

Title	Conflicts of Interest and Commitment
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Subcategory1	
Subcategory2	
Subcategory3	
Approval Date	6/27/2018
Contact	<u>Stephanie Guzik@rush.edu</u>
Applies To	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.
Purpose	
Executive Summary	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.
Definitions	<p><b>Benefit:</b> 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.</p> <p><b>Commercial Entity:</b> 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.</p> <p><b>Confidential Information:</b> 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.</p> <p><b>Conflict of Interest:</b> Circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.</p>

**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.

Equipment	
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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.

Outcome	
Guidelines	
Responsibility and Procedure	
Regulatory Elements	
Related Policies	
Reference	<p>[Approved by the Board of Trustees, February 12, 2015]  <a href="#">Rush University Medical Center Relationships with Vendors and Referral Source Guidelines</a>  [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]</p>
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