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UNIVERSITY of MARYLAND
CAPITAL REGION HEALTH

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 References:
 Applicability: UM Capital Region Health
 UM Bowie Health Center
 UM Laurel Regional Hospital
 UM Prince George's County Hospital

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 Capital Region Health (UMCRH) and its related entities have legal duties of care and loyalty to the organization. As a not-for-profit organization, UMCRH 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, UMCRH 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, UMCRH 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 UMCRH legal entities listed in Corporate Compliance Policy - 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 UMCRH legal entities represents a conflict of interest and financial interest in all of the UMCRH legal entities.

DEFINITIONS:

Financial	A person has a financial interest if, within the last twelve months and with an aggregated
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Interest	total value of at least \$5,000, the person has, directly or indirectly, through business, investment, or family:
	<ul style="list-style-type: none"> a. An ownership or investment interest in any entity with which the Organization has a transaction or arrangement; 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 Capital Region Health Affiliate; or f. Any discovery or acquisition of any of the above (i.e. through purchase, marriage, or inheritance).
	Compensation includes direct and indirect remuneration as well as gifts or favors that are not insubstantial.
	<p>Examples 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 mTay 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 Capital Region Health 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.**

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 President & Chief Executive Officer, or designee, is responsible for collecting and maintaining disclosures from all of the Governing Board(s) associated with UM Capital Region Health.

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. Vice President for Human Resources and Corporate Compliance and Privacy Officer are responsible for collecting and maintaining disclosures from all employees].

D. Vendor Selection.

The Corporate Director of Materials Management 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.

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 Capital Region Health 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 Capital Region Health 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 UMCRH and its related entities.

- G. **Research Investigators.** Senior Director of Research is responsible for ensuring that Investigators complete applicable disclosures within the required timeframes. Positive responses must be handled consistent with Attachment B.

- 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 [Corporate Compliance Director 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. The Affiliate Compliance Committee 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 UM Capital Region Health 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 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 Capital Region Health 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 UMCRH legal entities shall disclose any potential personal conflict of interests, regardless of any financial implications, as the situation arises. A nonfinancial conflict of interest 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. Non-financial conflicts do not always arise but, as a general policy, preemptive disclosure is encouraged. When identified, non-financial conflicts should be managed with the same consideration for the risks to the organization as a financial

conflict.

RELATED POLICIES:

UM Capital Region Health] Standards of Business Conduct

Vendor Relationships

Gifts to Patients

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:

Executive Compliance Committee Approved Revisions: 11/20/2017

ATTACHMENTS:

Attachment A: Protocol for Managing Research Related Conflicts of Interest

Attachment B: PHS Funded Research

Attachments:

[ATTACHMENT A - Protocol for Managing Research Related Conflicts of Interest.docx](#)
[Attachment B - PHS Funded Research.docx](#)

Approval Signatures

Approver

Date

Meredith Harrison: Meredith Harrison, CCO 08/2018

Applicability

UM Bowie Health Center, UM Capital Region Health, UM Laurel Regional Hospital, UM Prince George's County Hospital

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