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SUBJECT: Conflicts of Interest		

KEY WORDS: Disclosure of Financial Relationships, Conflict of Interest, Human Subjects Research

OBJECTIVE/BACKGROUND:

Board Members, Officers, and Employees of the University of Maryland Medical System (UMMS) and its related entities have legal duties of care and loyalty to the organization. As a not-for-profit organization, UMMS relies on the public trust to accomplish its mission and objectives. A written conflicts of interest policy promotes transparency of financial interests and demonstrates commitment to managing the organization with integrity and good faith.

Increased scrutiny has been directed towards these financial relationships and conflicts of interests in recent years from a variety of sources including the Internal Revenue Service and Congress. Not only do the potential conflicts of interest need to be disclosed within the organization, UMMS needs to manage these interests to protect its not-for-profit status and reputation. A financial interest is, by itself, not necessarily a conflict of interest. However, conflicts of interest can never be completely avoided; therefore, UMMS must take proactive steps to require disclosure and manage the financial interests once identified.


The purpose of the conflict of interest policy is to preserve the public trust; to protect the tax-exempt organizations’ interests when a transaction or arrangement is considered that might benefit the private interest of an officer or director of the Organization; to avoid possible excess benefit transactions; to promote adherence with fiduciary duties; and to ensure that human subjects research is free from bias resulting from a financial conflict of interest.

APPLICABILITY:

This policy applies to all Board Members, employees, vendors and agents of any of the UMMS legal entities listed in Corporate Compliance Policy CC1202 Development of Corporate Policies, Attachment A. For the purposes of this policy, including disclosure and management plans, financial interest or conflicts of interest in one of the UMMS legal entities represents a conflict of interest and financial interest in all of the UMMS legal entities.

DEFINITIONS:

Financial Interest	<p>A person has a financial interest if, within the last twelve months and with an aggregated total value of at least \$5,000, the person has, directly or indirectly, through business, investment, or family:</p> <ul style="list-style-type: none"> a) An ownership or investment interest in any entity with which the Organization has a transaction or arrangement;
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	<ul style="list-style-type: none"> b) A compensation arrangement with the Organization or with any entity or individual with which the Organization has a transaction or arrangement; c) A potential ownership or investment interest in, or compensation arrangement with, any entity or individual with which the Organization is negotiating a transaction or arrangement; d) Intellectual property rights and interests; e) Travel expenses reimbursed or sponsored by any entity other than the University of Maryland or University of Maryland Medical System Affiliate; or f) Any discovery or acquisition of any of the above (i.e. through purchase, marriage, or inheritance). <p>Compensation includes direct and indirect remuneration as well as gifts or favors that are not insubstantial.</p> <p><u>Examples</u> of financial interest: Any employment or consulting relationship; any commission-based payments (e.g., insurance broker); total value of gifts that exceed \$5000 in value on an annual basis; total value of entertainment events that exceeds \$5000 in value on an annual basis;</p> <p>Stock or ownership interests (including any subsidiary or affiliated entity) amounting to greater than a three percent (3%) ownership interest; stock-options regardless of amount or present value; or any other compensation, reimbursement, or remuneration arrangements not otherwise described above.</p>
Investigator	The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the Public Health Services, or proposed for such funding, which may include, for example, collaborators, fellows, graduate students, or consultants.

POLICY:

1. Duty to Disclose.

In order to ensure that all relationships meet the highest professional standards, the University of Maryland Medical System requires Board Members, Pharmacy and Therapeutics Committee Members, Employees, and persons influencing the selections of vendors fully disclose any Financial Interest that may result in perceived potential conflicts of interest. This reporting must be completed, at minimum, annually, and with changes in circumstances. Doubts about whether a disclosure should be made should be resolved by disclosure. If there is no Financial Interest to disclose, this must be certified to the requesting party. The requesting party may ask for additional information as needed to understand the risk and the needed mitigation strategies.

2. Ascertaining Conflict of Interest.

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A. Governing Board.

Board Determination. After disclosing the financial interest and all material facts (which may include an interview with the interested person), the person disclosing the Financial Interest shall leave the governing board or committee meeting while the determination of a conflict of interest is discussed and voted upon. The remaining board or committee members shall decide how to manage the conflict, however, at minimum, the member should not participate in further discussions or voting on conflicted matters. The Board, at its discretion, may make additional recommendations.

The Executive Assistants are responsible for collecting and maintaining disclosures from all of the Governing Board(s) associated with University of Maryland Rehabilitation & Orthopaedic Institute.

B. Pharmacy and Therapeutics Committee.

The Director of Pharmacy is responsible for collecting and maintaining disclosures from all of the Pharmacy and Therapeutics Committee members that are not collected under other circumstances (e.g. employed physicians submitting annually). Further, the Pharmacy and Therapeutics Committee must be informed if a Financial Interest has been disclosed in any of the considered vendors, products, purchases, uses, etc. The Pharmacy and Therapeutics Committee should take reasonable and necessary steps to mitigate the risks of these interests.


C. Employees.

The Deputy Affiliate Compliance Officer (ACO) and the Manager of Training & Development are responsible for collecting and maintaining disclosures from all employees, including physician employees.

D. Vendor Selection.

The Materials Management Manager is responsible for collecting and maintaining disclosures from persons involved in vendor selection in local purchasing and capital committees. Further, the purchasing or capital committee must be informed if there a Financial Interest in any of the considered vendors, products, purchases, etc. These committees should take reasonable and necessary steps to mitigate the risks of these interests.

E. Supply Chain.

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Corporate Supply Chain is responsible for ensuring that all contracts, invitations for bids, requests for proposals and other invitations or solicitations for offers include the following language:

“Any vendor, supplier, or other contractor must disclose any actual or potential transactions with any University of Maryland Medical System officer, board member, employee, or member of the medical staff, as applicable, including family members. Transactions include offers of employment, gifts, trips, or other things with a total accrued value of more than \$1,000. The disclosure must be made within five days of the transaction, whenever it occurs. Failure to comply with this provision is a material breach of agreement.”

Further, the Corporate Supply Chain must be informed if a person who influences the selection of vendors, products, purchases, or uses, has disclosed a Financial Interest in any of the considered vendors, products, purchases, uses, etc. Corporate Supply Chain is responsible for collecting and maintaining disclosures from all of the persons involved in purchasing decisions that are not collected under other circumstances (e.g. employed physicians submitting annually). Corporate Supply Chain should take reasonable and necessary steps to mitigate the risks of these interests.

F. Locally Held Contracts.


Contracts not managed, solicited, or engaged by Supply Chain must ensure this language is included in the contract:

“Any vendor, supplier, or other contractor must disclose any actual or potential transactions with any University of Maryland Medical System officer, board member, employee, or member of the medical staff, as applicable, including family members. Transactions include offers of employment, gifts, trips, or other things with a total accrued value of more than \$1,000. The disclosure must be made within five days of the transaction, whenever it occurs. Failure to comply with this provision is a material breach of agreement.”

Persons who have identified Financial Interests in any potential party to a contract must not negotiate, initiate, or sign agreements on behalf of UMMS and its related entities.

G. Research Investigators.

The Senior Program Specialist in the Rehabilitation Research Center is responsible for ensuring that Investigators complete applicable disclosures within the required timeframes. Positive responses must be handled consistent with Attachment B.

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3. Management Plans.

Management plans are generally required for positive responses on the Financial Interest disclosures, regardless of the individual's position. When a positive disclosure is received by any of the above areas with the exception of Shared Services' Supply Chain, the disclosure must be submitted to the Affiliate Compliance Officer/Deputy Affiliate Compliance Officer for review and management plan recommendation. Corporate Compliance and Business Ethics Group may be consulted, as needed, to determine if a management plan is needed.

Affiliate Compliance Officer/Deputy Affiliate Compliance Officer is responsible for developing and implementing a signed management plans that specifies the actions that have been and shall be taken to manage the conflict of interest. If, for any reason, a plan may not be obtained, the University of Maryland Rehabilitation & Orthopaedic Institute Chief Executive Officer or designee and Corporate Compliance and Business Ethics Group must be notified.

Management plans may include options such as.


- A. Disclosure to Patients
- B. Disclosure to Purchasing Committees / formal recusal if decisions
- C. Disclosure if authorship / speaking
- D. Periodic monitoring relationships and conflicts
- E. Limitation of hours of activity
- F. Formal approval required for new activity
- G. Limitation of use of any School of Medicine title
- H. Limitation on relationship with vendor
- I. Protocols for use of the vendor established by MEC / committee
- J. No family members as representatives/technicians
- K. Prohibiting employed persons from acting as vendor representatives

4. Health Services Cost Review Commission Reporting.

The Chief Financial Officer (CFO) will submit any required information to the Maryland Health Services Cost Review Commission, per COMAR 10.37.01.06, which includes any director or officer conducting more than \$10,000 of business with the relevant hospital, either directly or indirectly.

5. Other Conflicts of Interest

In addition to Financial Conflicts of Interest, the University of Maryland Medical System strives to maintain an ethical organization at all levels and as such, all Board Members, employees, vendors (explicitly including contracted staff particularly physicians with contracts) and agents of any of the UMMS legal entities shall disclose any potential personal conflict of interests, regardless of any financial implications, as the situation arises. A nonfinancial conflict of interest

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could arise in a variety of situations such as a surgeon performing surgery on a family member or an inappropriate relationship between an employee and a patient, etc. Nonfinancial conflicts do not always arise but, as a general policy, preemptive disclosure is encouraged. When identified, nonfinancial conflicts should be managed with the same consideration for the risks to the organization as a financial conflict.

ATTACHMENTS:

Attachment A: Protocol for Managing Research Related Conflicts of Interest
Attachment B: PHS Funded Research

RELATED POLICIES:

UMMS Standards of Business Conduct
[CC1301] Vendor Relationships
[CC1304] Gifts to Patients
[CC 1305] Gifts to or from Referral Sources

REFERENCES:


COMAR 10.37.01.06
Internal Revenue Services Form 990
Instructions for IRS Form 1023, Attachment A, Sample Conflict of Interest Policy
26 U.S.C. §4958
45 C.F.R. Part 94 Responsible Prospective Contractors
42 C.F.R. Subpart F Promoting Objectivity in Research
21 C.F.R. Part 54 Financial Disclosure by Clinical Investigators

DEVELOPER:

Corporate Compliance & Business Ethics Group will maintain this policy.

APPROVED:

This policy was previously known as the Disclosure of Financial Relationships Policy.
Executive Compliance Committee Approved Initial Policy: 06/10/2013
Executive Compliance Committee Approved Revisions: 11/16/2015; 11/20/2017


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ATTACHMENT A: Protocol for Managing Research Related Conflicts of Interest


Before the University of Maryland Rehabilitation & Orthopaedic Institute or an employed provider of UMMS may spend any funds under a PHS-funded research project, the Conflict of Interest Officer shall determine whether there are any Financial Conflict(s) of Interest.

The Conflict of Interest Officer in the Rehabilitation Research Center at the University of Maryland Rehabilitation & Orthopaedic Institute is the Senior Program Specialist.

- A. In consultation with the Research Compliance Committee, on an annual basis, the Conflicts of Interest Officer will ensure that Conflicts of Interest information is requested and received from Principal Investigators and related research staff.
- B. The Conflicts of Interest Officer will review any positive disclosure of Financial Interests responses and consult with the Office of General Counsel and the Corporate Compliance and Business Ethics Group to review the regulatory requirements and determine whether Public Health Services “PHS” reporting and/or other steps are required.
- C. Reporting to PHS:
 1. Prior to Expenditures. Before spending any PHS funds, a Financial Conflicts of Interest report must be provided to PHS by the Conflicts of Interest Officer, or designee.
 2. Eliminated Financial Conflict of Interest. If a Financial Conflict of Interest is eliminated before the expenditure of PHS funds, a Financial Conflict of Interest report is not required.
 3. Supplemental Reporting. If a Financial Conflict of Interest is identified after the initial Financial Conflict of Interest report is completed but while the PHS funded research project is still ongoing, the Conflicts of Interest Officer shall provide a Financial Conflicts of Interest report consistent with the requirements of the rule to the appropriate Public Health Services department and ensure the implementation of the management plan.
 4. Minimum PHS Reporting Elements. Minimum elements of the Financial Conflicts of Interest report submitted to PHS are:
 - i. Project number;
 - ii. Principal investigators;
 - iii. Name of the Investigator with the Financial Conflict of Interest;
 - iv. Name of the entity with which the Investigator has the Financial Conflict of Interest;
 - v. Nature of the Financial Conflict of Interest (e.g. equity, consulting fee, travel reimbursement, honorarium);
 - vi. Value of the Financial Interest 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. Description of how the financial interest relates to the PHS-funded research and basis for the determination that the financial interest conflicts with such 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;

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- 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.
- H. Annual Financial Conflicts of Interest. The Conflicts of Interest Officer shall annually report to PHS and to the Research Compliance Committee the status of any previously reported financial conflict of interest with regard to an ongoing PHS-funded research project. The annual report shall specify whether the financial conflict is still being managed or explain why the financial conflict no longer exists.
- I. Immediate training. Require each investigator to complete training on the financial conflicts of interest immediately if:
- a. There is a revision in the financial conflicts of interest policies that affects the requirements of Investigators
 - b. The Investigator is new to the Affiliate or
 - c. If the Investigator is not compliant with the financial conflict of interest policy or management plan.
- J. Policy Accessibility. Ensure that this policy is available on the internet.
- K. Routine training. Require each Investigator to complete training regarding the financial conflicts of interest prior to engaging in research and at least every four years. Ensure that this policy is enforced.
- L. Confirm Exceptions. If the Affiliate believes that this policy or portions of this policy do not apply, confirm with Office of Research Compliance annually.
- M. Communicate. Inform each Investigator of this policy.
- N. Enforce Compliance. Promote and enforce compliance with the requirements of this policy.
- O. Certify. As needed, certify, as appropriate, in contract proposals that the Rehabilitation Research Center complies with requirements.
- P. Cooperate in Investigations. Make information available, promptly upon request, to the Health and Human Services relating to any Investigator disclosure of financial interests and the review of, and response to, such disclosure, whether or not the disclosure resulted in the determination of a financial conflict of interest.
- Q. Responding to New or Not Previously Reviewed Disclosures. For Significant Financial Interests not timely disclosed or previously reviewed during an ongoing PHS-funded research project, within 60 days, the Conflicts of Interest Officer must review the Significant Financial interest; determine whether it is related to PHS-funded research; and determine whether a Financial Conflict of Interest exists. If a Financial Conflict of Interest exists, a management plan or interim management plan must be implemented.
- R. Corrective Actions. If a Financial Conflict of Interest was not identified or managed in a timely manner for any reason (e.g. not identified in a timely manner by Investigator or failure

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to review/manage the Financial Conflict of Interest), within 120 days of determining noncompliance, a retrospective review of the Investigator’s activities and the PHS funded project will be completed to determine whether any PHS funded research conducted in the time of noncompliance was biased in the design, conduct, or reporting of such research. This retrospective review must be documented with the following information:


- a. Project number;
- b. Project title;
- c. Principal Investigator;
- d. Name of the Investigator with the Financial Conflict of Interest;
- e. Name of the Entity with which the Investigator has a Financial Conflict of Interest;
- f. Reason for the retrospective review;
- g. Detailed methodology used for the retrospective review (e.g. methodology of review process, composition of review panel, documents reviewed);
- h. Findings of the Review; and
- i. Conclusions of the Review.

If appropriate, the previously submitted Financial Conflicts of Interest report must be updated with specifications of the actions that will be taken to manage the Financial Conflicts of Interest. If bias was found, the Conflict of Interest Officer must notify and submit a mitigation report to the appropriate PHS department.

- S. Publicly Accessible. If any person requests, in writing, information concerning any disclosed Significant Financial Interest, the Conflicts of Interest Officer must respond within five days with information responding to the request if:
 - a. The Significant Financial Interest was disclosed.
 - b. The Significant Financial Interest is still held.
 - c. The Significant Financial Interest is related to PHS-funded research.
 - d. The Conflicts of Interest Officer has determined that the Significant Financial Interest is a Financial Conflict of Interest.

The response must include, at minimum: Investigator name; Investigator title and role with respect to the research project; the name of the entity in which the Significant Financial Interest is held; the nature of the Significant Financial Interest; the approximate dollar value of the Significant Financial Interest (dollar ranges are permissible) 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; a statement that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

- T. Record Retention. The Conflicts of Interest Officer must retain records relating to all Investigator disclosures of financial interests and the review of, and response to, such disclosures for at least three years.

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Attachment B: PHS Funded Research

Funding from one of the following federal agencies results in mandated reporting of Financial Conflicts of Interest:

National Institute of Health	NIH Office of the Director	National Institute of Environmental Health Sciences
Food and Drug Administration	National Cancer Institute	National Institute of Diabetes and Digestive and Kidney Diseases
Substance Abuse and Mental Health Services Administration	National Eye Institute	National Institute of General Medical Sciences
Agency for Healthcare Research & Quality	National Heart, Lung and Blood Institute	National Institute of Mental Health
Agency for Toxic Substances and Disease Registry	National Human Genome Research Institute	National Institute on Minority Health and Health Disparities
Centers for Disease Control and Prevention	National Institute on Aging	National Institute of Neurological Disorders and Stroke
Health Resources and Services Administration	National Institute on Alcohol Abuse and Alcoholism	National Institute of Nursing Research
Indian Health Service	National Institute of Allergy and Infectious Diseases	National Library of Medicine
Office of Global Affairs	National Institute of Arthritis and Musculoskeletal and Skin Diseases	NIH Clinical Center
Office of the Assistant Secretary for Preparedness and Response	National Institute Biomedical Imaging and Bioengineering	Center for Information Technology
Office of the Assistant Secretary for Health	Eunice Kennedy Shriver National Institute of Child Health and Human Development	Center for Scientific Review
Office for Minority Health	National Institute on Deafness and other Communication Disorders	Fogarty International Center
Office for Population Affairs	National Institute of Dental and Craniofacial Research	National Center for Advancing Translational Sciences
Office of Research Integrity	Office of Foods and Veterinary Medicine	National Center for Complementary and Integrative Health
Office of the Surgeon General	National Institute on Drug Abuse	Office of Medical Products and Tobacco
Office on Women's Health	Arthritis Foundation	Office of Global Regulatory



		Operations and Policy
President’s Council on Fitness, Sports and Nutrition	Center for Global Health	Biomedical Advanced Research and Development Authority
Presidential Commission for the Study of Bioethical Issues	National Institute for Occupational Safety and Health	Office of Emergency Management
HRSA Office of Planning, Analysis and Evaluation	Office of Infectious Disease	National Vaccine Program Office
Office of Women’s Health	Office of Noncommunicable Diseases, Injury and Environmental Health	Office of Adolescent Health
Office of the Assistant Secretary for Mental Health and Substance Abuse	Office for State, Tribal, Local and Territorial Support	Office of Disease Prevention and Health Promotion
Center for Behavioral Health Statistics and Quality	Office of Public Health Preparedness and Response	Office of HIV/AIDS and Infectious Disease Policy
Center for Mental Health Services	Office of Public Health Scientific Services	Office for Human Research Protections
Center for Substance Abuse Prevention	Bureau of Health Workforce	Maternal and Child Health Bureau
Center for Substance Abuse Treatment	Bureau of Primary Health Care	Federal Office of Rural Health Policy
AHRQ Center for Delivery, Organization and Markets	Healthcare Systems Bureau	Office of Global Health
AHRQ Center for Evidence and Practice Improvement	HIV/AIDS Bureau	Office of Health Equity
AHRQ Center for Financing, Access and Cost Trends	National Advisory Council for Healthcare Research and Quality	
AHRQ Center for Quality Improvement and Patient Safety		
AHRQ Office of the Director		
AHRQ Office of Communications		
AHRQ Office of Extramural Research, Education and Priority Populations		
AHRQ Office of Management Services		

<https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices>

<https://research.gwu.edu/list-phs-funded-agencies>