



## PROCEDURE FOR INSTITUTIONAL POLICY R-04: CONFLICT OF INTEREST IN RESEARCH

### 1. PURPOSE

The purpose of this procedure is to provide specific guidance to assist the West Virginia School of Osteopathic Medicine (“WVSOM”) with implementation of and ensure institutional compliance with WVSOM’s Institutional Policy R-04: Conflict of Interest in Research, and the Public Health Service (“PHS”) regulation titled, “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought,” 42 C.F.R. Part 50, Subpart F (August 25, 2011), as applicable.

### 2. APPLICABILITY

This procedure applies to any situation where Institutional Policy R-04 is triggered.

### 3. DEFINITIONS

For purposes of this procedure, the capitalized terms used herein have the meanings assigned to them in Institutional Policy R-04.

### 4. IDENTIFICATION OF RESEARCH PARTICIPANTS AND INVESTIGATORS

The principal Investigator (“PI”) for each research project will identify on the WVSOM Research Project Personnel Roster all individuals who will be engaged in the research project and whether those individuals will be Investigators responsible for the design, conduct, or reporting of research or the preparing of proposals for research funding. This identification requirement includes sub-contractor/sub-recipient locations. The Research Project Personnel Roster must be submitted with the research project application to the COIR Officer.

### 5. REQUIRED CONFLICTS OF INTEREST IN RESEARCH TRAINING

- 5.1 Each Investigator who is planning to participate in a research study, whether funded by WVSOM, 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 Conflict of Interest in Research exists. Each Investigator must complete the required training prior to engaging in any research study. This training requirement also includes sub-contractor/sub-recipient locations.
- 5.2 The COIR training required of all Investigators under Section 5.1 above and Institutional Policy R-04, Section 7, is available to all WVSOM personnel through the Collaborative Institutional Training Initiative (CITI) website, at <http://citiprogram.org>.

### 6. SIGNIFICANT FINANCIAL INTEREST (SFI) REPORTING

- 6.1 Each Investigator who is planning to participate in, or who is participating in, a research study 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. If no such Significant Financial Interest exists, the Investigator shall so certify as part of the application submission process. The disclosure or certification must be made as a part of the research application submission process and includes sub-contractor/sub-recipient locations. The disclosure requirements must comply with Institutional Policy R-04, Section 8.
- 6.2 The Significant Financial Interest disclosure (or certification that no Significant Financial Interest exists) required under Section 6.1 above and Institutional Policy R-04, Section 8, must be completed on the WVSOM Significant Financial Interest Disclosure Form (“SFID Form”).

- 6.3 All SFID Forms must be submitted to the COIR Officer at the following times:
- 6.3.1 At or before the time of submission of an application for a research project;
  - 6.3.2 At least annually during the period of the research award, and must 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);
    - b. Updated information regarding any previously disclosed Significant Financial Interest (e.g., the updated value of a previously disclosed equity interest); and
  - 6.3.3 Within 30 days of the discovery or acquiring (e.g., through purchase, marriage, or inheritance) of a new Significant Financial Interest.
- 6.4 For Investigators participating in a PHS-funded research project, the annual update required under Section 6.3.2 above and Institutional Policy R-04, Section 8, must be submitted to the COIR Officer regardless of whether or not a Significant Financial Interest was previously disclosed.
- 6.5 The COIR Officer or COIR Committee may request additional information and supporting documentation at any time from any Investigator concerning a Significant Financial Interest.
- 6.6 No research project application may be approved unless each Investigator under the proposal has submitted a current SFID Form with the application or has a current SFID Form on file.
- 6.7 No research agreement, including any agreement with external persons or entities, may be finalized until each Investigator under the proposal has a current SFID Form on file and the research project application has been approved.
- 6.8 All required SFID Forms must be submitted to the COIR Officer no later than the time that a research project, an application for exemption, a protocol modification, or a research project renewal is submitted for review. The COIR Officer, COIR Committee, and, if applicable, WVSOM's Institutional Review Board ("IRB"), WVSOM's Institutional Animal Care and Use Committee ("IACUC"), or WVSOM's Institutional Biosafety Committee ("IBC") will not review any submission until after all SFID Forms for each Investigator under the proposal have been received and verified. If the proposed research project involves human subjects, the use of animals, or the use of potential biohazards, the IRB, the IACUC, or the IBC, as applicable, has the final authority to determine whether the proposed research project will be approved.

## **7. CONFLICTS OF INTEREST IN RESEARCH (COIR) COMMITTEE**

- 7.1 The COIR Committee is comprised of the Associate Dean for Preclinical Education, Associate Dean for Predoctoral Clinical Education, Assistant Dean for Osteopathic Medical Education, Associate Dean for Graduate Medical Education, and Chairperson of the Faculty Council.
- 7.2 To the extent possible and unless otherwise required by law including, but not limited to, the West Virginia Freedom of Information Act or federal or state regulations requiring WVSOM to make certain information publicly available, all SFID Forms and all information and written materials provided to or produced by the COIR Officer, the COIR Committee, the IRB, the IACUC, and the IBC shall be kept confidential and disclosed only to the COIR Officer, the COIR Committee, the IRB, the IACUC, the IBC, and other individuals identified by the COIR Officer, the COIR Committee, the IRB, the IACUC, or the IBC on a case-by-case, need-to-know only basis.
- 7.3 The COIR Officer, COIR Committee members, IRB members, IACUC members, and IBC members shall have a signed confidentiality agreement on file annually in the Office of Human Resources.

- 7.4 Issues involving institution-wide COIR policy shall be referred to the COIR Committee and coordinated by the COIR Committee to address any COIR issues.

## **8. REVIEW OF SIGNIFICANT FINANCIAL INTERESTS**

- 8.1 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, if applicable, the COIR Officer shall initially review each SFID Form submitted by the Investigator to determine whether the disclosures are sufficient and whether a Significant Financial Interest or other COIR exists concerning the research project.
- 8.2 If the COIR Officer determines that a Significant Financial Interest or other COIR exists (i.e., the COIR Officer identifies a situation in which financial or other personal considerations may compromise or have the appearance of compromising a researcher's professional judgment or integrity in conducting, analyzing, interpreting, or reporting research, and in hiring staff, procuring materials, sharing results, choosing protocols, using statistical methods, and training students and fellows), the COIR Officer shall forward the Investigator's SFID Form and the COIR Officer's initial written determinations to the COIR Committee for review and resolution. The COIR Officer shall also provide an initial written notification to the principal Investigator that a Significant Financial Interest or other COIR exists.
- 8.3 Upon receipt of the COIR Officer's documentation under Section 8.2 above, the COIR Committee shall make the following determinations as required by Institutional Policy R-04, Section 9:
- 8.3.1 Whether the Investigator's disclosures on the SFID Form are sufficient;
- 8.3.2 Whether a Significant Financial Interest or other COIR exists;
- 8.3.3 Whether the Significant Financial Interest or other COIR constitutes a Financial Conflict of Interest and/or a significant COIR; and
- 8.3.4 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 constitutes an impermissible conflict of interest.
- 8.4 If the COIR Committee determines that a Financial Conflict of Interest and/or a significant COIR exists, the research project may not undergo IRB, IACUC, or IBC review (if applicable) or receive institutional approval until the COIR Committee (a) determines that the Financial Conflict of Interest and/or significant COIR can be managed through a Management Plan (i.e., the Financial Conflict of Interest and/or significant COIR can be mitigated in such a way that it would not potentially compromise or have the appearance of compromising the integrity of the research, the Investigator, and/or WVSOM) and (b) reviews and approves the written Management Plan.
- 8.5 Management Plan
- 8.5.1 If the COIR Committee determines that the Financial Conflict of Interest and/or significant COIR can be managed through a Management Plan, the COIR Officer shall work with the Investigator to develop an appropriate, written Management Plan that is consistent with the requirements of Institutional Policy R-04, Section 10, and includes specific elements as to how the COIR Officer and the COIR Committee will oversee and monitor the Investigator's continued compliance with the Management Plan.
- 8.5.2 If approved, the Management Plan shall be signed by the Investigator, the COIR Officer, and the chair of the COIR Committee.
- 8.5.3 The COIR Committee shall provide a copy of the Management Plan to the principal Investigator for oversight of compliance with the Management Plan.

- 8.5.4 If the Management Plan requires the Investigator to complete certain actions with regard to the Financial Conflict of Interest and/or significant COIR prior to engaging in the research project, the Investigator must notify the COIR Committee, the IRB (if applicable), the IACUC (if applicable), the IBC (if applicable), and other specified individuals that the Investigator has completed the required actions. Upon notification, the COIR Officer and the COIR Committee must then confirm that the Investigator is in compliance with the Management Plan. The Investigator may not engage in the research project until the COIR Officer and the COIR Committee have confirmed the Investigator's compliance with the Management Plan.
- 8.6 If the COIR Committee determines that the Financial Conflict of Interest and/or significant COIR constitutes an impermissible conflict of interest, the COIR Committee will submit its findings in writing to the Associate Dean for Research and Sponsored Programs for ultimate determination on the research project.
- 8.7 The COIR Committee shall document in writing any determinations made under Section 8.3 above, including the basis for those determinations. Final determinations of the COIR Committee will be made by majority vote of the entire COIR Committee.
- 8.8 If the proposed research project involves human subjects, the COIR Committee's written determinations, including the approved written Management Plan (if applicable), will be forwarded to the IRB for review. The IRB may request any additional information, including the SFID Forms, necessary to make its determinations. The COIR Officer will serve as a liaison to the IRB to facilitate review between the IRB and the COIR Committee. The IRB has the final authority to determine whether the proposed research project will be approved. No research project involving human subjects may commence until after any Financial Conflict of Interest and/or significant COIR has been reduced, managed, or eliminated to the satisfaction of the COIR Committee and the IRB. The IRB may impose more, but not less, stringent requirements than the COIR Committee.
- 8.9 If the proposed research project involves the use of animals, the COIR Committee's written determinations, including the approved written Management Plan (if applicable), will be forwarded to the IACUC for review. The IACUC may request any additional information, including the SFID Forms, necessary to make its determinations. The COIR Officer will serve as a liaison to the IACUC to facilitate review between the IACUC and the COIR Committee. The IACUC has the final authority to determine whether the proposed research project will be approved. No research project involving the use of animals may commence until after any Financial Conflict of Interest and/or significant COIR has been reduced, managed, or eliminated to the satisfaction of the COIR Committee and the IACUC. The IACUC may impose more, but not less, stringent requirements than the COIR Committee.
- 8.10 If the proposed research project involves the use of potential biohazards, the COIR Committee's written determinations, including the approved written Management Plan (if applicable), will be forwarded to the IBC for review. The IBC may request any additional information, including the SFID Forms, necessary to make its determinations. The COIR Officer will serve as a liaison to the IBC to facilitate review between the IBC and the COIR Committee. The IBC has the final authority to determine whether the proposed research project will be approved. No research project involving the use of potential biohazards may commence until any Financial Conflict of Interest and/or significant COIR has been reduced, managed, or eliminated to the satisfaction of the COIR Committee and the IBC. The IBC may impose more, but not less, stringent requirements than the COIR Committee.

## **9. APPEAL OF COIR COMMITTEE DETERMINATION**

- 9.1 The COIR Appeals Committee is comprised of the Vice President for Academic Affairs and Dean, the Vice President for Community Engagement, and the Vice President for Finance and Facilities.
- 9.2 An Investigator may appeal any written COIR Committee determination by submitting a written appeal to the Vice President for Academic Affairs and Dean for review by the COIR Appeals Committee. An appeal will not be considered by the COIR Appeals Committee unless it meets the following criteria:

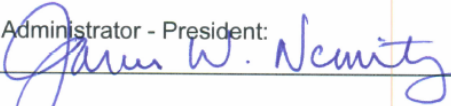
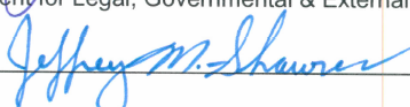
- 9.2.1 The written appeal must be received by the Vice President for Academic Affairs and Dean within ten (10) business days of the date of the COIR Committee's written determination being appealed. The written appeal may be submitted in person or electronically.
- 9.2.2 The appeal must be based upon one or more of the following grounds only:
- a. The determination of the COIR Committee was arbitrary, capricious, or biased;
  - b. The determination of the COIR Committee was based on a procedural or substantive error;  
or
  - c. New information exists that was unavailable to the COIR Committee in making its determination that could substantially impact the COIR Committee's determination (a detailed description of the new information and its potential impact on the determination must be included).
- 9.3 If the COIR Appeals Committee determines that the appeal does not comply with Section 9.2 above, the COIR Appeals Committee shall deny the appeal and the COIR Committee's determination will stand. The COIR Appeals Committee shall provide to the Investigator who submitted the appeal a written denial setting forth why the appeal failed to comply with Section 9.2 above. The written denial shall be provided within five (5) business days of receipt of the written appeal, and may be provided electronically.
- 9.4 If the COIR Appeals Committee determines that the appeal does comply with Section 9.2 above, the COIR Appeals Committee shall accept the appeal for review and shall notify the Investigator and the principal Investigator in writing that the appeal is pending. The COIR Appeals Committee may consult with any relevant individuals it deems appropriate in reaching a decision on the appeal. The COIR Appeals Committee shall provide to the Investigator who submitted the appeal a written decision setting forth: (a) how the appeal was addressed; (b) steps that must be followed by the COIR Committee, the Investigator, or others, if applicable; (c) deadlines for completion of those steps, if any; and (d) any other information deemed relevant to the appeal and decision. The written decision shall be provided within fifteen (15) business days of receipt of the written appeal, and may be provided electronically.
- 9.5 The COIR Appeals Committee shall provide a copy of its written denial or decision to the COIR Officer and the COIR Committee and, if applicable, to the IRB, the IACUC, or the IBC, within the applicable deadline set forth above.
- 9.6 The written denial or decision of the COIR Appeals Committee shall be final.

## **10. VIOLATIONS AND SANCTIONS**

- 10.1 The COIR Committee shall review and investigate all reported alleged violations of Institutional Policy R-04 and this procedure, including but not limited to: (a) failure to make a required report, disclosure, or certification; (b) the provision of incomplete or inaccurate information in any report, disclosure, or certification; (c) failure to update a disclosure or certification when required to do so; (d) non-compliance with an established Management Plan; (e) failure to provide timely annual report information or other required information; (f) noncompliance with any directive of the COIR Officer, the COIR Committee, the IRB, the IACUC, or the IBC; or (f) failure to comply with any other requirement of Institutional Policy R-04 or this procedure.
- 10.2 If the COIR Committee determines that a violation of Institutional Policy R-04 or this procedure did not occur, the COIR Committee will file its written determination with the original report of alleged violation and close the file. The written determination must be made within fifteen (15) business days of receipt of the reported alleged violation.

- 10.3 If the COIR Committee determines that a violation of Institutional Policy R-04 or this procedure did occur, the COIR Committee will provide written notification to the Investigator, the PI, the IRB (if applicable), the IACUC (if applicable), the IBC (if applicable), and the applicable WVSOM administrator (for administrative action determination, if any, under Section 10.9 below) specifying the following: (a) action(s) that constituted a violation of Institutional Policy R-04 and/or this procedure; (b) the applicable policy and/or procedure section(s); (c) corrective action required of the Investigator and the timeframe for compliance; (d) whether the research project should be allowed to continue or be suspended (final determination of continuation or suspension of the research project shall be made by the IRB, the IACUC, or the IBC, as applicable); and (e) any other information deemed relevant to the violation. The written notification shall be provided within fifteen (15) business days of receipt of the reported alleged violation, and may be provided electronically.
- 10.4 The Investigator may appeal the notification of violation by submitting a written appeal to the Vice President for Academic Affairs and Dean for review by the COIR Appeals Committee. An appeal will not be considered by the COIR Appeals Committee unless it meets the following criteria:
- 10.4.1 The written appeal must be received by the Vice President for Academic Affairs and Dean within ten (10) business days of the date of the COIR Committee's written notification of violation. The written appeal may be submitted in person or electronically.
- 10.4.2 The appeal must be based upon one or more of the following grounds only:
- a. The determination of the COIR Committee was arbitrary, capricious, or biased;
  - b. The determination of the COIR Committee was based on a procedural or substantive error;  
or
  - c. New information exists that was unavailable to the COIR Committee in making its determination that could substantially impact the COIR Committee's determination (a detailed description of the new information and its potential impact on the determination must be included).
- 10.5 If the COIR Appeals Committee determines that the appeal does not comply with Section 10.4 above, the COIR Appeals Committee shall deny the appeal and the COIR Committee's determination of violation will stand. The COIR Appeals Committee shall provide to the Investigator a written denial setting forth why the appeal failed to comply with Section 10.4 above. The written denial shall be provided within five (5) business days of receipt of the written appeal, and may be provided electronically.
- 10.6 If the COIR Appeals Committee determines that the appeal does comply with Section 10.4 above, the COIR Appeals Committee shall accept the appeal for review. The COIR Appeals Committee may consult with any relevant individuals it deems appropriate in reaching a decision on the appeal. The COIR Appeals Committee shall provide to the Investigator who submitted the appeal a written decision setting forth: (a) how the appeal was addressed; (b) whether the Investigator violated Institutional Policy R-04 or this procedure, including applicable section(s); (c) corrective action required of the Investigator, if any, and the timeframe for compliance, if applicable; (d) whether the research project should be allowed to continue or be suspended (final determination of continuation or suspension of the research project shall be made by the IRB, the IACUC, or the IBC, as applicable); and (e) any other information deemed relevant to the alleged violation, appeal, and decision. The written decision shall be provided within fifteen (15) business days of receipt of the written appeal, and may be provided electronically.
- 10.7 The COIR Appeals Committee shall provide a copy of its written denial or decision to the COIR Officer, the COIR Committee, the PI, and the applicable WVSOM administrator (for administrative action determination, if any, under Section 10.9 below) within the applicable deadline set forth above.
- 10.8 The written denial or decision of the COIR Appeals Committee shall be final.

- 10.9 In addition to any corrective action required by the COIR Committee or the COIR Appeals Committee, as applicable, any Investigator ultimately determined to have violated Institutional Policy R-04 or this procedure may be subject to administrative action, including but not limited to the following:
- 10.9.1 Inclusion in the violating Investigator's personnel file of a letter from the appropriate administrator indicating censure, warning, or other documentation of violation;
  - 10.9.2 Ineligibility of the violating Investigator to (a) submit an application for funding to the WVSOM Office of Research and Sponsored Programs; (b) submit a protocol to the IRB, the IACUC, or the IBC; and/or (c) conduct research;
  - 10.9.3 Unpaid suspension;
  - 10.9.4 Non-renewal of appointment, contract, or agreement; and/or
  - 10.9.5 Termination of employment, dismissal from WVSOM, or termination of any applicable contract or agreement.
- 10.10 In the case of PHS-funded research:
- 10.10.1 If the failure of an Investigator to comply with Institutional Policy R-04 or this procedure appears to the COIR Officer to have biased the design, conduct, or reporting of the PHS-funded research, the COIR Officer shall promptly notify the PHS Awarding Component that issued the award of the corrective action taken or to be taken, as required by PHS regulations.
  - 10.10.2 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, could not be Managed, or was not reported by WVSOM in accordance with PHS regulations and Institutional Policy R-04, 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.

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