



INSTITUTIONAL POLICY: R-04

Category:	Research
Subject:	Conflict of Interest in Research
Effective Date:	November 13, 2015
Updated:	January 7, 2019
Applicability	Faculty, Students, Staff, other Investigators and Subrecipients

R 04-1. Authority

W. Va. Code § 18B-1-6

R 04-2. Purpose

- 2.1 The West Virginia School of Osteopathic Medicine (“the School” or “WVSOM”) is a public institution committed to its mission of education, service and research. WVSOM is in a position of trust with respect to the public and many external organizations and has a responsibility to be a prudent steward of the public and private resources entrusted to it, including in the area of research. Given the diverse nature of WVSOM’s mission and the variety of activities conducted to accomplish it, apparent, potential and actual conflicts of interest are inevitable.
- 2.2 WVSOM seeks to provide investigators with an environment that will permit them to pursue important research while maintaining the highest standards of research integrity. The purpose of this policy is to ensure that WVSOM complies with State and Federal laws, rules, and regulations regarding Conflicts of Interest in Research, including United States Public Health Service (“PHS”) regulatory requirements, and to ensure that WVSOM meets the following objectives:
 - 2.2.1 Provide information for identifying and addressing perceived, potential, and actual Conflicts of Interest in Research;
 - 2.2.2 Maintain the highest standards of objectivity, freedom from bias, and integrity of research data;
 - 2.2.3 Protect human subjects who participate in research from risks and provide them with information they can use in reaching decisions about entering or remaining in research protocols;
 - 2.2.4 Protect WVSOM and its investigators from even the appearance of bias in the creation, analysis, interpretation and publication of data;
 - 2.2.5 Provide clear guidance on responsibilities and procedures to investigators and employees to assist them in reaching decisions about the activities in which they engage, in view of their research and commitment to WVSOM;

- 2.2.6 Assist investigators and employees with the management of potential Conflicts of Interest in Research in a way that facilitates and encourages the full professional and personal development of investigators through their research, as long as their relationships with industry and their personal financial and other rewards do not adversely affect their objectivity, integrity or professional commitment; and
- 2.2.7 Reduce or eliminate Conflicts of Interest in Research wherever possible.

R 04-3. Applicability and Scope

- 3.1 This policy applies to anyone responsible for the design, conduct, or reporting of research, regardless of the person's title or role on the project or the receipt of funding. This includes all WVSOM employees, adjunct faculty, students, volunteers, subcontractors, consultants, collaborators, research coordinators, research assistants, and other research staff.
- 3.2 This policy also applies to all current and future research activities, research grants, projects, or programs and shall also apply 12 months retrospectively. If an individual is also a member of and has duties and responsibilities to another institution or agency that conflict with the Conflicts of Interest in Research policies of WVSOM, the most restrictive of the conflicting policies shall prevail.

R 04-4. Definitions

- 4.1 "Compensation" means anything of monetary value including, but not limited to, salary, consulting fees, honoraria, gifts, or other payments for services including equity interest.
- 4.2 "Conflict of Interest in Research" or "COIR" means a situation in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting, analyzing, interpreting, or reporting research, and also in hiring staff, procuring materials, sharing results, choosing protocols, using statistical methods, and training students and fellows.
- 4.3 "Conflict of Interest in Research Officer" or "COIR Officer" means the Associate Dean for Research and Sponsored Programs, or his or her designee, whose functions are defined in this policy and in the COIR procedures.
- 4.4 "Conflict of Interest in Research Committee" or "COIR Committee" means a committee consisting of members of the faculty and administration as defined in the COIR procedures.
- 4.5 "Employee" means any person possessing either a full-time or part-time faculty or staff appointment at WVSOM who is eligible to receive benefits and receives a salary or wage for his/her defined responsibilities. For purposes of this policy, this definition may include students, both graduate and undergraduate, who work on a grant or contract and have responsibility, in whole or in part, for the reporting of research.
- 4.6 "Equity Interest" means stocks, stock options, partnerships, limited liability companies, or other ownership interests.

- 4.7 “Family” means any individual who is a spouse, parent, child, stepparent, stepchild, mother-in-law, father-in-law, son-in-law, daughter-in-law, grandparent or grandchild of an employee or a member of the employee's household.
- 4.8 “Financial Conflict of Interest” or “FCOI” means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research.
- 4.9 “Gift” means a contribution with no reciprocal benefit to the donor. The definition of gift is further explained in the West Virginia State Ethics Commission Rules Governing the Ethical Conduct of State Officers and Employees, as may be amended from time to time.
- 4.10 “Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of WVSOM, and as set forth in this policy, which may include, but not be limited to, research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the Institutional Review Board.
- 4.11 “Investigator” means the project director or principal investigator and any other person responsible for the design, conduct, or reporting of research or the preparing of proposals for research funding, regardless of the person’s title or role on the project or the receipt of funding. This term includes adjunct faculty, students, volunteers, subcontractors, consultants, collaborators, visiting scientists, research coordinators, research assistants, and other research staff.
- 4.12 “Manage” means to take action to address a Financial Conflict of Interest or other significant Conflict of Interest in Research, which may include reducing or eliminating the Financial Conflict of Interest or other significant Conflict of Interest in Research, to ensure to the extent possible that the design, conduct, and reporting of research will be free from bias.
- 4.13 “Management Plan” means a plan to Manage a Financial Conflict of Interest or other significant Conflict of Interest in Research.
- 4.14 “PHS Awarding Component” means an agency within the Public Health Service such as CDC, NIH, NIOSH, and others.
- 4.15 “Research” means any systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). The term further includes any such activity for which research funding is available from a governmental awarding component or through a grant or cooperative agreement, whether private or authorized under statutory authority.
- 4.16 “Senior/Key Personnel” means the project director or principal Investigator and any other person identified as senior/key personnel by WVSOM in the grant application, progress report, or any other report submitted to the PHS.
- 4.17 “Significant Financial Interest” or “SFI” means a financial interest consisting of one or more of the following interests of the Investigator, and those of the Investigator's Family, that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- 4.17.1 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;
- 4.17.2 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 Family, holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- 4.17.3 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 4.17.4 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 the Investigator's 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.
- 4.17.5 "Significant Financial Interest" does not mean the following:
- (i) Salary, royalties, or other remuneration paid by WVSOM to the Investigator if the Investigator is currently employed or otherwise appointed by WVSOM, including intellectual property rights assigned to WVSOM and agreements to share in royalties related to such rights;
 - (ii) 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;
 - (iii) 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;
 - (iv) 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; or
 - (v) 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.

R 04-5. Principle for the Conduct of Research

Research must meet the following criteria and any other conditions deemed appropriate by WVSOM through the COIR Officer and/or the COIR Committee under the unique circumstances presented by a specific case. The research arrangement will safeguard the academic integrity of School research by ensuring that:

- 5.1 The nature and scope of the research is appropriate and consistent with Investigators' academic and research interests.
- 5.2 Any financial interests (e.g., equity interest or compensation) of an Investigator that could affect the design, conduct, or reporting of research or affect educational activities are disclosed and reduced, eliminated, or managed, as appropriate.
- 5.3 Students and other School personnel are assigned appropriate duties consistent with their status or position.
- 5.4 Research sponsors' access to School equipment, supplies, personnel, space, intellectual property rights, etc. is appropriate and consistent with the School's legal, policy, financial, and reputational interests.

R 04-6. Investigator Responsibilities

- 6.1 Investigators shall conduct their research activities so as to avoid or minimize Conflicts of Interest in Research and must respond appropriately and in a timely manner in accordance with WVSOM's policies and procedures regarding COIR when conflicts arise. Individuals who cannot disclose to the COIR Officer or COIR Committee adequate information upon which to base informed decisions without violating confidentiality or other requirements of the external person or entity with whom they have a proposed or active research, teaching, consulting, business, or other similar arrangement must forego such arrangement.
- 6.2 Any Investigator engaged in a research study, whether funded by the School, externally sponsored from federal sources, state sources, foundation, industry, or other private sources; or unfunded and unsponsored, who wishes to be eligible to engage in particular research shall have an ongoing duty to comply with applicable federal, state, and local laws and regulations, as well as WVSOM's policies and procedures regarding COIR.

R 04-7. Required Training

- 7.1 Each Investigator who is planning to participate in, or is participating in, a research study, whether funded by the School, externally sponsored from federal sources, state sources, or foundation, industry, or other private sources; or unfunded and unsponsored, shall complete COIR training (regardless of whether or not a COIR exists).
- 7.2 COIR training shall be completed:
 - 7.2.1 Prior to engaging in research;

7.2.2 At least every 4 years; and/or

7.2.3 Immediately, if:

- (i) An Investigator is new to WVSOM;
- (ii) WVSOM revises its policies and procedures regarding COIR in any manner that affects the requirements of Investigators; and/or
- (iii) When so directed as a result of an Investigator's non-compliance with WVSOM's policies and procedures regarding COIR or any management plan as described in Section 10 of this policy.

7.3 WVSOM shall provide the COIR training, or access to the training, required by this Section 7. Such training shall include information regarding the Investigator's responsibilities under WVSOM's policies and procedures regarding COIR, including the responsibility to disclose Significant Financial Interests of the Investigator and of the Investigator's Family.

R 04-8. Disclosure Requirements

8.1 Disclosure of Significant Financial Interests

8.1.1 Each Investigator who is planning to participate in, or who is participating in, a research study, whether funded by the School, externally sponsored from federal sources, state sources, or foundation, industry, or other private sources; or unfunded and unsponsored, shall disclose any Significant Financial Interest, including of the Investigator's Family, to the COIR Officer if it reasonably appears that a Significant Financial Interest is related to the Investigator's Institutional Responsibilities. Such disclosure shall be made as part of the application submission process. Alternatively, if no such Significant Financial Interest exists, the Investigator shall so certify as part of the application submission process.

8.1.2 Disclosures of Significant Financial Interests or certifications that no such Significant Financial Interests exist shall be made by each Investigator as follows:

- (i) At or before the time of submission of an application for a research project;
- (ii) At least annually during the period of the research award;
 - a. The annual disclosure shall include: (a) any new information that was not disclosed to the COIR Officer either initially or subsequently (e.g. any Financial Conflict of Interest identified on a research project that was transferred from another institution); and (b) updated information regarding any previously disclosed Significant Financial Interest (e.g. the updated value of a previously disclosed equity interest);
 - b. Annual updates shall be required of all Investigators participating in a PHS-funded research project, regardless of whether or not a Significant Financial Interest was previously disclosed; and/or
- (iii) Within 30 days of the discovery or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

8.1.3 The disclosures shall include, without limitation, the following information:

- (i) The nature and amount of remuneration received from any entity in the 12 months preceding the disclosure;
- (ii) The name and address of the entity;
- (iii) If there is an equity interest in the entity, any value as of the date of disclosure; and
- (iv) With respect to reimbursed or reimbursable travel expenses that require disclosure: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the travel.

8.1.4 The COIR Officer shall notify the Investigator if further information is needed, including without limitation a determination or disclosure of monetary value, in order to decide whether the disclosed Significant Financial Interest constitutes a Financial Conflict of Interest. The Investigator shall provide any such additional information, as requested.

8.2 Disclosures for Federally Funded Research

In addition to the disclosures required in Section 8.1 of this policy, any Investigator who wishes to engage in a federally funded research study shall disclose fully any of the following to the COIR Officer and receive approval prior to submitting any formal proposal for the research:

8.2.1 Any ownership interest, stock options, or other financial interest related to the research unless it meets four tests:

- (i) Less than \$5,000 when aggregated for the Investigator and the Investigator's Family.
- (ii) Publicly traded on a stock exchange.
- (iii) Value will not be affected by the outcome of the research.
- (iv) Less than 5% interest in any one single entity.

8.2.2 Any compensation related to the research unless it meets two tests:

- (i) Less than \$5,000 in the past year when aggregated for the Investigator and the Investigator's Family.
- (ii) Amount will not be affected by the outcome of the research.

8.2.3 Any proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.

8.2.4 Any board or executive relationship related to the research, regardless of compensation.

8.3 The Investigator shall provide details to the COIR Officer of the disclosable financial arrangements, as required under Sections 8.1 and 8.2 of this policy, along with a description of steps taken to minimize the potential bias of research study results by any of the disclosed arrangements or interests.

R 04-9. Disclosure Review and Determination of Financial Conflicts of Interest

- 9.1 The COIR Officer is designated as WVSOM's institutional official with overall responsibility for the solicitation and review of disclosures made pursuant to Sections 8.1 and 8.2 of this policy from each Investigator who is planning to participate in, or is participating in, a research project.
- 9.2 The COIR Committee is responsible for making determinations regarding Significant Financial Interests, Financial Conflicts of Interest, and/or Conflicts of Interest in Research, and Management Plans, as provided in this policy.
- 9.3 The COIR Officer and the COIR Committee may solicit input and advice in making their determinations from appropriate WVSOM personnel, federal agencies, and from others who may have relevant expertise.
- 9.4 Prior to an Investigator's participation in, or continued participation in, a research project and prior to the expenditure of any funds for the research project, the COIR Officer shall review the Investigator's disclosures made pursuant to Sections 8.1 and 8.2 of this policy and the following determinations shall be made, as applicable:
 - 9.4.1 The COIR Officer shall determine whether the disclosures are sufficient and whether a Significant Financial Interest or other Conflict of Interest in Research exists concerning the research project. If a Significant Financial Interest or other COIR is determined to exist, the COIR Officer shall forward the Investigator's disclosures to the COIR Committee for resolution.
 - 9.4.2 The COIR Committee shall make the following determinations:
 - (i) Whether the Investigator's disclosures made pursuant to Sections 8.1 and 8.2 are sufficient;
 - (ii) Whether a Significant Financial Interest or other COIR exists;
 - (iii) Whether the Significant Financial Interest or other COIR constitutes a Financial Conflict of Interest and/or a significant COIR; and
 - (iv) Whether the Financial Conflict of Interest and/or significant COIR can be managed, in which case a Management Plan must be presented, or whether the Financial Conflict of Interest and/or significant COIR constitute(s) an impermissible conflict of interest.
 - 9.4.3 The COIR Committee shall communicate its determinations made under Section 9.4.2 of this policy to the Investigator.
- 9.5 In the case of research involving human subjects, the disclosures made pursuant to this policy and the Management Plan will be reviewed by WVSOM's Institutional Review Board ("IRB"). The IRB has the final authority to determine, given the Financial Conflicts of Interest or other Conflicts of Interest in Research and the Management Plan, whether the research will be approved. The COIR Officer will serve as a liaison to the IRB.
- 9.6 Detailed information concerning the appeals process and administration of the COIR review is set forth in the COIR procedures.

- 9.7 All records relating to all Investigator disclosures of financial interests and the review of and response to such disclosures, whether or not the disclosure resulted in a determination of an FCOI, by the COIR Officer, COIR Committee, or other appropriate WVSOM board, committee, or administrator, and all actions under this policy, including retrospective review under Section 11.3 if applicable, shall be maintained in the Office of the COIR Officer for at least 3 years from the date the final expenditures report is submitted to the PHS (for PHS-funded research) or at least 3 years beyond the termination or completion of the research or at least 3 years beyond resolution of any action by any governmental agency involving the record, whichever is longer (for non-PHS funded research), or where applicable, from other dates set forth in Section 12 of this policy.

R 04-10. Management Plans

- 10.1 If it is determined that a Financial Conflict of Interest or other significant Conflict of Interest in Research exists, the COIR Committee will undertake such actions as are deemed necessary to Manage the FCOI or other significant COIR.
- 10.2 The COIR Officer shall work with the Investigator and the Investigator's supervisor to develop an appropriate, written Management Plan. The purpose of the Management Plan is to establish rules and procedures that provide a reasonable expectation that the research associated with the Investigator's FCOI or other significant COIR will be free from bias. The Management Plan must specify the actions that have been, and shall be, taken to Manage any FCOI or other significant COIR in accordance with this policy, United States Public Health Service regulations, and other applicable regulations and procedures.
- 10.3 The COIR Officer shall submit the Management Plan to the COIR Committee for review and approval.
- 10.4 The COIR Officer and COIR Committee may require additional information from the Investigator and/or the Investigator's supervisor and may seek input and advice from others, as provided herein, in connection with the development and/or implementation of the Management Plan.
- 10.5 Actions, conditions, or restrictions that may be required under the Management Plan may vary depending upon the nature and extent of the FCOI or other significant COIR. Examples of actions, conditions, or restrictions that might be imposed to Manage an FCOI or other significant COIR include but are not limited to the following:
- 10.5.1 Public disclosure of the FCOI or other significant COIR on all publications and in oral presentations concerning the research;
 - 10.5.2 Annual or more frequent reporting requirement to the COIR Committee of status and changes in the relationship and the research;
 - 10.5.3 For research projects involving human subjects, disclosure of the FCOI or other significant COIR directly to participants and through informed consent forms;
 - 10.5.4 Informed consent from human subjects obtained by person(s) other than the Investigator and supervisees;

- 10.5.5 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI or other significant COIR;
 - 10.5.6 Data analysis and interpretation by independent reviewer(s) or review of raw data and manuscript by external independent reviewer(s);
 - 10.5.7 Reformulation/modification of the research plan;
 - 10.5.8 Close monitoring of the conduct of the research;
 - 10.5.9 Requirement for inclusion of double-blind data analysis;
 - 10.5.10 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - 10.5.11 Reduction or elimination of the Significant Financial Interest (e.g., sale of an equity interest); and/or
 - 10.5.12 Severance of the relationships that create financial or other conflicts.
- 10.6 The Management Plan shall be signed by the Investigator, the COIR Officer, and the chair of the COIR Committee. The COIR Committee shall provide a copy of the Management Plan to the department chair of the principal Investigator for oversight of compliance with the Management Plan. Distinction between the Management Plans for basic science research and clinical research involving human subjects shall be made by the COIR Committee.
- 10.7 The COIR Officer and the COIR Committee are responsible for (i) ensuring that steps set forth in the Management Plan are implemented and (ii) taking reasonable steps to ensure the Investigator's compliance with the Management Plan.

R 04-11. Additional Requirements for PHS-Funded Research

11.1 Reporting Requirements to PHS

- 11.1.1 For PHS-funded research, the COIR Officer shall report any conflicting interest to the PHS Awarding Component that issued the award, as required by PHS regulations.
- 11.1.2 The FCOI report required in Section 11.1.1 of this policy shall be filed as follows:
 - (i) Prior to expenditure of any funds under the PHS-funded research project, the COIR Officer shall provide to the PHS Awarding Component the FCOI report regarding any Investigator's SFI found by the COIR Officer and COIR Committee to be conflicting and ensure that a Management Plan has been implemented in accordance with PHS regulations. In cases in which an FCOI is identified and eliminated prior to the expenditure of PHS-awarded funds, the COIR Officer shall not submit a FCOI report to the PHS Awarding Component.
 - (ii) For any SFI that is identified as an FCOI subsequent to the initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the PHS-funded research project), the COIR Officer shall provide to the PHS Awarding Component, within 60 days, the FCOI report regarding the FCOI and ensure that a Management Plan has been implemented in accordance with PHS regulations.

- (iii) For any FCOI previously reported by WVSOM with regard to an ongoing PHS-funded research project, the COIR Officer shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the Management Plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being Managed or explain why the FCOI no longer exists. The COIR Officer shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.
- (iv) The annual FCOI reporting requirement set forth in this Subsection 11.1.2 shall be completed at the same time as when WVSOM is required to submit to the National Institutes of Health (NIH) the annual progress report, multi-year progress report, if applicable, or at the time of grant extension.

11.1.3 The FCOI report required in Section 11.1.1 of this policy shall include the following:

- (i) Project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the FCOI;
- (iv) Name of the entity with which the Investigator has the FCOI;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) Value of the financial interest (dollar ranges are permissible: \$0 - \$4,999; \$5,000 - \$9,999; \$10,000 - \$19,999; amounts between \$20,000 - \$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- (vii) A description of how the financial interest relates to the PHS-funded research and the basis for determining that the financial interest conflicts with the research; and
- (viii) A description of the key elements of the Management Plan, including:
 - a. Role and principal duties of the conflicted Investigator in the research project;
 - b. Conditions of the Management Plan;
 - c. How the Management Plan is designed to safeguard objectivity in the research project;
 - d. Confirmation of the Investigator's agreement to the Management Plan;
 - e. How the Management Plan will be monitored to ensure Investigator compliance; and
 - f. Other information as needed.

11.2 New Significant Financial Interests during Ongoing PHS-Funded Research

- 11.2.1 This Subsection 11.2 applies: (a) whenever an Investigator discloses a Significant Financial Interest that was discovered or acquired after research under a PHS-funded award had begun; or (b) whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a Significant Financial Interest.
- 11.2.2 In the event of a disclosure under Subsection 11.2.1, within 60 days of the disclosure, the COIR Committee shall:
- (i) Review the disclosed interest;
 - (ii) Determine whether the disclosed interest is related to the PHS-funded research; and
 - (iii) If the disclosed interest is related to the PHS-funded research, determine whether a Financial Conflict of Interest exists.
- 11.2.3 If a Financial Conflict of Interest exists, the COIR Committee shall implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to Manage such Financial Conflict of Interest going forward. The COIR Officer shall report to the PHS Awarding Component that issued the award, as required by the PHS regulations.
- 11.2.4 Depending on the nature of the disclosed interest, additional interim measures may be taken with regard to the Investigator's participation in the PHS-funded research between the date of disclosure and the completion of the review process.

11.3 Retrospective Review and Mitigation Report

- 11.3.1 If a Significant Financial Interest is not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the COIR Committee during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the COIR Committee shall, within 60 days of the disclosure:
- (i) Review the disclosed interest;
 - (ii) Determine whether the disclosed interest is related to the PHS-funded research; and
 - (iii) If the disclosed interest is related to the PHS-funded research, determine whether a Financial Conflict of Interest exists.
- 11.3.2 If a Financial Conflict of Interest exists, the COIR Committee shall implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to Manage such Financial Conflict of Interest going forward. The COIR Officer shall report to the PHS Awarding Component that issued the award, as required by the PHS regulations.
- 11.3.3 Depending on the nature of the Financial Conflict of Interest, the COIR Officer may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that

the Financial Conflict of Interest or the Investigator's non-compliance is determined and the completion of the retrospective review process.

- 11.3.4 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 to constitute a Financial Conflict of Interest; failure by the COIR Committee to review or Manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a Management Plan), the COIR Officer shall, within 120 days of the determination of non-compliance: (a) complete a retrospective review of the Investigator's activities and the PHS-funded research, or portion thereof, conducted during the time period of the non-compliance; and (b) determine whether or not there was bias in the design, conduct, or reporting of the PHS-funded research. The COIR Officer shall document the retrospective review as required by PHS regulations, which documentation shall include but not necessarily be limited to all of the following key elements:
- (i) Project number;
 - (ii) Project title;
 - (iii) PD/PI or contact PD/PI if a multiple PD/PI model is used;
 - (iv) Name of the Investigator with the FCOI;
 - (v) Name of the entity with which the Investigator has a financial conflict of interest;
 - (vi) Reason(s) for the retrospective review;
 - (vii) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - (viii) Findings of the review; and
 - (ix) Conclusions of the review.
- 11.3.5 Based on the results of the retrospective review required under Subsection 11.3.4, if appropriate, the COIR Officer shall update the previously submitted Financial Conflict of Interest report, specifying the actions that shall be taken to Manage the Financial Conflict of Interest going forward. If bias is found, the COIR Officer shall notify the PHS Awarding Component that issued the award promptly and submit a mitigation report to the PHS Awarding Component that issued the award, in accordance with the PHS regulations. The mitigation report must include, at a minimum, the key elements documented in the retrospective review set forth in Subsection 11.3.4 and a description of the impact of the bias on the research project and the plan of action or actions 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 quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the COIR Officer shall submit Financial Conflict of Interest reports annually, as required by Subsection 11.1 of this policy. Depending on the nature of the FCOI, the COIR Officer and the COIR Committee may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that

the FCOI or the Investigator's noncompliance is determined and the completion of the retrospective review.

11.4 Monitoring of Management Plan

Whenever a Management Plan is implemented with regard to a PHS-funded research project, the COIR Officer and the COIR Committee shall be responsible for monitoring and for taking reasonable steps to ensure Investigator compliance with the Management Plan on an ongoing basis until the completion of the PHS-funded research project.

11.5 Public Accessibility

11.5.1 Prior to the expenditure of any funds under a PHS-funded research project, the COIR Committee shall ensure public accessibility of information concerning any disclosed Significant Financial Interest that meets the following criteria:

- (i) The Significant Financial Interest was disclosed and is still held by Senior/Key Personnel;
- (ii) The COIR Committee determines that the Significant Financial Interest is related to the PHS-funded research; and
- (iii) The COIR Committee determines that the Significant Financial Interest is a Financial Conflict of Interest.

11.5.2 The information meeting the criteria in Subsection 11.5.1 shall be made accessible via written response to any requestor within 5 business days of the COIR Officer's receipt of a written request. Such information shall include at a minimum the information required by the PHS regulations. The response will note that the information provided is current as of the date of the response and is subject to updates, on at least an annual basis and within sixty 60 days of the COIR Committee's identification of a new Financial Conflict of Interest, and that such updates should be requested subsequently by the requestor.

11.5.3 Information concerning the Significant Financial Interests of an individual subject to Subsection 11.5 of this policy shall remain available for responses to written requests for at least 3 years from the date that the information was most recently updated.

11.6 Subrecipient Collaborations (WVSOM as Prime Recipient)

11.6.1 If WVSOM carries out PHS-funded research through an Investigator who is a subrecipient (e.g., subcontractors, or consortium members), the COIR Committee shall be responsible to ensure that there is a written agreement with the subrecipient which contains terms that establish whether this policy or the financial conflicts of interest policy of the subrecipient will apply to the subrecipient's Investigators.

- (i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement shall require that the subrecipient certify as part of the agreement that its policy complies with this policy and the PHS regulations. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to this policy

for disclosing Significant Financial Interests that are directly related to the subrecipient's work for WVSOM;

- (ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the COIR Officer. Such time period(s) shall be sufficient to enable the COIR Committee to provide timely Financial Conflict of Interest reports, as necessary, to the PHS Awarding Component that issued the award, as required by this policy and the PHS regulations;
- (iii) Alternatively, if the subrecipient's Investigators must comply with WVSOM's financial conflicts of interest policy, the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to the COIR Officer. Such time period(s) shall be sufficient to enable WVSOM to comply timely with its review, management, and reporting obligations under this policy and the PHS regulations.

11.6.2 The COIR Officer shall be responsible to provide Financial Conflict of Interest reports to the PHS Awarding Component that issued the award regarding all financial conflicts of interest of all subrecipient Investigators consistent with this policy and the PHS regulations (i.e., prior to the expenditure of funds and within 60 days of any subsequently identified Financial Conflict of Interest).

11.7 WVSOM as a Subrecipient

11.7.1 If WVSOM is a subrecipient of PHS-funded research where another entity is the prime recipient, the COIR Committee shall be responsible to ensure that there is a written agreement with the prime recipient which contains terms that establish whether this policy or the financial conflicts of interest policy of the prime recipient will apply to WVSOM's Investigators.

11.7.2 If the agreement specifies that WVSOM's Investigators must comply with the prime recipient's financial conflicts of interest policy, then WVSOM's Investigators shall so comply with the prime recipient's policy, and this policy shall not apply.

11.7.3 If the agreement specifies that WVSOM's Investigators must comply with this policy, then WVSOM's Investigators shall so comply with this policy, and this policy shall apply.

R 04-12. Retention of Records

12.1 The COIR Officer shall maintain records relating to all Investigator disclosures of financial interests and the review of and response to such disclosures, whether or not a disclosure resulted in determination of an FCOI, by the COIR Officer, COIR Committee, or other applicable WVSOM board, committee, or administrator, and all actions under this policy, including retrospective review under Section 11.3 if applicable.

12.2 The records listed in Subsection 12.1 shall be retained for at least three years from the date the final expenditures report is submitted to the PHS (for PHS-funded research) or at least 3 years beyond the termination or completion of the research or at least 3 years beyond

resolution of any action by any governmental agency involving the record, whichever is longer (for non-PHS funded research), or where applicable, from other dates specified in 45 C.F.R. 75.361 (records pertaining to a Federal award) for different situations.

- 12.3 The records listed in Subsection 12.1 may be destroyed within 90 days following the expiration of the retention period, unless there is relevant pending or active administrative or legal action or otherwise required by applicable law or policy.

R 04-13. Noncompliance

- 13.1 It shall be considered a violation of WVSOM policy, subject to disciplinary action in accordance with applicable policies, if an Investigator: (a) fails to disclose a Significant Financial Interest as required herein; (b) fails to comply with an established Management Plan; (c) fails to provide timely annual report information or other required information; or (d) fails to comply with any other requirement of this policy.
- 13.2 In the case of PHS-funded research, if the failure of an Investigator to comply with this policy or a Management Plan appears (in the reasonable judgment of the COIR Officer) to have biased the design, conduct, or reporting of the PHS-funded research, the COIR Officer shall be responsible to promptly notify the PHS Awarding Component that issued the award of the corrective action taken or to be taken, as required by the PHS regulations.
- 13.3 In the case of PHS-funded research, in the event that the U.S. Department of Health and Human Services determines that a PHS-funded research project involving 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 Financial Conflict of Interest that was not Managed or reported by WVSOM in accordance with the PHS regulations and this policy, such Investigator shall be required to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

R 04-14. Regulatory Requirements

- 14.1 This policy complies with applicable federal, state, and local laws, regulations, and policy statements including:
- 14.1.1 Federal law and regulations: 18 U.S.C. § 201-209 (or 18 U.S.C. 208), 5 C.F.R. § 2635.201-205, 45 C.F.R. 94.1-94.6, and 42 C.F.R. 50 Subpart F.
- 14.1.2 West Virginia law and regulations: W. Va. Code §§ 6B-2-5 through 6B-2-8, W. Va. Code R. § 158-4, and W. Va. Code R. § 158-6 through 8.
- 14.1.3 West Virginia School of Osteopathic Medicine policies and procedures relevant to this policy: WVSOM IRB guidelines, WVSOM institutional policy on ethics, other WVSOM policies and relevant WVSOM forms, as defined in the COIR procedures.
- 14.2 WVSOM employees should be aware that they are also subject to various provisions of the West Virginia Governmental Ethics Act (“Act”) governing ethics and conflicts of interest in public employment. For example, the Act prohibits WVSOM employees from accepting anything of value that will exert a substantial and improper influence upon them with respect

to their WVSOM duties. Additional information about the requirements of West Virginia law may be obtained by consulting the WVSOM Office of the General Counsel.