Interest. The Investigator must disclose the purpose of the trip, the

identity of the sponsor and/or organizer, the destination and its duration. Additional information, including the estimated cost of travel, may be requested by the RIO and must be furnished upon request.

2) **Exclusions.** The term “Significant Financial Interest” does not include: a) salary, royalties, or other remuneration from West Virginia State University; b) income from investment vehicles such as mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; c) income from seminars, lectures, or teaching engagements sponsored by government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education; d) income from service on advisory committees or review panels for government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.

### **C. Timing of Required Disclosures.**

1. Investigators must provide all required financial disclosures at the time a proposal is submitted.

2. In addition, Investigators must update those financial disclosures:

a. Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest; and

b. Annually within the period of the award, beginning with the anniversary date of the original disclosure.

**D. Review of Financial Disclosures.** The following process shall apply to financial disclosures submitted by Investigators.

1) Determination of Financial Conflicts of Interest. The RIO shall review each disclosed Significant Financial Interest; determine whether such Significant Financial Interest relates to federally-funded research, and, if so related, determine whether a Financial Conflict of Interest (as defined below) exists; and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflict or interest. The RIO may, depending on the scope of the potential conflict, request that additional staff or faculty serve on an *ad hoc* review committee to assist in its timely review.

2) “Financial Conflict of Interest.” A “Financial Conflict of Interest (FCOI)” exists when the RIO reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of federally-funded research or educational activities.

3) Management of Financial Conflicts of Interest. If the RIO determines that a Significant Financial Interest constitutes a Financial Conflict of Interest, the RIO will convene a committee consisting of faculty, senior staff and/or outside experts, referred to as the “FCOI Committee”. The FCOI Committee will review the research, the financial interests in question, and the areas of conflict, and devise a plan for the management of the Financial Conflict of Interest (a “Management Plan”) with a combination of elements it deems most conducive to the continued objective pursuit of research. The Management Plan may include conditions or restrictions to manage, reduce, or eliminate Financial Conflicts of Interest, which may include (but are not limited to): a) monitoring of research by independent reviewers; b) modification of the research plan; c) disqualification from participation in the portion of the federally-funded research that would be affected by Significant Financial Interests; d) divestiture of Significant Financial Interests; e) severance of relationships that create conflicts; or f) public disclosure of Financial Conflicts of Interest. The Investigator will be consulted as to the implementation of the Management Plan; the Investigator must agree to the plan before the research can proceed. If the FCOI Committee and the Investigator cannot agree upon a management plan, the relevant regulatory bodies and funding agencies will be notified.

#### 4) Reporting of Financial Conflicts of Interest.

a. *Sponsoring agency.* Significant Financial Interests that are determined by the RIO to be Financial Conflicts of Interest will be reported to the sponsoring agency in accordance with its requirements within 60 calendar days of the original disclosure.

b. *Public request.* As required by sponsoring agency regulations, information on the nature of such Financial Conflicts of Interest will be made available to members of the public by the RIO in response to inquiries specifying the investigator name and the research project in question within 5 business days of receipt of such requests.

c. *University reporting.* The RIO will also compile regular reports to the Committee on Audit of the West Virginia State University Board of Governors for review and oversight.

**E. Enforcement.** The University shall establish appropriate mechanisms for enforcement of this policy, which shall provide for sanctions where appropriate.<sup>1</sup> Disciplinary proceedings initiated in connection with this policy shall be conducted in accordance with the West Virginia State University Faculty Handbook, the West Virginia State University Employee Handbook or the Student Code of Conduct. All relevant regulatory bodies and funding agencies will be promptly informed of disciplinary sanctions.

**F. Records.** The University shall maintain records of all financial disclosures and of all actions taken to resolve Financial Conflicts of Interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any federal action involving those records, whichever is longer.

#### **G. Training**

- *Investigators on NIH/PHS-funded projects.* Each Investigator (including senior/key personnel) on projects funded by or proposed to NIH or other Public Health Service (PHS)-affiliated agencies must complete training in the University's financial conflict of interest policy. For Investigators of current or pending NIH grants as of July 23, 2012, this training will consist of a mandatory workshop to be scheduled by the Office of Research and Public Service no later than August 24, 2012, covering institutional policies, Investigator responsibilities under that policy, and the federal regulations that mandate the policy.
- *New or previously unfunded Investigators.* New and/or previously unfunded Investigators who notify the Office of Research and Public Service of their intent to submit a research proposal to NIH or another PHS-affiliated agency after August 24, 2012 will be required to complete training (and make the disclosures described above) prior to submission of their proposal. This training will consist of a scheduled meeting with an assigned member of the Office of Research and Public Service staff and the RIO.

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<sup>1</sup> Such sanctions may include, but are not limited to, any one or more of the following: Letter of admonition; temporary suspension of access to active research funding, either for a fixed term or pending completion of a remediation plan; temporary suspension of rights to apply for internal and external research funding as a PI, either for a fixed term or pending completion of re-training and remediation; investigation and mitigation of possible research bias resulting from improperly disclosed Significant Financial Interests, and reporting of corrective action to the relevant funding agency or agencies; inquiry into possible research misconduct in accordance with the University's policies and procedures; non-renewal of appointment, as per the terms and procedures outlined in the Faculty Handbook; involuntary termination of employment, as per the terms and procedures outlined in the Faculty Handbook. This passage shall not be construed to contradict or supersede any disciplinary policies and procedures detailed elsewhere in the Faculty Handbook.

- *Investigators on non-NIH/PHS projects.* For Investigators sponsored by or seeking funding from NSF and/or other federal agencies, as well as any Investigators initiating research sponsored by a private, for-profit entity, the above training activities are optional but strongly recommended.
- *Repeat training.* Group training of active NIH/PHS-funded Investigators, consisting of the mandatory workshop, will be repeated (i) every four years and (ii) on any occasion when West Virginia State University revises its Financial Conflict of Interest policies and procedures in any manner that affects the requirements of Investigators.

**H. Disclosure Statement.** Copies of the University's Disclosure Statement are available online at [http://www.wvstateu.edu/research and public service/guidelines and procedures](http://www.wvstateu.edu/research_and_public_service/guidelines_and_procedures). This Disclosure Statement must be completed by all senior personnel who are submitting proposals to a federal funder. The certification page of a proposal cannot be signed until forms for all Investigators are submitted to the RIO. By signing this form the applicant certifies that he/she has read this section of the Faculty Handbook, Employee Handbook and/or Student Code of Conduct and that he/she either a) does not have potential Financial Conflicts of Interest (*"I hereby certify that I have read the Financial Disclosure Policy in the West Virginia State University Faculty Handbook, Employee Handbook and/or Student Code of Conduct which is effective for all federal proposals submitted through the University. I certify to the best of my knowledge that neither I nor my spouse, partner, or dependents hold any significant financial interests that would reasonably appear to be related to my research, teaching and service responsibilities to West Virginia State University"*) or b) does have potential conflicts (*"I have the following relationships, affiliations, activities, or interests (financial or otherwise) which constitute potential conflicts under the West Virginia State University Conflict of Interest policy"*). In either case, the applicant also declares that he/she will notify the RIO of any change or discovery requiring modification of the above statement.

**I. Sub-recipients.** The University is responsible for ensuring all sub-recipients' compliance with the applicable federal regulations regarding Financial Conflicts of Interest. To this end, the University shall enter a written agreement with each sub-recipient that shall specify whether this policy, or the applicable policy of the sub-recipient's institution, will apply to sub-recipient Investigators. Said agreement will specify the timing for reporting of FCOIs by sub-recipients to West Virginia State University to enable the timely review and reporting of such FCOIs in compliance with funding agency requirements.