

Conflict of Interest in Research Committee (CIRC)

Procedural Guidelines

I. Administration

- A. The Vice President for Research and Economic Development shall appoint a Conflict of Interest in Research (COIR) Officer.
- B. The COIR Officer shall be responsible for administering the Conflict of Interest in Research Guidelines.
- C. The COIR Officer shall provide staff support for implementation of the Guidelines and assistance to University employees in identifying, managing, or eliminating any COIR and shall periodically inform and educate the University community about the Guidelines and other issues relating to COIR.
- D. The COIR Officer shall be responsible for providing reports to outside funding agencies as may be required by Federal regulations or the terms of sponsored research agreements.
- E. The CIRC will be established and function as follows:

COIR Officer

The COIR Officer shall review all Disclosure of Interest in Research forms and determine in his/her professional judgment whether any further action should be taken to manage, reduce, or eliminate a potential COIR. If the COIR Officer determines that the potential or perceived COIR requires management beyond mere disclosure, (s)he will convene the CIRC to create a management plan. The CIRC will be provided and will review all necessary information to be able to develop an appropriate COIR management plan to meet all applicable regulatory requirements. The CIRC, as part of developing the management plan, will obtain information from the investigator in order to understand the nature of the financial interest and the conflict of interest, and to consider various potential courses of action.

Reporting Relationship: COIR Officer and CIRC

In the organizational structure, the CIRC is autonomous but has a communication and advisory relationship with the Vice President for Research; the CIRC does not report to the COIR Officer. The COIR Officer is responsible for administering the COIR Guidelines and making the initial determination if a conflict of interest needs to be referred to the CIRC. The COIR Officer shall receive direction from the CIRC Chair with regard to specific cases. Administratively, the COIR Officer reports to the Director of the Office of Research Integrity and Compliance.

CIRC

A CIRC is established to review and manage conflicts of interest that arise in research and related activities in light of federal, state, and University rules, laws, and administrative requirements.

1. **CIRC Duties** The CIRC is charged with the following duties and responsibilities:

- a) Provide oversight and review of research-related conflicts of interest;
- b) Develop management plans to manage, reduce, or eliminate conflicts of interest that arise in the conduct of research, in light of federal, state, and University rules, laws, and administrative requirements;
- c) Periodically review the COIR Guidelines and operating procedures, and make recommendations for change, as needed; and
- d) Collaborate with Office of Research Integrity and Compliance staff to ensure timely communication with faculty and compliance-related reporting.

2. **CIRC Composition**

The CIRC shall be composed of 7 voting members (3 faculty representatives and 4 representatives from the Deans of the Eberly College of Arts & Sciences; the Davis College of Agriculture, Natural Resources, and Design; the College of Engineering and Mineral Resources; and the Robert C. Byrd Health Sciences Center) and 4 ex-officio, nonvoting members selected by the Vice President for Research which shall include representatives from the WVU General Counsel's Office; WVU Research Corporation's General Counsel; a representative designated by the Chancellor of Health Sciences; and the Office of Research Integrity and Compliance Director, who will serve as the COIR Officer. All 7 voting members must be tenured/tenure-track faculty with a University academic appointment. Deans from each school will make a recommendation to the Vice President for Research as to the representatives from their respective schools; the Vice President for Research will then choose the representatives with due consideration of the Deans' recommendations. The 3 at-large faculty representatives will also be appointed by the Vice President for Research at his/her discretion based on achieving fair University representation.

3. Membership Term

CIRC members shall serve for a fixed term of three (3) years, commencing July 1st and terminating June 30th. New members shall be selected by the Vice President for Research as described above.

4. Quorum

The CIRC Chair, or her/his designee, shall preside at all meetings. A quorum is required for Committee business to be conducted. The participation of at least 4 voting members constitutes a quorum.

5. Voting

No regular motion before the CIRC shall pass unless a majority of the votes is in favor of the motion.

6. Meeting Schedule

The CIRC shall have regular, monthly meetings during the calendar year, as needed. Meetings may be conducted telephonically or electronically at the discretion of the CIRC Chair, as long as quorum is met.

7. Meeting Minutes

The COIR Officer, or his/her designee, shall prepare meeting minutes and present them for approval at the next scheduled CIRC meeting. All minutes will be maintained by the COIR Officer.

II. Communication of the Recommendations and the Management Plan

• **Communication with the WVU Institutional Review Board**

The CIRC shall provide a copy of its report on matters before it that involve IRB issues to the WVU IRB concurrently with the delivery of that report to the COIR Officer. The WVU IRB shall review such report prior to any approval from that body of the research protocol.

• **Other Communication**

A finding of a conflict of interest in a matter in which the University is aware of a significant impact on third parties may dictate provision of a copy of the CIRC report to such parties. An example is pending action of a commercial nature by the WVU Office of Technology Transfer. It would be appropriate to provide a copy of

the CIRC report to that office so that it could determine whether a commercial arrangement with any appropriate restrictions is needed.

III. Questions for Disclosure Review and Determination

Presented below are questions that should be utilized by anybody evaluating a potential case of conflict of interest. This list is not exhaustive and other questions appropriate for special circumstances should be added.

When presented with the facts of a given situation, the reviewer must first determine if there is legitimate cause for concern over inappropriate behavior or the injection of undue bias into the professional activities of the employee. Initial questions might include:

- Has all relevant information concerning the investigator's activities been acquired (i.e., has there been full disclosure)?
- Do the investigator's relevant financial interests exceed predetermined thresholds of acceptability, where specified?
- Is there any indication that research results have not been faithfully and accurately reported? Have results been withheld or modified to create financial gain?
- Is there any indication that the investigator in his or her professional role has improperly favored an outside entity or appears to have incentive to do so?
- Has the investigator inappropriately represented the University to outside entities?
- Does the investigator appear to be subject to incentives that might lead to inappropriate bias?
- Is the investigator involved in a situation similar to any of those described earlier that might raise questions of bias, self-dealing, inappropriate use of University assets, poor data management, or impropriety?
- Could the investigator's circumstances represent any possible violation of federal, state, or local laws and requirements?
- Do the current engagements of the investigator present any conflicts between outside interests (e.g. working on projects simultaneously for competing business entities)?

If it appears that there is genuine cause for concern, the reviewer(s) must ascertain whether appropriate controls are in place to deal with possible conflicts. The reviewer should ask, as relevant,

- Will the negotiation of relevant research affiliations or other contracts, be handled by truly disinterested representatives of the University?
- Will the research work plan receive independent peer review prior to its initiation?
- Are there mechanisms in place to prevent the introduction of bias into the research projects (i.e., Is the protocol double-blinded? Are research subjects randomly selected?)?
- Will the project be supervised by someone with authority and no conflicting interests?
- Are there means to verify research results (e.g., independent corroboration in another lab, FDA review)?

- Will data and materials be shared openly with independent researchers? If not, who determines accessibility to such resources?
- Will the product of the collaborative effort with an outside party be published in the peer-reviewed scientific literature?
- Will the sponsorship and relevant interests receive acknowledgement in public presentations of the research results?

The goal in applying these questions should be to determine the correct mode for dealing with any real or apparent conflicts as discussed earlier.

IV. Noncompliance, Appeal Mechanisms, and Sanctions

A. The COIR Officer shall report to the CIRC any filing party who he/she believes has:

1. Failed to file a required report after specific notification, or knowingly files a false or misleading report;
2. Refused to cooperate with the COIR Officer to resolve a potential conflict of interest;
3. Knowingly failed to observe the terms of a management plan agreed to by the filing party or that was established by the CIRC; or
4. Participated in an activity or transaction that has been found by the CIRC to be a conflict of interest for which no satisfactory management plan can be developed.

B. The CIRC shall review the report and attempt to resolve the matter. If a resolution is not achieved, and if the CIRC determines that a violation of University rules may have occurred, the Committee may initiate such action or disciplinary procedure as may be indicated after consultation and approval of the Vice President for Research and the WVU Office of the General Counsel.

Failure to comply with the Guidelines may result in action against the employee under University policy or state law. If the conflict of interest involves a research project administered by the University, whether or not that administration is through the WVU Research Corporation, any action legally required by the funding agency will also be taken. Review of the decision of the CIRC may be pursued by the investigator/filing party through the appeal mechanism as follows:

V. Appeal Procedures

Introduction: If an investigator disagrees with any CIRC decision or action, he/she may request reconsideration by either appearing before the CIRC or by requesting a review by an Advisory Review Panel. This request must be made to the CIRC, in writing, within seven (7) calendar days of the investigator's receipt of the CIRC's notification.

Procedure: The entire appeal process must be completed within one hundred twenty (120) calendar days of the investigator's receipt of the CIRC's notification to suspend or terminate a study. The decision of the CIRC becomes final under any of the following circumstances:

- The investigator chooses not to appeal.
- The investigator fails to notify the CIRC of a decision to appeal within seven (7) calendar days of receipt of the Committee's notification.
- The investigator or a representative fails to appear before the Committee at its next regularly scheduled meeting.
- The investigator fails to request the formation of an Advisory Review Panel within seven (7) calendar days after appearing before the CIRC.
- The investigator fails to make documents concerning the study available to the Advisory Review Panel within seven (7) calendar days of being requested to do so.

The Committee will notify all appropriate parties of the outcome of an appeal.

Investigator Appears before the CIRC: An investigator may ask to appear before the CIRC to request reconsideration of a decision. Based on this meeting, the CIRC may affirm, modify, or reverse its original decision. Within seven (7) calendar days after the meeting, the CIRC will notify the investigator of its decision. If the investigator is still dissatisfied, he/she has seven (7) calendar days from receipt of the decision to request (in writing to the CIRC) formation of an Advisory Review Panel.

Advisory Review Panel: An investigator may request reconsideration based on the report of an Advisory Review Panel. The Advisory Review Panel must be formed within fifteen (15) calendar days of the investigator's request for its formation.

Composition: An Advisory Review Panel shall consist of three persons:

- One member chosen by the CIRC with expertise in research integrity (this person may not be a current member of the CIRC);
- One member chosen by the investigator (this person must not be a member of the investigator's academic department and may not have had any direct involvement in the activities in question); and
- One member chosen by the Vice President for Research (this person will serve as Chair, may not be a current member of the CIRC, may not be a member of the investigator's academic department, and may not have had any direct involvement in the activities in question.)

Meeting and Report:

Within thirty (30) calendar days of its formation, the Advisory Review Panel will complete its investigation and transmit to the CIRC Chair a written report of its findings and recommendations. During its investigation, the panel may involve the

WVU Office of the General Counsel. The CIRC will consider this report at a regular or special meeting held within thirty (30) calendar days of the Chair's receipt of the report. The CIRC will provide written notice (within seven (7) calendar days) of its decision to the appropriate investigator(s), department chair(s), members of the Advisory Review Panel, and others as deemed appropriate.

CIRC Determination: The CIRC's determination whether to accept the Advisory Review Panel's recommendation will constitute the final decision regarding the investigator's appeal.

Failure to comply with the determinations of the CIRC will be forwarded to the Academic Integrity Committee and the Provost.

- **For PHS-funded research:** If the investigator/filing party has biased the research, the University (or the Vice President for Research, through the COIR Officer) is required to promptly notify the PHS awarding component of the corrective action taken or to be taken.
- Also, if the DHHS determines that a PHS-funded project to evaluate a drug, medical device or treatment was conducted by an investigator with a conflict that was not disclosed or managed, the University requires the investigator to disclose the conflict in each public presentation of the results of the research.

VI. Relevant References

1. Federal Law and Regulation Relevant to the Guidelines: 18 U.S.C. § 201-209 (or 18 U.S.C. § 208), 5 C.F.R. § 2635.201-205, 26 U.S.C. § 501(c)(3), 42 C.F.R. § 601-607, 45 C.F.R. § 94.1-94.6, 42 C.F.R. § 50(F), 21 C.F.R. § 54.
2. West Virginia Law and Regulation Relevant to the Guidelines: W.Va. Code § 6B-2-5 through §6B-2-8, 158 C.S.R. § 4,158 C.S.R. § 6 through 8,128 C.S.R. 36.
3. West Virginia University Policies Relevant to the Guidelines:; Office of Technology Transfer Policies, West Virginia University IRB Guidelines, WVU-HR-18 (Hiring of Relatives), Disclosure Form, Other WVU Policies
4. AAMC Guidelines
5. Form FDA 3455 (10/09)