

MARSHALL UNIVERSITY BOARD OF GOVERNORS

Policy No. AA-41

INDIVIDUAL CONFLICT OF INTEREST IN RESEARCH

1 General Information:

Marshall University is a community of scholars, students and staff dedicated to the preservation, dissemination and creation of knowledge. The research component of this effort has as one of its goals discoveries that benefit society. This knowledge transfer inevitably leads to increasingly close relationships between the University, and its researchers, and those with financial resources for investment in the private sector. The benefits that can accrue from this proximity are accompanied by real and/or apparent risks that economic interests might compromise academic research by influencing an investigator's judgment about the design, conduct, results, reporting, or management of the project, and, in the case of research involving human subjects, place at risk the safety of participants.

The University recognizes that commercialization of research is important but must be done in ways that protect research integrity. The vast majority of Marshall scholars and staff are honest and conduct research with the highest standards and integrity. For this reason, the University establishes this conflict of interest policy to guide its investigators in structuring relationships with outside ventures so that they are compatible with academic responsibilities. While not all conflicts of interest are inherently wrong, they involve a continuum of activities from benign actions that actually further research and technology transfer to egregious misconduct. This policy is not intended to eliminate all conflict of interests, but rather to enable investigators to recognize situations that may be subject to question and resolve them before personal and institutional integrity are questioned or impugned.

- 1.1 Scope: Marshall University, its faculty, and other members of the University research community commit themselves to the pursuit of the University's research mission in accordance with the highest standards of integrity and in compliance with all legal, professional, ethical and other requirements that promote objectivity and protect against conflicts of interests, financial and otherwise. These policies and procedures will permit faculty, staff members and students to identify, evaluate, correct, remove or manage real or apparent and potential conflicts of interest. The appearance that a conflict of interest may exist is as important as the reality. Accordingly, the first essential step in all of the procedures set forth below is disclosure and discussion. The University will publish this policy so that it is known to all investigators. In making application for external funding for research grants and contracts, investigators will be required to certify that they have read and understand this policy.
- 1.2 Authority: WV Code §18B-1-6, §6B-2-5 through §6B-2-8, 158CSR4, 158CSR6, 128CSR36. Federal, state, and institutional regulations ([Appendix 1](#)) require Marshall to have policies and procedures that ensure that investigators disclose any significant financial interests that may present an actual or potential conflict of interest in relationship to sponsored research projects. Such disclosure must be made prior to the submission of a proposal for funding, as well as at the time a potential conflict develops during the conduct of a funded project.
- 1.3 Passage Date: June 28, 2006
- 1.4 Effective date: June 28, 2006

- 1.4.1. The policy will be reviewed every two years as a minimum and revised as needed.
- 1.5 Controlling over: The purpose of this policy is to avoid both actual and apparent conflicts of interest between the obligations faculty, staff and students have to the University and those that arise from external financial interests. This policy applies to all research activities conducted, sponsored, or administered by Marshall University and the Marshall University Research Corporation (MURC). It applies to all members of Marshall University, MURC and related organizations including all institutes and centers. This includes any person possessing either full-time or part-time appointment at Marshall, MURC and related organizations, receiving wages or benefits from same who is responsible for designing, conducting and reporting the results of research, education, public services or administrative activities. It includes individuals who have executive or principal responsibility for the accomplishment of project objectives, and those individuals, whether salaried or not salaried, who, on behalf of Marshall University, are responsible for conduct of the policy or business of the University, MURC or related organizations. Unless otherwise stated, the term “University” will be used hereafter to include Marshall University, MURC and all affiliated institutes and centers.
- 1.6 History:
 - 1.6.1. Statutory references: refer to Appendix 1.
 - 1.6.2. This policy replaces Interim Executive Policy Bulletin No. 10.

2 Definitions:

- 2.1 Associate: An associate of an investigator includes his or her spouse, parents, siblings, children, domestic partner and any other relative if the latter resides in the same household or is financially dependent upon the investigator. It also includes any person, trust, organization or enterprise (of a business nature or otherwise) with respect to which the investigator or any of the above (1) is a director, officer, employee, member, partner, or trustee, or (2) has significant financial interest or any other interest which enables him or her to exercise control or significantly influence policy.
- 2.2 Business: A business is any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, real estate trust, or any other nongovernmental legal entity organized for profit, not-for-profit, or charitable purposes.
- 2.3 Compelling Circumstances: These are facts that must be used to convince Marshall University’s Conflict of Interest Committee (See Conflict of Interest Committee, defined below.) that an investigator with significant financial interest should be permitted to conduct the research project. When considering a request by such an investigator, the circumstances that the Committee should evaluate include the nature of the research, the magnitude of the significant financial interest and the degree to which it is related to the research, the extent to which the interest can be directly and substantially affected by the research, and the degree of risk to the human subjects involved that is inherent in the research protocol. The Committee will also consider the extent to which the interest is amenable to effective oversight and management.
- 2.4 Conflict of Interest: An investigator is considered to have a personal conflict of interest when he/she or any of his/her family or associates either (1) has an existing or potential significant financial interest (or other material interest) which impairs, or might appear to impair, the investigator’s independence and objectivity of judgment in the design, conduct, or reporting of research, or (2) may receive a financial or other material benefit from knowledge of information confidential to the University.

- 2.5 Conflict of Interest Committee (COIC): The COIC is a standing committee of the University that provides second level review of an investigator's *Significant Financial Interest Disclosure (SFID) Form*. It reviews the SFID Form and makes recommendations concerning appropriate measures for the reduction, elimination or management of any potential financial conflict of interest relating to research. The COIC consists of seven members appointed by the Vice President for Research for staggered three-year renewable terms. The membership includes the Chair (Director of the Office of Research Integrity), three faculty/staff familiar with the ethical, legal and regulatory issues involved in the oversight of financial conflicts of interest in research, the Executive Director of MURC, one representative of the Marshall University Office of Technology Transfer, and one representative of the community with no current or past (within the last two years) affiliation with the University. The COIC reports to the Vice President for Research or his/her designee.
- 2.6 Conflict of Interest Specialist (COIS): A staff member of the Marshall University Office of Research Integrity who is specifically knowledgeable in the ethical, legal and regulatory issues involved in the identification, management and oversight of financial conflicts of interest in research. He/she will assist the investigator and designated institutional officials in the identification of potential conflicts of interests and the completion of the *Significant Financial Interest Disclosure Form*. The COIS will provide staff support for the Conflict of Interest Committee and be responsible for all related notifications, reporting and record keeping.
- 2.7 Designated University Official: The university official designated to complete the first level of review of an investigator's *Significant Financial Interest Disclosure (SFID) Form* and determine whether the research project reasonably appears to be affected by any reported conflicts of interests or conflicts of commitment. (See Significant Financial Interests, defined below.) These officials will be individuals with immediate supervisory responsibility for the person submitting the disclosure.
- 2.8 Executive Position: Executive position refers to any position that includes responsibilities and authority for a significant segment of the operation or management of a business.
- 2.9 Gift: A gift means any unrestricted donation of assets to Marshall University or any affiliate of Marshall University. The donor may specify the general purpose for which the gift may be used, but there may be no other terms and conditions concerning the use of such assets. Assets may be in the form of cash, securities, tangible personal property, partnership interests, or pledges for acceptable assets that are assigned to Marshall University. For the purposes of this policy, disclosure is required when a gift is from an individual or business in which an investigator has significant financial interest, or the value of the gift exceeds \$10,000 in a given year.
- 2.10 Investigator: Any Marshall University or MURC employee or student who is responsible for the design, conduct, or reporting of research. This includes the Principal Investigator, Co-investigators, and any other key research personnel who contribute in a substantive way to the development or execution of a project.
- 2.11 Management Plan: This is a written plan for the management, reduction or elimination of a known or potential financial conflict of interest related to research. It relies upon, and is therefore limited by, good faith disclosures about significant financial interests made in the *Significant Financial Interest Disclosure Form*, provided annually and ad hoc by Marshall University investigators.
- 2.12 Research: Research includes any systematic investigation designed to develop or contribute to generalized knowledge. The term includes clinical and health-related research, behavioral and social science research, and encompasses basic and applied research and product development. It

also includes both sponsored and non-sponsored research that involves the use of University personnel, patients, students, facilities, or resources, or the expenditure of University funds.

- 2.13 Significant Financial Interest: Significant financial interest includes, but is not limited to, any economic or monetary interest that is held either by the investigator (his/her family or associate) or any entity in which the investigator (his/her family or associate) has a financial or fiduciary interest. Appendix 2 provides a more detailed description of (1) types of significant financial interest that must be disclosed; (2) those types that are not considered significant financial interest and are not required to be disclosed; and (3) those interests and actions and affiliations that are prohibited by the University.
- 2.14 Sponsored Research Agreement: This is a contract or formal agreement between an outside sponsor and Marshall University or MURC.

3 Policy:

- 3.1 A *Significant Financial Interest Disclosure Form* is a written statement made, signed, and attested to by the investigator that identifies all significant financial interests (and those of his/her family and associates). This Disclosure must identify, describe, and state the nature and amount of the significant financial interest.
- 3.2 All Marshall investigators (principal investigators, co-investigators and key research staff) must fully disclose all significant financial interests for each sponsored research proposal prior to a proposal submission. The principal investigator must insure that all investigators on the proposal disclose their significant financial interests.
- 3.3 All investigators must provide updates of significant financial interests on an annual basis and within 30 days after they acquire new financial interests.
- 3.4 The *Significant Financial Interest Disclosure Form* is treated as confidential by the University to the extent allowed by law.

4 Disclosure: Records and Reporting:

- 4.1 Disclosure statements, other documentation used in the review of such statements, and records of institutional actions taken pursuant to this policy shall be maintained for a period of three years following the completion of the research project that generated the disclosure, for a period of time needed for resolution of government action involving such records, or for a period fixed by the VP for Research, whichever is longer. To the extent permitted by law, such records shall be maintained confidentially in the Office of Research Integrity.
- 4.2 Marshall University will make the information described in the preceding paragraph available, upon request, to external funding agencies, along with requested information as to how the relevant potential or actual conflict of interest was managed, reduced, or eliminated to protect the objectivity of the research. If a potential or actual conflict of interest is identified after a grant or contract has been awarded, the University will inform the awarding agency of that conflict within sixty days of its discovery (or as otherwise required by law) along with actions taken to manage, reduce, or eliminate the actual or potential conflict of interest.
- 4.3 If the University determines that it is unable to manage satisfactorily a potential or actual conflict of interest that threatens the objectivity of a particular research activity, the University will promptly inform the relevant external funding agencies of that fact.

5 Responsibilities and Administration: Disclosure Review and Appeal Processes

- 5.1 Levels of Review

- 5.1.1. The initial level of review begins with the identification of a potential significant financial interest by the investigator and submission of a *Significant Financial Interest Disclosure (SFID) Form* to his/her designated institutional official/immediate supervisor. The Conflict of Interest Specialist (COIS) can assist at this level, if needed.
- 5.1.2. If a potential significant financial interest is identified, the SFID Form is forwarded to the COIS who, in consultation with the Chair of the Conflict of Interest Committee, schedules the second level review by the Conflict of Interest Committee (COIC).
- 5.1.3. The COIC reviews the SFID Form to determine whether a real or apparent conflict of interest exists or has the potential to exist. The COIC may conclude that (1) no significant conflict of interest exists, (2) a significant conflict of interest exists but it can be managed, or (3) the conflict of interest cannot be effectively managed and the research project, as written is denied. If denied, it is then up to the PI to determine whether the project can be redesigned to resolve the conflict. If so, the PI must submit the amended plan to the COIC for reconsideration. If the COIC concludes the significant financial interest can be managed, it makes written recommendations concerning appropriate measures for the reduction, elimination or management of the conflict to the principal investigator, the initial level reviewer and the Vice President for Research or his/her designee.

5.2 IRB Notification

- 5.2.1. Special precautions must be taken to protect human research subjects and to avoid the appearance of or actual bias in clinical research involving evaluation of therapeutic strategies or products, particularly under circumstances when a commercial success may benefit of the University and its investigators. When an investigator is determined to have a significant financial interest, the details of that interest and a management plan, if any, shall be submitted to the appropriate Marshall University Institutional Review Board (IRB1 or IRB2) for approval.

5.3 Recommendations and Appeals

- 5.3.1. The Vice President for Research may accept the COIC report and recommendations, or return the matter to the COIC with stated concerns or suggestions. If the VP for Research accepts the COIC recommendations, documented compliance with all recommendations is required before the proposal will be authorized by MURC or Marshall University.
- 5.3.2. The principal investigator may appeal the decision of the COIC to the VP for Research, if he/she believes the COIC conclusions and recommendations are not justified. The VP for Research will respond to this appeal within 30 days. The decision of the VP for Research is final.

6 Management of conflicts of interest:

- 6.1 When the COIC concludes that the conflict of interest can be effectively managed, reduced or eliminated, a written management plan must be created by the COIS working with the principal investigator and relevant institutional official(s). For greater details of various management options, see **Appendix 3**.
- 6.2 Whenever Marshall undergraduate or graduate students are involved in the research, the management plan must describe mechanisms in place to protect their academic progress. A general outline of management of potential conflicts of interest involving students is provided in **Appendix 4**.

7 Sanctions

- 7.1 Violations of this policy include, but are not limited to, failure to file; intentionally filing an incomplete, erroneous, or misleading disclosure form; failure to provide additional information as requested; and intentionally tardy responses or a pattern of non-cooperation in responding to requests for additional information. If sanctions are necessary, they will be imposed in accordance with University policies and procedures as defined in *The Greenbook* (<http://www.marshall.edu/academic-affairs/The%20Greenbook/May2005GB.pdf>). Sanctions may include, but are not limited to:
- 7.1.1. Letter of reprimand or admonition;
 - 7.1.2. Suspension of the processing of any grant application made by the individual, or a declaration of ineligibility of the individual for future grant applications.
 - 7.1.3. Suspension of research contract negotiations involving the individual as investigator, or a declaration of ineligibility of the individual for future research contracts;
 - 7.1.4. Suspension or ineligibility of the individual for IRB approval or for supervision of graduate students;
 - 7.1.5. Removal as principal or co-principal investigator in respect to any current research activity;
 - 7.1.6. Suspension;
 - 7.1.7. Non-renewal of appointment; or
 - 7.1.8. Dismissal.

APPENDIX 1

RELEVANT REFERENCES

Federal

- Public Health Service (PHS) Federal Register July 11, 1995
http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=35810&dbname=1995_register
- National Science Foundation (NSF), Federal Register July 11, 1995
http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=35820&dbname=1995_register
- PHS Policy Title 42, Part 50, Subpart F
http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm
- National Institutes of Health (NIH) Grants Policy Statement
http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm#_Toc54600065
- NSF Grant Policy Manual Notice
http://www.nsf.gov/pubs/2002/nsf02151/gpm02_151.doc
- Food and Drug Administration (FDA), Federal Register February 2, 1998 “Financial Disclosure by Clinical Investigators” http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=5233&dbname=1998_register

West Virginia (www.wv.gov)

- WV Code §6B-2-5 through §6B-2-8
<http://www.legis.state.wv.us/WVCODE/06b/masterfrmFRM.htm>
- WV Code of State Rules 158CSR4, 158CSR6, 128CSR36
<http://www.wvsos.com/csr/verify.asp?TitleSeries=158-04>
<http://www.wvsos.com/csr/verify.asp?TitleSeries=158-06>
<http://www.wvsos.com/csr/verify.asp?TitleSeries=128-36>

(Note: To search from the main WV State web site, go to “How do I?” and click on links to Search WV Code or Search Code of State Rules for appropriate sections)

Marshall University

- MURC Handbook <http://www.marshall.edu/cos/MURCEmpHandBook.pdf>
- Classified Staff Handbook <http://www.marshall.edu/human-resources/handbook/contents.htm>

- Marshall University *Greenbook* <http://www.marshall.edu/www/greenbook/>
- Office of Research Integrity for IRB members
<http://www.marshall.edu/research/ori/Sops/ConflictofInterest.htm>

Other

- Association of American Universities, Taskforce on Research Accountability, *Report on Individual and Institutional Financial Conflicts of Interests*, Washington, D.C., 2001, <http://www.aau.edu/research/COI.01.pdf>
- Association of American Medical Colleges, Taskforce on Conflicts of Interests in Clinical Research, *Protecting Subjects, Preserving Trust, Promoting Progress: Policies and Guidelines for the Oversight of Individual Financial Interests in Human Subject Research*, Washington, D.C., 2001, <http://www.aamc.org/members/coitf/firstreport.pdf>

APPENDIX 2
SIGNIFICANT FINANCIAL INTERESTS

1. Significant Financial Interests that must be reported

A. "*Compensation interest*," meaning salary, consulting fees, wages, retainers, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts or other emoluments, "in kind" compensation from a financially interested company (or entitlement to the same), or any other thing of economic or monetary value whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the past 12 (twelve) months exceeded \$10,000, or are expected to exceed that amount in the next twelve months;

B. "*Equity interest*," meaning (1) any ownership (or entitlement to the same), in a publicly-traded financially interested entity that exceeds \$10,000 in value or represents more than 5% ownership interest in any single entity (see exclusions below), or (2) equity interests, including stock options, warrants, or other convertible securities, of any amount in a non-publicly-traded financially interested entity (or entitlement to the same);

C. "*Intellectual property interest*" meaning (1) royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work; or (2) any other direct or indirect interest in a patent, trademark, copyright, trade secret, know-how or other intellectual property right where the research is directly related to the interest;

D. "*Extraneous research payments*," meaning any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution), including any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested entity or from the institution;

E. "*Fiduciary relationship*," meaning service as an officer, director, or in any other fiduciary role for a financially interested entity, whether or not remuneration is received for such service.

2. Financial Interests that do not need to be reported

A. "*Mutual fund interests*," meaning interests of any amount in publicly traded, diversified mutual funds;

B. "*De minimis equity interests*," meaning stock or stock options in a publicly traded company that, when aggregated for the investigator (and/or his or her immediate family members) meets both the following tests: it does not exceed \$10,000 in value (as measured in reference to public prices or other reasonable measure of fair market value) and does not represent more than a 5% ownership interest in any single entity;

C. "*Outside payments*," meaning salary, royalties, and other payments from entities other than the University, or via the University to the individual, that when aggregated for the investigator (and/or his or her immediate family members), over the next 12 months, are not expected to exceed \$10,000;

D. "*Regular research payments*," meaning payments to the University, or via the University to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement between the sponsor and the University;

E. "*University compensation*," meaning salary, royalties, and other remuneration for services from the University;

F. "*Public or non-profit income*," meaning income for service on advisory committees or review panels for public or non-profit entities, or from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.

3. Prohibited Situations

A. Marshall investigators cannot purchase goods and services for the University from an entity in which the individual or his/her family or associates has a significant financial interest.

B. Investigators responsible for, or who may influence purchasing decisions or contracting on behalf of Marshall University, must comply with all University policies and applicable state law (<http://www.marshall.edu/purchasing/>).

C. Investigators may not enter into a patent, copyright, trademark or sponsored research agreement with a business or government agency without the written approval of the VP for Research or his/her designee, if the invention is covered under Marshall University Intellectual Property Policy (www.marshall.edu/president/Board/policies/19.pdf).

APPENDIX 3

MANAGEMENT OPTIONS FOR CONFLICTS OF INTEREST

The management plan may include, but is not limited to:

- A.** Disclosure of significant financial interests – in writing or verbally as appropriate: to the public, to human subjects, to sponsors, to IRBs, to researchers and other participants, to publishers, and to conference organizers and attendees;
- B.** Monitoring and/or auditing of the conduct of the research activity by independent, qualified overseers or reviewers or panel thereof (e.g. a data safety monitoring board), who have no professional ties to the research or direct reporting relationships to the researchers, and who are authorized by the University to obtain whatever information they need from the researchers in order to conduct their oversight activities;
- C.** Safeguarding data or the placement of copies of research data in custody of an impartial party;
- D.** Modification of the research plan, methodology, or conduct;
- E.** Disqualification from participation or restrictions on a researcher's role in all or a portion of the research (e.g. data analysis);
- F.** Divestiture or restructuring of the significant financial interest;
- G.** Placement of the significant financial interest in a blind trust;
- H.** Modification of the significant financial interest or severance of relationships that create actual or perceived potential conflicts of financial interest;
- I.** Oversight of the individual's research activities and significant financial interests creating the possible conflict, and of the management plan, by disinterested individuals or committees;
- J.** Change in terms and conditions of agreement relating to the research;
- K.** Prohibiting or restricting involvement of the investigator in recruitment of human subjects and/or in the informed consent process;
- L.** Requiring that a patient or human subject representative or ombudsman be present during recruitment and/or the informed consent process;
- M.** Requiring that the significant financial interest be held in escrow until the investigational product has been approved and on the market for a specified time period;
- N.** Requiring additional disclosures or actions with respect to the significant financial interest to an IRB for its consideration and possible disclosure to human subjects as part of the informed consent;
- O.** Requiring recusal from any business transactions between the University and parties to sponsored research agreements; and
- P.** In the case of human subjects research that is justified by compelling circumstances and that may be conducted by a Marshall investigator with significant financial interests in the research, requiring that rigorous, effective, and objective monitoring be undertaken by individuals

with no financial or professional ties to the research or direct reporting relationships to the researchers, which monitoring might include the following oversight mechanisms:

1. regular audits of the informed consent and enrollment process;
2. the involvement of a patient representative or ombudsman when subjects are recruited and informed consent is obtained;
3. a requirement to escrow the financial interest until an investigational product, if any, has been approved and on the market for a specified time period; and
4. the use of data and safety monitoring boards.

APPENDIX 4 STUDENT PROTECTIONS

A conflict of interest may be raised at any time and at the level of the academic unit by the student, the mentor/advisor, a departmental representative or the COIS.

Initially, the conflict issue will be assessed by a designated resource person in the academic unit who is not connected with the research project in question. The conflict of interest issue is reviewed by all relevant parties to determine if the conflict has the potential to negatively impact upon the academic interests of the student.

If the conflict poses minimal risk to the academic interest of the student, the resource person shall write a brief statement to that effect. This statement shall include a summary of the situation and reasons for the decision. The investigator and student shall co-sign this statement and copies provided to both parties. Additional copies are placed in the student's file, and with the Dean of the Graduate School, if appropriate.

If the conflict of interest is judged to be potentially harmful to the student, then the designated resource person shall notify the appropriate dean (academic unit and/or Graduate School) and the COIS for the creation of a management strategy.

Generally, the management plan involves the appointment of an "Oversight Member" to assist both the mentor/advisor and the student in the recognition and elimination of any student risks. The Oversight Member shall not be implicated in any way with the conflict of interest matter, and may need to be someone outside the affected department. He/she should be familiar with the student's research interests whenever possible.

The Oversight Member shall assist the mentor/advisor in student advising and serve as a non-voting member on all student research advisory and/or thesis/dissertation committee meetings. He/she will sign all academic documents indicating there was no evidence of student harm as a result of the mentor/advisor's conflict of interest. When the Oversight Member perceives that there is a problem arising from conflict of interest issues, he/she will notify the mentor/advisor, the mentor/advisor's department chair, appropriate dean(s) and the COIS.

Resolution of conflicts of interest negatively affecting student progress is the responsibility of the academic units involved, but documentation of that resolution shall be provided to the COIS for the file.