

MARSHALL UNIVERSITY BOARD OF GOVERNORS

Rule No. AA-11

INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH

1 General Information.

- 1.1 Scope: This policy applies to any situation involving research where there are actual or potential conflicts involving University officials who have the authority to make research decisions with institution-wide implications, and who hold positions with, or have financial interests in, entities that have an interest in University-sponsored research.
- 1.2 Authority: W. Va. Code §18B-1-6
- 1.3 Passage Date: December 19, 2019
- 1.4 Effective Date: January 28, 2020
- 1.5 History:
 - 1.5.1 This policy amends a previous version of AA-44 approved by the Board on October 21, 2010. This policy is in addition to MUBOG Policy AA-41 Individual Conflict of Interest in Research. As a requirement of the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), this policy has been created by the Office of Research Integrity and reviewed and approved by the Conflict of Interest in Research Committee. The current policy was updated and approved by the Marshall University Board of Governors on December 19, 2019.

2 Introduction.

- 2.1 It is the policy of Marshall University to ensure that its human and non-human subject research (hereinafter referred to only as “research” unless specifically stated) is conducted with integrity and is free from any actual or apparent institutional conflict of interest in research. This policy establishes the principles and procedures that enable the University to identify and avoid institutional conflicts of interest of a financial nature that present a significant risk to the perceived or actual objectivity of such research. The purpose of this policy is to provide a process by which the University can ensure that the decision-making processes for its financial and research activities related to research are separate; and that they are independently managed and monitored to avoid any institutional conflict of interest.

3 Definitions.

- 3.1 **Associate:** includes a University official’s spouse, parents, siblings, children, domestic partner and any other relative if the latter resides in the same household or is financially dependent upon the University official.
- 3.2 **Affiliation:** includes any trust, organization or enterprise (of a business nature or otherwise) with respect to which the University Official (1) is a director, officer, employee, member, partner, or trustee, or (2) has significant financial interest or any other interest which enables them to exercise control or significantly influence policy.
- 3.3 **Business Entity:** means any entity recognized by law through which business for profit is conducted, including a sole proprietorship, partnership, firm, corporation, holding company, joint stock company receivership, or trust.

3.4 **Human Subject Research** occurs when:

3.4.1 Under DHHS regulations research is defined as a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.

- A human subject under DHHS regulations is defined as living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

3.4.2 Under FDA regulations research is any experiment that involves a test article and one or more human subjects, and that either is subject to requirements for prior submission to the FDA.

- A human subject under FDA regulations is defined as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A participant may either be a healthy human or a patient.

3.5 **Non-human Subject Research:** occurs when research does not fall under DHHS or FDA guidelines listed above.

3.6 **Institutional Conflict of Interest in Research:** can occur whenever the external financial interests or business relationships of the University or of one of its officials are such that their actions could affect, or could reasonably appear to affect, the conduct, review or oversight of the University's research. The potential for institutional conflict of interest in research that could compromise the integrity of the University's research mission generally arises in one of the two situations described below:

3.6.1 When the University holds a patent, license, or right to royalties on a process, technique, or production that it licenses to external companies, which in turn use University employees to conduct research on that process, technique or product; or

3.6.2 When a University official, with the authority to act on behalf of the University and to make decisions that have institution-wide implications, or whose decisions could reasonably be seen as affecting the conduct, review, or oversight of research, holds a significant financial interest in, consults for, serves on the board of, or is otherwise expected to act for the benefit of an entity that has a financial interest in University-sponsored research.

3.7 **Significant Financial Interest in a Business Entity:** means (1) a controlling interest; (2) ownership of more than 5% of the voting interest; (3) ownership of more than 5% of the fair market value; (4) a direct or indirect participating interest by share, stock, or otherwise, regardless of whether voting rights are included, in more than 5% of the profits, proceeds or capital gains; (5) service as a member of the board of directors or other governing board; including a trustee or advisory director; (6) service as an officer; or (7) service as an employee.

3.8 **University Official:** is defined as an individual who, because of their position with the University, has the capacity to affect, or can reasonably appear to affect, University processes for the conduct, review or oversight of research. Such officials include the President, Provost, Vice Presidents, Associate Vice Presidents, Deans, Department Chairs, and Directors of Organized Research Units.

4 Procedures for Disclosure, Review, and Responding to Information Reflecting Institutional Conflict of Interest in Research.

4.1 The Vice President for Research (VPR) has the responsibility for overseeing the process for

reviewing, resolving and monitoring institutional conflict of interest in research that may arise from the business relationships of the University or its officials and/or their associates/affiliations with outside entities. Disclosures that may identify actual or potential institutional conflict of interest in research shall be handled as provided in Section 4.6 below.

4.2 Disclosure of University Financial or Business Relationships

4.2.1 The University's Technology Transfer Office (TTO), which serves as a bridge between University-sponsored research and commercialization partners, shall provide the Office of the VPR with annual reports that disclose the entities in which the University holds equity positions or from which it has the right to receive royalty payments.

4.3 Disclosure of Officials' Financial or Business Relationships

4.3.1 University officials, as defined by this policy, shall submit a "Significant Financial Interest Disclosure (SFID)" filed annually with the Office of the VPR, providing information concerning any significant financial interest in, or position held with a business entity. The VPR or delegate shall review the statements and identify any situations where an actual or potential institutional conflict of interest in research exists and respond as provided in Section 4.6 below.

4.4 The General Counsel shall review the VPR's own SFID for any institutional conflict of interest in research; and, pursuant to Section 4.6 below, will notify the VPR of the need to either:

4.4.1 Totally divest themselves of the financial interest; and/or

4.4.2 Resign from the board or other position with the external entity that has a financial interest in University research.

4.5 Review of Disclosure Information

4.5.1 The Office of Research Integrity (ORI) assists, supports, and reviews all proposed human subjects research. The VPR shall provide the director of ORI with copies of the SFIDs received annually, and with the annual reports received from the Technology Transfer Office.

4.5.2 The ORI director shall review all proposed human subjects research proposals it receives with the disclosure information provided by the VPR to identify any actual or potential institutional conflict of interest present in the proposals. The ORI director shall refer any research proposals for which an actual or potential institutional conflict of interest in research has been identified to the VPR for a response pursuant to Section 4.6 below. Once the institutional conflict of interest in research is resolved, the affected proposal shall be returned to ORI for review by the University's Institutional Review Board.

4.6 Acting upon Information Reflecting Actual or Apparent Institutional Conflict of Interest in Research

4.6.1 Actual or Apparent Conflict of Interest in Research of the President, Provost, or the VPR:

If the President, Provost, or the VPR is found to have an actual or apparent institutional conflict of interest in research, they shall either

- 4.6.1.1 Totally divest themselves of the financial interest; and/ or
- 4.6.1.2 Resign from the board or other position with the external entity that has a financial interest in University-sponsored research. Proposed research cannot be approved or continued until such action is taken by the affected official.
- 4.6.2 All other Institutional Conflicts of Interest in Research
 - 4.6.2.1 The VPR shall appoint an Institutional Conflict of Interest in Research Committee, which shall consult with the VPR where other actual or apparent institutional conflicts of interest are identified to determine whether to:
 - 4.6.2.1.1 Develop an institutional conflict of interest in research (ICOIR) management plan, if feasible.
OR, if not feasible, to:
 - 4.6.2.1.2 Require the TTO to divest the University's current equity holdings or right to royalties; and its right to acquire equity holdings in the future;
 - 4.6.2.1.3 Propose modifications to the proposed research that would remove the possibility that the University, or any of its units or officials, would benefit financially from the results of the proposed research;
 - 4.6.2.1.4 Prohibit the proposed research when in the best interests of the public or the University, upon recommendation from the Director of the Office of Research Integrity;
 - 4.6.2.1.5 Direct that the University official who holds a significant financial interest divest themselves of that interest, or remove themselves from the decision process involving such research;
- 4.7 Monitoring the Conflict of Interest in Research Process
 - 4.7.1 The Institutional Conflict of Interest in Research Committee shall monitor the Institutional Conflict of Interest in Research Process. It shall meet as required but not less than annually to:
 - 4.7.1.1 Ensure that University Officials are in compliance with the disclosure obligations of this policy;
 - 4.7.1.2 Review and propose to the VPR modifications to the plans for managing institutional conflict of interest in research.

Any member of the ICOIR committee who has a financial interest in or serves as a paid consultant for an entity that is involved in a research proposal shall not participate in the review under this policy.

5 Delegation of Authority for Compliance with Policy.

- 5.1 The President delegates the VPR as the University Official responsible for interpreting and overseeing implementation of and compliance with this Policy.