RUSH	**Policy Title:** Conflicts of Interest and Commitment		**Former Policy Number:** OP-0359
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Applies To: RUMC ☒ RUMG ☒ ROPH ☒ RCMC ☒ RCH ☒ ROPPG ☒ RCMG ☒ RU ☒			

I. Policy

The Comprehensive Policy Statement Regarding Conflicts of Interest is applicable to the Rush board of trustees, corporate officers, employees, faculty, students and members of Rush's medical, nursing, professional and technical staffs.

This document sets forth the Rush Comprehensive Policy Statement Regarding Conflicts of Interest in detail, including descriptions of business, institutional, clinical and research conflicts; conflicts of commitment; the steps Rush mandates to avoid, reduce or manage such conflicts; and definitions of key terms used in this document. This document should be read together with Rush's Relationships with Vendor and Referral Source Guidelines, which supplement and provide additional guidance with respect to certain areas of this Comprehensive Policy Statement Regarding Conflicts of Interest.

As one of the nation's leading academic medical centers, Rush University Medical Center (hereinafter "Rush") strives to practice medicine in a caring manner, conduct research in an objective and responsible manner, transact business in a transparent manner and discharge all other duties to the general public avoiding, where possible, bias, favor, preference or partiality. Therefore, Rush's board of trustees, corporate officers, employees, faculty, students and members of its medical, nursing, professional and technical staffs must use their best efforts and judgment to avoid any influences which could compromise their patient care, their research, their business transactions, their objectivity or their integrity.

Conflicts of interest are defined as circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest. Conflicts can be more or less severe. The severity of a conflict depends on: (1) the likelihood that professional decisions made under the relevant circumstances would be unduly influenced by a secondary interest and, (2) the seriousness of the harm or wrong that could result from such influence. Under certain limited circumstances a conflict may be allowed to continue if such conflicts cannot otherwise be eliminated, the likelihood of undue influence is minimized and the relationship is appropriately managed to reduce the risk of possible harm.

The Comprehensive Policy Statement Regarding Conflicts of Interest is subdivided here to address the specific nature of institutional conflicts, clinical conflicts and research conflicts. In addition, Rush's Relationships with Vendor and Referral Source Guidelines (the "Vendor Guidelines") provide supplemental detail with respect to certain conflicts addressed in this document.

I. Institutional and Business Conflicts

A. A "direct" institutional financial conflict of interest may occur when Rush has an external relationship or financial interest in a company that itself has or seeks a financial interest in or benefit from Rush Research, Intellectual Property and/or Technology Transfer. Examples of direct institutional financial conflicts of interest include licensing agreements, including equity holdings, royalty payments, other payments, and their stipulations.

B. An "imputed" institutional conflict of interest may occur when Rush corporate officers, employees and board members, acting within their authority on behalf of the institution, have financial interests that may affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution.

C. Prohibited Conduct: The following conduct on the part of the Rush board of trustees, corporate officers and employees and/or members of their families is considered to be a conflict of interest:

1. Disclosing confidential information regarding Rush's business, clinical, research or other activities to third parties without clear and expressed authorization of Rush;

2. Having a financial interest in an organization doing or seeking to do business with Rush, its subsidiaries and/or affiliates;

3. Serving as a consultant, a board member or an advisory board member for, or entering into contracts with an organization doing or seeking to do business with Rush, its subsidiaries and/or affiliates unless such service or contract complies with Section III of the Vendor Guidelines ("Consulting and Other Compensation Arrangements"), which require, among other things, a written contract that specifies the services to be provided;

4. Contracting on behalf of oneself for the purchase, sale or lease of any kind of property, facility, equipment or services to or from Rush, its subsidiaries and/or affiliates; and/or

5. Accepting any business courtesy (gratuity, gift, loan, service, entertainment, or other favor) unless such business courtesy is permitted under Section I of the Vendor Guidelines ("Gifts and Other Business Courtesies")(generally, business courtesies must be reasonable (not to exceed $100) and the purpose must never be to induce or influence a business transaction);

D. Procedure for Direct Institutional Conflicts of Interest: Rush requires the following steps to avoid, reduce or manage direct institutional conflicts:

1. All employees are required to make a clear disclosure of any conflict of interest to their immediate supervisor at the earliest possible opportunity before an arrangement is entered into which would result in a conflict or as soon thereafter as the employee becomes aware that such a conflict exists. Supervisors may consult with the Corporate Compliance Office and take action to address a conflict of interest as is consistent with Rush Policies including, but not limited to, the Department of Human Resources policies; and

2. Members of the Rush Board of Trustees and Rush corporate officers are required to disclose any conflicts to the Secretary of the Board and General Counsel. An initial review will be undertaken by the Secretary of the Board and General Counsel, who shall make such recommendations as they deem appropriate to the Audit Committee of the Board. If time does not permit a full review by the Audit Committee, such review may be undertaken by the Chair of the Audit Committee. Thereafter, the Chair of the Audit Committee shall submit the material facts of the conflict along with his/her recommendations to the Audit Committee which shall make a final determination on the matter.

E. Disclosure: On an annual basis, members of the Rush Board of Trustees and Rush corporate officers shall complete and return a disclosure of conflicts form. The disclosures will be reviewed by the Secretary of the Board and the General Counsel, who will thereafter submit their reports to the Audit Committee, which shall make any final determinations as deemed appropriate or necessary.

II. Clinical Conflicts

A. Prohibited Conduct: The following conduct on the part of members of the medical staff, nursing staff and faculty of Rush University and/or Rush administrative, clerical or technical personnel (hereinafter "person subject to this policy") is considered to be a clinical conflict of interest:

1. Accepting gifts from pharmaceutical, medical device and biotechnology companies. A gift includes receipt of any good, service, courtesy or other item of value without paying money or giving something of comparable or equal value in return, either before or after receipt. Gifts include, by way of example, the following: cash, checks, gift certificates, securities, property, favors, prizes, services, referrals, attendance at plays, concerts, sporting events, golf outings or any other entertainment events or hospitality (See Section I of the Vendor Guidelines) (Note that the acceptance of meals are addressed in #12 below and Section II of the Vendor Guidelines);

2. Making educational presentations or publishing scientific articles that are controlled by a commercial entity or contain substantial portions written by someone who is not identified as an author or who is not properly acknowledged;

3. Accepting drug samples or coupons except in specified situations for patients who lack financial access to medications, as approved by the Chief Medical Officer;

4. Using, prescribing, implanting or recommending the utilization, prescription or implantation of a drug or device sold by a commercial entity in which a person subject to this policy has a financial interest without making a full disclosure of that financial interest to the patient or patient's family as part of the informed consent process or as otherwise recommended by the Clinical Conflicts Committee;

5. Permitting sponsorship by a commercial entity of an educational event which does not comply with the Accreditation Council for Continuing Medical Education standards, and/or which does not comply with Section IV ("Third Party Medical Education Programs") or Section VII ("Funding for Medical Education Programs Accredited by ACCME") of the Vendor Guidelines;

6. Accepting funds or contributions from a commercial entity earmarked for specific recipients or to support specific projects which have not been approved by the Department Chairperson and which do not comply with Section V ("Educational Grants and Donations") of the Vendor Guidelines;

7. Accepting financial support or other personal or financial benefit from a commercial entity for the training of clinical trainees on medical devices unless the Department Chairperson or Administrative Head has determined that the conference or training has educational merit and the conference or training complies with Section VI ("Training and Education Regarding Use of Medical Devices") of the Vendor Guidelines (note that sponsorship of fellowships is permitted under Section V ("Educational Grants and Donations") of the Guidelines);

8. Accepting promotional items from a commercial entity for use or display in offices or elsewhere on the Rush campus which incorporate or display a company product name and/or logo unless they are items which are used for patient education, such as models or anatomical drawings. This restriction includes wearing any article of clothing, uniform, badge, pin, sign or other item that displays the name of a non-Rush health care service, product or logo;

9. Permitting sales representatives of commercial entities to come on the Rush campus without an invitation or appointment. Representatives must register at the security desk on the 4th floor of the Atrium Building or at other designated registration sites and all meetings with sales representatives must occur in non-patient care areas;

10. Participating in speakers' bureaus or other events sponsored by commercial entities if the presentation, lecture or talk by the person subject to this policy is without proper professional independence (e.g., the commercial entity creates the slides or presentation materials, has final approval of the presentation content, or if the person subject to this policy is expected to disseminate company or product information on behalf of the commercial entity);

11. Accepting personal or financial benefit for serving as a consultant or a member of an advisory board to a commercial entity without providing reciprocal professional service or advice, or providing professional service or advice in excess of fair market value. All consulting arrangements must comply

with Section III of the Vendor Guidelines ("Consulting and Other Compensation Arrangements"), which require, among other things, a written contract that specifies the services to be provided;

12. Accepting meals or other hospitality from a commercial entity on or off the Rush campus unless such meals comply with Section II of the Vendor Guidelines ("Meals") (note that meals provided in connection with permitted business courtesies are addressed in Section I of the Vendor Guidelines; meals provided in connection with consulting arrangements are addressed in Section III of the Vendor Guidelines; meals provided in connection with third party medical education programs are addressed in Section IV of the Vendor Guidelines; meals provided in connection with educational grants and donations are addressed in Section V of the Vendor Guidelines; meals provided in connection with training and education regarding use of medical devices is addressed in Section VI of the Vendor Guidelines; and meals provided in connection with ACCME sponsored events are addressed in Section VII of the Vendor Guidelines.).

B. Exceptional Circumstances: Committees, panels or groups within Rush which develop clinical practice guidelines or review, recommend or approve the purchase of any commercial product, including but not limited to pharmaceuticals and medical devices, should generally exclude as members individuals with conflicts of interest. In the exceptional situation in which avoidance of members with conflicts of interest is impossible because of the critical need for their expertise and where there has been a good faith effort to find experts without conflicts of interest, then such committees, panels or groups should:

1. appoint a chair without a conflict of interest;

2. limit members with conflicting interests to a distinct minority of the membership;

3. exclude individuals who have a promotional relationship with the commercial entity whose product is being considered;

4. exclude panel members with conflicts from deliberating, drafting or voting on recommendations concerning matters about which they have a conflict; and

5. publicly disclose any relevant conflicts of interest of members. All committees, panels and groups are to report their handling of potential conflicts on a regular basis to the Chief Medical Officer.

C. Procedure: Rush requires the following steps to eliminate, reduce or manage clinical conflicts:

1. On an annual basis those persons subject to this policy who have any interest which might constitute a conflict of interest as defined under this policy or those who sit on a medical center committee as defined above shall complete and return a disclosure of conflicts survey. This information is transmitted to the Corporate Compliance Office for processing. In the event that a person subject to this policy

becomes aware of any additional conflict after the submission of the disclosure of conflicts form, that person must amend his/her annual disclosure of conflicts form to include the additional conflict of interest.

2. The Clinical Conflicts Committee shall review such disclosures submitted and determine how best to avoid, reduce or manage such conflicts of interest.

Any exemptions under this policy must be granted in writing to persons subject to this policy by the Clinical Conflicts Committee. The Clinical Conflicts Committee shall recommend and monitor plans as to the elimination, reduction or management of conflicts.

3. A first violation of this policy will require that the person who committed the violation receive counseling, training or education concerning this policy to prevent any further infraction. Additional violations of this policy may subject a person to disciplinary action according to the applicable procedure as determined by the Clinical Conflicts Committee.

III. Research Conflicts

A. Prohibited Conduct: The following conduct on the part of members of the Rush medical staff and nursing staff, faculty members and students of Rush University and any employees engaged in research at Rush in the basic or clinical sciences is considered to be a research conflict of interest:

1. Accepting a financial interest in a commercial entity or receiving a benefit from a commercial entity through oneself or one's family that could influence how he/she designs, conducts or reports any research in which he/she is involved.

2. Receiving compensation or personal or financial benefit based upon the outcome of the research (for example, compensation would be higher for a favorable outcome than for an unfavorable outcome or tied to the sales of the drug, device or product).

3. Accepting a personal or financial benefit from a commercial entity engaged in research or a research sponsor without providing reciprocal professional service of fair market value.

B. Exceptions: Exceptions to the above stated policy are only permitted if the Research Conflicts Committee:

1. determines that the researcher's participation is integral for the conduct of the research; and

2. approves an effective mechanism for managing the conflict and protecting the integrity of the research.

C. Disclosure: Rush requires the following disclosure of financial conflicts of interest to the Rush Office of Research Compliance (ORC). All significant financial relationships will be reviewed in order to eliminate, reduce or manage research conflicts:

1. On an annual basis, researchers subject to this policy shall complete and submit the annual survey in the Rush Research Portal (RRP). The information is transmitted to the ORC for processing. In the event a researcher becomes aware of any additional financial interests after the submission of the annual survey, the researcher is required to report new significant financial interest in research within thirty (30) days and must amend his/her annual disclosure survey to include the additional financial interest.

2. The COIIR Committee shall review such disclosures submitted and determine how best to avoid, reduce or manage such conflicts of interest.

3. The COIIR Committee may require such action be taken as deemed appropriate to eliminate, reduce or manage a researcher's conflict of interest, including, without limitation:

a. publicly disclosing the researcher's conflict;

b. monitoring and managing the investigator's research;

c. disqualifying the researcher from taking part in the relevant federally funded or other sponsored research;

d. compelling the divestiture of the researcher's ownership interest in a commercial entity, or severance of the researcher's business relationship with a commercial entity.

4. The COIIR Committee shall notify each researcher of its findings with regard to the existence of a conflict of interest and the action it deems appropriate to eliminate, reduce or otherwise manage the conflict of interest.

5. When the COIIR Committee finds the existence of a conflict of interest or takes action to eliminate, reduce or manage a conflict of interest, the COIIR Committee will provide any affected researchers the opportunity to petition for a reexamination and reassessment of the decision or action within ten (10) days of notification of the COIIR Committee's findings. Such reexamination and reassessment shall take place in the context of a meeting of the COIIR Committee wherein the researcher shall have the opportunity to address the COIIR Committee's findings and concerns. Within a reasonable period of time following this meeting, the COIIR Committee will render its findings based on this reexamination and reassessment. Such findings shall be final and binding on the researcher.

6. The ORC in conjunction with the Associate Provost for Research may perform items 2-4 above in situations where the disclosure is identical to situations presented to the Committee previously. This

review process is considered an "expedited review." These actions and determinations are based on COIIR Committee precedence. All expedited reviews will be presented, reviewed and ratified at the next COIIR Committee meeting.

IV. Conflict of Commitment

A. The following conduct on the part of Rush officers, employees, and faculty members is considered to be a conflict of commitment:

1. For officers and employees (with the exception of faculty members) failing to devote one's time and energy during assigned working hours to activities solely related to Rush so as to deprive Rush of the full measure of one's time and attention as needed to fulfill the demands of one's employed position.

2. For faculty members, devoting more than ten percent (10%) effort to outside professional and commercial activities. The faculty member's department chair must review and provide written approval of the outside activity before it is carried out.

B. Rush requires the following steps to avoid, reduce or manage conflicts of commitment:

1. All officers, employees and faculty members are required to make a clear disclosure of any conflict of commitment to their immediate supervisor at the earliest possible opportunity before an arrangement is entered into which would result in a conflict of commitment or as soon thereafter as the employee, officer or faculty member becomes aware that such a conflict exists.

2. Officers, employees and faculty members shall not enter into an arrangement that creates a conflict of commitment without the prior approval of their immediate supervisor. Such approval will only be provided in very limited circumstances if the supervisor is able to conclude that the arrangement may be managed in such a way that it will not negatively impact the individual's commitment to Rush.

3. Supervisors may take action to address a conflict of commitment as is consistent with Rush policies including, but not limited to, the Department of Human Resources policies.

V. Review and Approval Process

A. Approval and Amendment: This Comprehensive Policy Statement Regarding Conflicts of Interest shall be approved and may be amended from time to time by the Rush Board of Trustees.

B. Conflicts of Interest Committee: The CEO of the Medical Center shall appoint an institution-wide Conflicts of Interest Committee composed of the Deans of the Colleges of Rush University or their delegates, the Associate Provost for Research, the President of the Rush Medical Staff, the Chief Medical Officer, the Secretary to the Board of Trustees, the Executive Vice President of Clinical Affairs and the

Chief Financial Officer or his/her designee and the General Counsel or his/her designee. The Committee shall be chaired by the Provost of Rush University. The CEO of the Medical Center shall serve on the Committee in an ex-officio status with vote. The Chairperson of the Department of Religion, Health and Human Values and the Associate Dean of Continuing Medical Education shall serve on the Committee in ex-officio status without vote. The Committee shall meet as necessary or when convened by the President of Rush University Medical Center or the Provost of Rush University. The Committee shall have the authority to promulgate any operational rules consistent with the Comprehensive Policy Statement Regarding Conflicts of Interest, may from time to time propose changes and amendments to the Comprehensive Policy Statement for approval by the Rush Board of Trustees and shall submit an annual report to the Audit Committee of the Rush Board of Trustees as to the identification, reporting, management, reduction and/or elimination of conflicts of interest within Rush. The Audit Committee shall review the report and recommend any action required by the Executive Committee and/or the Rush Board of Trustees.

II. Definitions

Benefit: A gift, gratuity, compensation, remuneration, loan, service, meal, entertainment, scholarship, reimbursement of travel expenses or other favor given to oneself and/or one's family.

Commercial Entity: Any for-profit enterprise that develops, manufactures, sells, or distributes drugs or medical devices or other goods and/or services to the health care industry, including but not limited to, pharmaceutical companies, medical device manufacturers, laboratories, imaging companies, sales organizations, banks, auditing firms, law firms, insurance companies and consulting firms.

Confidential Information: Information of a sensitive nature of any kind and in any form concerning Rush, including but not limited to, its business operations, finances, planning, strategy, marketing and service areas, real estate, patient care activities, research, data on pricing and/or costs of services, employee compensation and/or intellectual property as well as internal quality control or legal documents, any disclosure of which to third parties will presumptively be considered injurious and damaging to the interests of Rush.

Conflict of Interest: Circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.

Corporate Officer: A president, executive vice president, senior vice president, vice president, associate vice president or assistant vice president.

Fair Market Value: The value of a good or service in business transactions, consistent with the general market value (that is, the compensation that would be included in a service agreement as the result of genuine bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party at the time of the agreement).

Family: Any relation by blood or marriage, domestic partner and/or any person residing in the same household.

Financial Interest: Means anything of monetary value, whether or not the value is readily ascertainable.

Significant Financial Interest in Research:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

i. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures or fair market value;

ii. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interest); or

iii. Intellectual property rights and interest (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Institutional Conflicts: Such conflicts arise when an institution's own financial interests or those of its board of directors, senior officials or employees pose risks of undue influence on decisions involving the institution's primary interests.

Organization: Any company, firm, business, proprietorship, partnership, corporation, trust or any other business, professional or social organization.

Person: A person who is subject to the Rush Comprehensive Policy Statement on Conflicts of Interest.

Research or Engaged in Research: The design, development, conduct, evaluation, testing or reporting of clinical or basic science, scholarly or other scientific investigations at Rush, including but not limited to, research that requires approval by the Rush Institutional Review Board as well as research specifically exempt from regulations for the protection of human research subjects. Persons subject to this policy may include but not be limited to principal investigators, co-investigators or any other person responsible for the design, conduct or reporting of research.

Conflict of Individual Interest in Research (COIIR) Committee: Members include the Provost of Rush University who shall appoint a Committee of at least five (5) voting members and a Chairperson of the Committee; Dean of Rush Medical College; the Associate Vice Provost for Research (who shall act as the Chairperson of the Committee); and other members of the Rush faculty and Medical Staff actively involved in clinical and basic science research.

Speakers Bureau: Any speaking arrangement with a company to promote its products or services which has one or more of the following characteristics:

1. the selection of speakers is based upon criteria other than medical expertise and reputation, knowledge and experience regarding a particular skill or specialty or communication skills;
2. the selection of speakers may serve as an inducement or reward for prescribing a particular medicine or course of treatment;
3. compensation for speaking is in excess of fair market value;
4. the programs and events are conducted in a setting or locale other than a clinical or educational setting (e.g., a resort setting);
5. speakers are provided with food and/or hospitality which subordinates or distracts from the educational purpose of the meeting;
6. speakers are reimbursed for travel and lodging costs in excess of costs which are reasonable or fair market value; or
7. critical portions of the speaker's presentation are prepared for the speaker by the company.

Subsidiaries and/or Affiliates: Any company, corporation or other business organization controlled or closely associated with Rush, particularly the following firms: Rush/Copley Health Care System, Inc,; Rush-Copley Medical Center, Inc.; Copley Memorial Hospital, Inc.; Rush Copley Foundation; Rush-Copley Medical Group, NFP; Johnston R. Bowman Health Center; Room 500; Riverside Health System; Riverside/Rush Corporation; Rush System for Health, Inc.; Rush Health Associates; Rush Oak Park Hospital; Synergon Health System, Inc.; The Core Foundation; RML Health Providers, LP; RMLHP Corporation; Vyridian Revenue Management, LLC; Health Delivery Management, LLC; Oak Park Imaging Services, LLC; Circle Imaging Partners, LP; Circle Medical Management, Inc.; Rush Surgicenter at the Professional Building Limited Partnership; RUMC Insurance Co.; and Rush-Wood Imaging Partners Ltd.

III. Procedure

n/a

IV. Attachments

Vendor Guidelines.pdf

V. Related Policies or Clinical Resources

n/a

VI. References and Regulatory References

[Approved by the Board of Trustees, February 12, 2015]

Rush University Medical Center Relationships with Vendors and Referral Source Guidelines

[Approved by the Rush Medical Staff Executive Committee, July 2, 2009]
[Approved by the Audit Committee, August 25, 2009]
[Approved by the Board of Trustees, September 9, 2009]

[Approved by the Senior Management COI Committee, April 27, 2011]

[Approved by the Board of Trustees, September 14, 2011]

[Approved by the Senior Management COI Committee, July 31, 2012]

[Approved by the Audit Committee, August 22, 2012]

[Approved by the Board of Trustees, September 12, 2012]

RUSH UNIVERSITY MEDICAL CENTER

RELATIONSHIPS WITH VENDORS AND REFERRAL SOURCE GUIDELINES

Purpose and Scope

Consistent with the Rush University Medical Center ("**RUMC**") Conflict of Interest and Commitment Policy ("**COI Policy**"), these Relationships with Vendors and Referral Source Guidelines ("**Guidelines**") require that business transactions and relationships between RUMC Persons and Vendors and Referral Recipients be at arms-length and free from offers or solicitation of gifts and favors, or other inducements that may have the potential to improperly influence, or appear to improperly influence, clinical, purchasing, prescribing or research decisions by RUMC Persons. RUMC also prohibits RUMC Persons from accepting or paying any amount, in cash or in kind, in exchange for or to induce the purchasing, prescribing or ordering of any item or service covered under a federal health care program.

Supervisors are responsible for communicating these Guidelines to RUMC Persons, for providing training that will give RUMC Persons in their departments a firm understanding of the Guidelines, and for taking steps to effectively monitor and enforce compliance with these Guidelines. Violations of these Guidelines are subject to disciplinary action in accordance with applicable RUMC disciplinary policies.

Any questions about these Guidelines should be addressed to the RUMC Corporate Compliance Office.

Who is Covered by these Guidelines?

These Guidelines shall apply to all RUMC directors and officers, all other full-time or part-time RUMC employees, members of the RUMC Medical Staff, Faculty, and independent contractors retained by RUMC from time to time ("**RUMC Persons**" or "**Persons**").[1]

Definitions

Business Courtesy: A meal, entertainment or other hospitality or favor for which fair market value is not paid by the recipient.

Gift: A gift includes receipt of any good, service, courtesy (including a Business Courtesy) or other item of value without paying money or giving something of comparable or equal value in return, either before or after receipt. Gifts include, by way of example, the following: cash, checks, gift certificates, securities, property, favors, prizes, services, referrals, food, attendance at plays, concerts, sporting events, golf outings or any other entertainment events or hospitality.

[1] While certain Sections of these Guidelines involve arrangements or activities that are more likely to apply to only certain types of RUMC Persons (e.g., physicians, purchasing department personnel), all RUMC Persons should be familiar with the terms of the Guidelines to support a systemwide understanding of, and compliance with, its requirements.

Referral Recipient: Any individual or entity that obtains health care business or referrals from RUMC, or potentially could obtain health care business or referrals from RUMC, including, for example, hospitals, nursing homes, ambulatory surgical centers, imaging facilities, health care suppliers, non-medical suppliers and any family member, officer, director, employee, agent or representatives of individuals or agents.

Referral Source: Any person or entity that is a source of patient referrals to RUMC, such as community physicians who refer patients to RUMC for specialty services.

Vendor*:* Any for-profit enterprise that develops, manufactures, sells, or distributes drugs or medical devices or other goods and/or services to the health care industry, including but not limited to, pharmaceutical companies, medical device manufacturers, laboratories, imaging companies, sales organizations, banks, auditing firms, law firms, insurance companies and consulting firms.

RUMC Person or Person: The individuals described above under the heading "Who is Covered by these Guidelines?"

Guidance Regarding Specific Financial Relationships.

The following additional Sections of these Guidelines are intended to implement the purpose set forth above and shall be considered part of these Guidelines:

Section I	Gifts and Business Courtesies
Section II	Meals
Section III	Consulting and Other Compensation Arrangements
Section IV	Third Party Medical Education Programs
Section V	Educational Grants and Donations
Section VI	Training and Education Regarding Use of Medical Devices
Section VII	Funding for Medical Education Programs Accredited by the Accreditation Council for Continuing Medical Education
Section VIII	Purchase Contracts; Discounts and Other Reductions in Price

All interactions with Vendors or Referral Recipients not covered by specific Sections of these Guidelines will be governed by the general policy statement set forth above. In addition, any Gifts or other financial arrangements with entities that provide and bill patients or payors for any of the following services should be discussed with the Office of Legal Affairs: clinical laboratory services; physical and occupational therapy services; radiology and other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. Such gifts or financial relationships shall also be established and implemented in accordance with the provisions of other applicable RUMC policies.

I. Gifts and Other Business Courtesies

A. Gifts from Vendors or Referral Recipients. As a general rule, RUMC Persons shall not accept or use Gifts (including Business Courtesies) from Vendors or Referral Recipients, except for permitted Business Courtesies discussed below. Any Gift or Business Courtesy given to an immediate family member of an RUMC Person is prohibited.

B. Gifts and Business Courtesies from Pharmaceutical, Medical Device, and Biotechnology Companies. Gifts and Business Courtesies from pharmaceutical, medical device and biotechnology companies are prohibited under all circumstances (See Section II(A)(1) of the COI Policy). Refer to Section II (Meals) for additional information.

C. Permitted Business Courtesies. There may be times when it is permissible to accept a Business Courtesy or other invitation offered by a current or potential Vendor. However, the purpose must never be to induce or influence a business transaction. As a general rule, the cost must be reasonable (not to exceed $100 per RUMC Person). If the occasion appears extravagant or if the invitation could be perceived as intended to influence a business decision involving RUMC, attendance at such an occasion is prohibited. To be acceptable, the occasion should conform to the following guidelines:

1. The cost and location must be reasonable and not extravagant.

2. Paid expenses for any travel costs or overnight lodging for the RUMC Person or his/her family are prohibited.

3. The invitation is for an ordinary business meal or gathering during which the host is present and business is conducted.

D. Gifts to RUMC Referral Sources. RUMC Persons are prohibited from making any gift to a RUMC Referral Source. A RUMC Person may not use his/her own funds to pay for gifts for the purpose of influencing referrals.

II. Meals

A. Meals Furnished by Vendors or Referral Recipients.

1. Vendors and Referral Recipients are not permitted to provide food to RUMC Persons on-site at RUMC facilities. Except as provided below, if RUMC Persons attend a meal (off-site of RUMC facilities) to discuss business-related or education-related matters with Vendors or Referral Recipients, then RUMC Persons must pay for his or her own meal. Under no circumstances may RUMC Persons accept or provide money, entertainment or other Business Courtesy in exchange for attending the meal. In addition, RUMC Persons may not allow a Vendor or Referral Recipient to pay for meals for the RUMC Person's spouse, other immediate family member or other guests who do not have a bona fide professional interest in attending the meal.

2. Food may be accepted from Vendors or Referral Recipients only in the following limited circumstances:

a. The meal is related to a permitted Business Courtesy pursuant to Section I(C) of these Guidelines (Permitted Business Courtesies).

b. Off-Site Educational Presentations and Meetings: RUMC Persons may attend meals and receptions provided by a Vendor in connection with an educational conference, training or meeting if the Vendor sponsoring the educational presentation or meeting is a signatory to the Pharmaceutical Research and Manufacturers of America's (PhRMA) Code on Interactions with Healthcare Professionals. The PhRMA Code requires that meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.

c. Medical Device Training Sessions: RUMC Persons may attend modest meals and receptions when attending Vendor-sponsored training and education regarding the use of medical devices.

d. Consulting Services: RUMC Persons may attend modest meals and receptions in connection with RUMC Persons performance of legitimate contractual services.

B. Meals and Business Courtesies Furnished to Referral Sources.

1. RUMC Persons may only provide meals to Referral Sources if doing so is part of a bona fide business purpose (e.g., as part of an information presentation to educate community physicians about RUMC capabilities). However, the meals must be modest in value, occur at venues appropriate

for the exchange of information, and be approved by the Corporate Compliance Office in advance of the meeting.

2. Under no circumstances may such meals be paid for by a Vendor unless otherwise permitted under these Guidelines.

C. Other Provisions of these Guidelines Relating to Permitted Meals. As noted above, additional guidance relating to meals also may be found in the following Sections of these Guidelines: Gifts and Other Business Courtesies (relating to meals provided as part of a permitted business courtesy); Consulting and Other Compensation Arrangements (relating to meals provided as part of or incident to a physician's compensated services to a Vendor or Referral Recipient); Third Party Medical Education Programs (relating to meals and receptions provided by Vendor or Referral Recipient to program attendees, where permitted by the program sponsor); Educational Grants and Donations (relating to funding of meals provided in connection with programs conducted by RUMC); and Training and Education Regarding Use of Medical Devices (where meals, travel and lodging are provided in connection with training provided by a manufacturer in order to facilitate safe and effective use of certain medical technology).

III. Consulting and Other Compensation Arrangements

This Section applies to all consulting and compensation arrangements between RUMC Persons and Vendors or Referral Recipients, including all consulting, medical director, product development, advisory committee, teaching and speaking, or other services that RUMC Persons provide to Vendors or Referral Recipients (collectively, referred to as "consulting arrangements"). All such arrangements shall be memorialized in writing, reflect fair market value compensation for legitimate purposes, and involve only reasonable, necessary and documented services.

A. Prohibited Arrangements. A Person may not enter into a contract that involves the provision of services or other terms that would restrict or interfere with the Person's RUMC-related duties. Also, under no circumstances should a Person enter into a contract that is, or appears to be, motivated by any improper purpose, such as to induce the individual to change or maintain his or her purchasing or prescribing habits or his or her decision-making or judgment in research or clinical matters. Each Person is responsible for determining that a proposed consulting arrangement complies with these Guidelines.

B. Mandatory Written Contract. RUMC Persons may be engaged by Vendors or Referral Recipients to perform such services only pursuant to a written contract signed by both parties that details the Person's duties, provides for no more than reasonable fair market compensation for necessary services that are actually rendered, and requires ongoing documentation of the actual provision of services.

C. Contract Guidelines. Each consulting arrangement must meet the following guidelines:

1. The consulting arrangement must be documented by a written contract, signed by the appropriate parties. RUMC, rather than the individual Member, is the appropriate contracting party for certain arrangements, such as facility medical director agreements, as well as arrangements involving a Person's clinical, administrative or consulting services if such Person is an RUMC employee. Departments are not separate legal entities, and therefore are not appropriate contracting parties. Any questions about the appropriate contracting party should be addressed to the Office of Legal Affairs.

2. The contract must specify the services to be provided, and the services must be legitimate, commercially reasonable services needed by the contracting party.

3. The payment amount or formula must be set in advance and must reflect fair market value for the services to be provided. When compensation is based on a royalty or similar arrangement, the payment amount should not take into account sales or use of products by RUMC or any Persons, nor

should it include other payment methodologies that will inappropriately influence clinical decision-making.

4. The contract must specify a means for the RUMC Vendor to document on an ongoing basis the actual provision of the services and require documentation as a condition of payment.

D. Other Requirements and Restrictions.

1. Use of RUMC facilities or staff, by either the RUMC Person or the third party in connection with a consulting arrangement is prohibited.

2. The arrangement cannot involve or permit the use of RUMC's confidential or proprietary information. The contract must prohibit the use of the RUMC name by any third party, except with RUMC's written consent.

3. Meals, travel and other Business Courtesies provided in connection with performance of the services must be modest and incidental to the services being performed (e.g., a meal in connection with an all day meeting is acceptable; a three hour meeting followed by golf or other entertainment is not).

E. Notice/Approval Process for Consulting Arrangements.

1. Contracts for consulting arrangements that are executed by RUMC are subject to review and approval by the Office of Legal Affairs and the appropriate RUMC signatory.

2. RUMC Persons must report any permissible individually executed consulting contracts in accordance with RUMC's Conflict of Interest and Commitment Policy.

F. Other Provisions of these Guidelines, and other Policies, Applicable to Consulting and Compensation Arrangements. These Guidelines do not apply to service as an expert witness for an entity that is not a Vendor or Referral Recipient. Service as an expert witness is permitted only if the compensation is reasonable, paid time off is taken for the time spent on the engagement, and the Person additionally receives written confirmation from the Office of Risk Management that no Conflict of Interest exists with RUMC. Questions about such arrangements should be addressed to the Office of Risk Management.

G. In addition, while the general principles set forth in these Guidelines apply to research arrangements, any arrangements involving research must also comply with and be processed through the applicable research-related policies and procedures of RUMC. Similarly, while the general principles set forth in this Section apply to medical education programs sponsored by entities accredited by the Accreditation Council for Continuing Medical Education ("**ACCME**"), funding for such arrangements must comply with the specific criteria set forth in

these Guidelines in Section VII (Funding for Medical Education Programs Accredited by ACCME).

IV. Third Party Medical Education Programs

This Section applies to attendance or participation by Persons in third party conferences, including continuing medical education events, professional society meetings, roundtables and other educational or scientific programs. RUMC permits Persons to attend bona fide third party conferences and to accept associated meals and receptions sponsored by Vendors or Referral Recipients at such conferences so long as they are modest and clearly subordinate to the conference goals of promoting objective scientific and educational activities and discourse.

A. **Program Faculty.** Subject to compliance with Section III of these Guidelines (Consulting Agreements and other Compensation Arrangements), a Person may serve as a faculty member for a third party educational conference and may accept a reasonable honorarium and reimbursement for his or her own transportation, lodging and meals expenses relating to the conference. Such compensation and reimbursement must be paid by the conference sponsor and not by Vendors or Referral Recipients. In such circumstances, the Person must ensure that no Vendor or Referral Recipient influences the content of the presentation made by the Person, and that there is appropriate disclosure of any financial ties to any Vendors or Referral Recipients, consistent with the rules of the third party sponsor, the body accrediting the program, if any (e.g., ACCME), and RUMC policies.

B. **Attendees.** If a Person is attending a third party conference only as an attendee and not as a bona fide faculty member of the conference, the individual may not accept reimbursement from any Vendor or Referral Recipient for the program registration fee, transportation, lodging, meals or other expenses of attending the program. Under no circumstances may a Person accept reimbursement for transportation, lodging or meals for the cost of his or her spouse or other guest(s).

C. **Conference-Related or Approved Meals and Receptions.** A Person may participate in a meal or reception sponsored by a Vendor or Referral Recipient at a third party conference if the event complies with the guidelines of the organization sponsoring the conference. The meal or reception should be modest in value and conducive to discussion among those participating in the event. The amount of time at any such meals or receptions should be clearly subordinate to the amount of time spent at the conference's educational activities.

D. **Attendance by Healthcare Professionals in Training.** RUMC does not accept financial assistance from Vendors or Referral Recipients to allow medical students, residents, fellows and other healthcare professionals in training to attend educational conferences.

E. **Other Provisions of these Guidelines and Other Policies, Applicable to Medical Education Programs.** Educational programs provided by RUMC are addressed in Section V of these Guidelines (Educational Grants and Donations). Funding for medical education programs sponsored by sponsors accredited by the ACCME must comply with Section VIII of these Guidelines.

V. Educational Grants and Donations

This Section applies to acceptance of grants and donations from Vendors or Referral Recipients only where such grants and donations directly benefit RUMC patients or serve an educational purpose. RUMC will not accept funding that is offered in connection with the purchase or sale of goods or services. The provision of funding by Vendors or Referral Recipients should never influence clinical decision-making, research, purchasing or prescribing decisions, or the awarding of contracts.

A. In General. All educational grants received from Vendors or Referral Recipients must be documented in a writing, approved by the Office of Legal Affairs, signed by all applicable parties, and must not be made for any improper purpose, such as in exchange for changing (or maintaining) any purchasing, research, prescribing or other clinical decisions or practices. Permitted support includes, but is not limited to: funding for fellowships and funding for educational programs conducted by RUMC and related meals in compliance with Section II of these Guidelines (Meals), funding for textbooks or other educational materials, and funding of outside speakers.

B. Solicitation of Support. To ensure that contributions from Vendors or Referral Recipients do not inappropriately influence RUMC's or a RUMC Member's purchasing, contracting, research, prescribing or other clinical decisions, RUMC and its Persons should not solicit or accept contributions from the marketing or sales department of a Vendor or Referral Recipient.

C. Management of Grant Funds. RUMC will maintain a separate fund for the receipt, management and dispensing of grant monies. The Department conducting the educational activity must independently develop a budget for any such project, and must ensure that donated funds are applied toward the applicable educational program. Any funds remaining after completion of the educational program shall be used for educational purposes, or as otherwise required by the funding agreement. Funds from other sources will not be commingled with grant monies. No donated funds may inure to the benefit of any RUMC Person.

D. Program Requirements. Vendors or Referral Recipients may direct grants to a specific Department and indicate the general topic of the program to be funded. However, Vendors or Referral Recipients are not permitted to specify or pre-approve the program content or speakers. Program speakers must disclose any financial relationships with the Vendor or Referral Recipient providing a grant and any other relevant financial relationships. Any program support by a Vendor or Referral Recipient shall be disclosed to program attendees and any recipients of program materials.

E. Grants vs. Marketing/Promotional Activities. In some cases, funding from Vendors or Referral Recipients could be characterized, in whole or in part, as support of RUMC marketing or promotional activities rather than support of an educational program. Examples of such arrangements include website or other

media references to RUMC or its Persons and support of RUMC outreach to RUMC Referral Sources. Any proposed arrangement that involves marketing of RUMC or Person services, even in an educational context, must be reviewed by RUMC's Marketing Department and Office of Legal Affairs. The appropriate individuals in the Marketing Department and Office of Legal Affairs will determine whether it is appropriate for RUMC's or a RUMC Person's name to be used in connection with the arrangement, whether RUMC may accept such funding consistent with these Guidelines, and whether RUMC should pay a share of funding for the proposed activity or event.

F. Other Sections of these Guidelines, and other applicable RUMC Policies. Grants to fund research (including clinical research) must comply with and be processed through the applicable RUMC research policies. Grants to fund medical education programs sponsored by entities accredited by the ACCME must comply with Section VII of these Guidelines (Funding for Medical Education Programs Accredited by ACCME).

VI. Training and Education Regarding Use of Medical Devices

This Section applies to the receipt by RUMC Persons of appropriate training regarding medical devices free from any inappropriate influence, or the appearance of any improper influence, which might interfere with the physician-patient relationship or improperly influence clinical, prescribing, research, or purchasing decisions.

A. Guidelines for attendance at training sessions. RUMC recognizes that the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain medical technology. RUMC further recognizes that proper training in and awareness of new and innovative medical technology may contribute to better and/or more cost-effective patient care. However, the activities surrounding training provided to physicians and others may raise at least the appearance of impropriety. To ensure that RUMC Persons receive appropriate training free from inappropriate influences over their prescribing or other clinical decision-making, their research decisions, or their purchasing decisions, the following guidelines shall be followed regarding attendance at Vendor-sponsored training sessions:

1. RUMC Persons may attend Vendor-sponsored training and education programs in order to further their knowledge on the subject(s) presented. Such programs must contain objective scientific and educational information that will benefit RUMC patients.

2. Training and education programs must be conducted in settings that are conducive to the effective transmission of knowledge, such as hotel or other commercially available meeting facilities, medical institutions, laboratories or other training facilities. Resort settings are not appropriate settings.

3. RUMC Persons attending training programs should only accept associated hospitality in the form of modest meals and receptions. Any meals and receptions provided in connection with the training program should be subordinate in time and focus to the educational/training purpose(s) of the program.

4. RUMC Persons may not allow a Vendor to pay for meals, hospitality, travel or other expenses for their spouses or other guests who do not have a *bona fide* professional interest in the information being provided at the training program.

B. Other Provisions of these Guidelines, and Other Policies, Applicable to Medical Education Programs. Educational programs provided by RUMC are addressed in Section V of these Guidelines (Educational Grants and Donations). Funding for medical education programs sponsored by sponsors accredited by the ACCME must comply with Section VII of these Guidelines (Funding for Medical Education Programs Accredited by ACCME).

VII. Funding for Medical Education Programs Accredited by ACCME

When RUMC acts as a provider of ACCME-accredited continuing medical education ("**CME**"), it shall abide by the requirements set forth in the ACCME Standards for Commercial Support (the "**Standards**"). Compliance with the Standards encourages medical education programs that are free from the improper influence by the entity providing financial support for the CME program.

A. **Disclosure of Financial Interests.** All individuals responsible for controlling or developing the content of an education activity or presenting at a CME event must disclose all relevant financial relationships with any commercial interest to the provider. An individual who refuses to disclose this information will be prohibited from having any control or responsibility over the development, management, presentation, or evaluation of the CME activity.

The following information must be disclosed to CME event attendees prior to the beginning of the educational activity:

1. Name of the individual
2. Name of the commercial interest
3. Nature of the relationship the person has with each commercial interest.
4. If an individual has no relationships, that information must also be provided.

B. **Appropriate Use of Commercial Support.** RUMC, and not the commercial sponsor, will make all decisions regarding the disposition and disbursement of commercial support. RUMC may not agree to accept advice or services concerning teachers, authors or participations or other education matters, including content, from a commercial interest as a condition of contributing funds or services.

C. **Written Agreement Required.** The terms, conditions, and purposes of the commercial support must be documented in a signed, written agreement between RUMC and the commercial supporter.

D. **Fair Market Value.** The amount of honoraria or reimbursement for out-of-pocket expenses for planners, teachers, and authors must be of fair market value, must be set forth in a written contract, and must not take into account any time spent by the individual participating in the CME event as a learner. The Office of Legal Affairs must approve any honoraria or reimbursement paid to planners, teachers, or authors prior to RUMC entering into a contract that includes such provisions.

E. **Educational Value.** Social events or meals cannot compete with or take precedence over the educational events during a CME program.

F. **Restrictions on Funds.** RUMC may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of the CME program.

G. **Commercial Promotion.** RUMC shall follow the ACCME's guidelines with respect to the Appropriate Management of Associated Commercial Promotion, which, among other things, restrict the use of product-specific advertisements.

H. **Documentation.** RUMC must maintain accurate documentation detailing the receipt and expenditure of the commercial support.

I. **Content and Format.** The content and format of a CME activity must promote improvements or quality in healthcare and must not reflect a specific proprietary business interest of a commercial interest. For example, presentations must give a balanced view of therapeutic options, and the use of trade names should be limited when possible.

VIII. Purchase Contracts; Discounts and Other Reductions in Price

This Section applies to contracts for the purchase of goods and services on behalf of RUMC. All such contracts must be negotiated and entered into by authorized RUMC Members, and any discounts, free samples or other reductions in price from Vendors or Referral Recipients must comply with RUMC policies, and satisfy the applicable legal requirements.

A. Approval by Office of Legal Affairs. Discounts or other reductions in price that reduce the cost of patient care and are appropriately structured and reported are permissible and beneficial. However, certain arrangements characterized as discounts may be viewed as kickbacks (e.g., providing a free item for a RUMC Member's personal use as part of a package of discounted products sold to RUMC). Because discounting and pricing raise complex legal issues, any discounting or pricing arrangement that involves other than a straightforward discounted price reflected on the seller's invoice must be reviewed by the Office of Legal Affairs.

B. Additional Guidelines for Discounts and other Reductions in Price.

1. RUMC may only accept a discount that is made at the time it purchases the goods or services or where the terms of any rebate are fixed and set forth in writing at the time of the initial sale of a good or service.

2. Any invoice, coupon or statement provided by the supplier must accurately reflect the discounted price.

3. RUMC must retain documentation of any discount received from a supplier for items or services billed to federal or state health care programs so that such documentation is readily accessible should it be requested by a federal or state health agency.