



<b>Policy Title:</b> Conflicts of Interest and Commitment		<b>Former Policy Number:</b> OP-0359	
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## I. Policy

This policy, “Conflicts of Interest and Commitment” (Policy) serves as the overarching comprehensive policy statement regarding Conflicts of Interest (COI) across the RUSH System. For the purpose of this Policy, RUSH includes Rush University Medical Center (RUMC), Rush Oak Park Hospital (ROPH), Rush Copley Medical Center (RCMC), Rush Medical College (RMC), Rush University (RU) and all subsidiary corporations. This Policy is applicable to RUSH board members, corporate officers and executives, employees, faculty, students, and members of RUSH medical, nursing, professional and technical staffs. These groups must use their best efforts and judgment to avoid any influence which could compromise patient care, research, business transactions, objectivity, or integrity.

COI’s 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.

RUSH is a non-profit charitable tax-exempt organization that must abide by specific regulatory requirements and should adhere to best ethical and compliance practices, including those regarding COI. This Policy sets forth the RUSH comprehensive statement regarding COI 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. This document should be read together with applicable RUSH entity policies including RUMC and ROPH’s Relationships with Vendor and Referral Source Guidelines, which supplement this comprehensive policy statement regarding COI. In addition, the policy “External Relationships and Financial Conflicts of Interest in Research” should be read for all individuals involved in research at RUMC and ROPH.

This comprehensive policy is subdivided to address the specific nature of the following:

- I. Institutional and Business Conflicts;
- II. Clinical Conflicts;
- III. Research Conflicts; and
- IV. Conflicts of Commitment

### I. Institutional and Business Conflicts

To avoid the appearance, perception, or actual conflict of interest, requirements set forth are to protect the interests of RUSH when it is contemplating entering into a transaction or arrangement that might benefit the private interest of a Covered Person. This section of the policy is intended to ensure that all institutional decisions are made solely to promote the best interest of RUSH without favor or preference based on any other considerations.



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- A. A “direct” institutional 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 COI include licensing agreements, including equity holdings, royalty payments, other payments, and their stipulations.
- B. An “imputed” institutional conflict of interest may occur when those who have a fiduciary responsibility to RUSH 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. The following conduct on the part of the RUSH board members, corporate officers and executives, and employees and/or members of their families may constitute a conflict of interest and is **prohibited** unless an exception is granted by the Institutional Conflict of Interest Committee (ICOI), a sub-committee of the RUSH System Audit Committee of the Board:
  - 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 may 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 RUMC/ROPH Vendor Guidelines (“Gifts and Other Business Courtesies”) (generally, business courtesies must be reasonable (not to exceed \$200), and the purpose must never be to induce or influence a business transaction).
- D. Procedure for Institutional COI: RUSH requires the following steps to avoid, reduce or manage institutional conflicts:
  - 1. Individuals in a leadership position are required to make a clear disclosure of any potential, perceived or actual conflict of interest to their immediate supervisor. This must occur at the earliest possible opportunity before an arrangement is entered into which would result in a conflict or as soon thereafter as the individual becomes aware that such a conflict exists. Supervisors should consider whether the time requirements or nature of the activity



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could compromise the Covered Person’s ability to fulfill their institutional responsibilities. In addition, supervisors should consider whether the activity adheres to RUSH’s Mission, Vision and Values. Supervisors may consult with the Conflict of Interest Office in Corporate Compliance (COI Office) to take action in addressing the disclosed activity consistent with RUSH policies. Supervisors must review and provide written approval of the outside activity before it is carried out. Board members should confer with the appropriate Chairperson and RUSH employee who is the executive liaison to support the Chairperson about such interests before any board business takes place. The Chair, in consultation with management, will determine if the matter requires recusal. Regardless of if recusal is necessary or not, the determination will be noted in the meeting minutes and a notification to the COI Office is required.

2. Annually and as new instances arise, RUSH board members, corporate officers/executives, and select administrators are required to disclose any financial/economic interests and/or “associational interests”. RUSH employees who are Covered Persons will disclose interests and associated time and commitment related to disclosed interests and attest to their understanding of and compliance with RUSH’s policies on Conflict of Interest. Disclosures are completed and returned via the conflicts survey. In the event that an individual becomes aware of any additional interests after the submission of the disclosure of interests survey (form), the individual must amend their annual disclosure of conflicts form to include the additional interest(s). Disclosures are transmitted to the COI Office for processing.
3. An initial review will be undertaken by the COI Office, and determine if an actual, potential, or perceived COI exists and make recommendations to the ICOI Committee. The ICOI Committee will conduct a case-by-case review and may take into account any of the following, as applicable, in determining whether an institutional COI exists and the extent to which it can be managed:
  - a. Whether the nature and magnitude of the disclosure and the extent to which the RUSH activity or decision is related to the interest, could directly and substantially affect the RUSH activity/business decision.
  - b. In the case of business or purchasing decisions, the existence of objective processes for decision-making, and the role of the Covered Persons in the decision-making process, and/or the availability of other qualified persons to make such decisions.
  - c. A Covered Person’s business is completely unrelated to their institutional responsibilities or RUSH’s mission (e.g., legacy family business).
  - d. Consider reputational risks to RUSH and any appearance of self-dealing.
4. If time does not permit a full review by the ICOI Committee, such review may be undertaken by the Chair of the ICOI Committee based on Committee precedent. Thereafter, the material facts of the disclosure and situation along with their recommendations will be presented to the ICOI Committee which shall make a final determination on the matter.



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5. The COI Office will submit an annual report to the RUSH System Audit Committee of the Board and the Rush University Board of Governors summarizing the determinations and outcomes of Institutional COI management.

- E. Compliance and Enforcement: Covered Persons who fail to comply with this Policy, including failure to disclose or submission of an erroneous, misleading, or incomplete disclosure as required by this Policy, or failure to comply with an Institutional management plan, may be subject to disciplinary action, up to and including termination of employment. If there is reasonable cause to believe a board member has failed to disclose an interest, the ICOI Committee shall inform the board member of the basis for such belief and afford the individual an opportunity to explain the alleged failure to disclose. If, after hearing the response and making further investigation as warranted by the circumstances, the ICOI Committee determines the board member has failed to disclose an Interest, it shall recommend to the Board appropriate disciplinary and corrective action.

RUSH reserves the right to check the accuracy of the annual COI disclosure forms.

## II. Clinical Conflicts

RUSH Physicians and Health Professionals commit to avoiding COI or the appearance of COI as it relates to their individual financial interests and the best interests of their patients, as well as their commitments to RUSH. It is also recognized that physicians and health professionals, as highly trained specialists, have a unique opportunity to improve and advance patient care and support the mission of RUSH through collaboration with industry. By adopting a position on Conflict of Interest in clinical care, RUSH demonstrates its commitment to establishing a disclosure and review process to promote integrity and objectivity in clinical care, such that collaborations with industry can optimally benefit patients.

This Policy applies to Physicians on RUMC, ROPH, RCMC medical staffs, Health Professionals on faculty at Rush University (RU) and employed Healthcare Professionals at RUSH in all clinical settings regardless of practice location.

- A. A *Clinical Conflict of Interest* may arise when there is a divergence between an individual’s private interests and their professional obligations to the medical staff, hospital, patients, and employees such that an independent observer might reasonably question whether the individuals’ professional actions or decisions in healthcare delivery are determined by personal gain, financial or otherwise. Examples of clinical COI include (and are not limited to): influence on purchase of equipment, materials, instruments from private firms in which the individual has a financial interest; unauthorized disclosures of patient or hospital information for personal gain; and recommendation of therapies to patients in which the individual has a financial interest.



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B. The following conduct on the part of Physicians who are members of the medical staff, Health Professionals who are clinical staff, nursing staff and/or faculty of Rush University and/or RUSH administrative, clerical, or technical personnel or students (hereinafter "Person Subject to this Section of the Policy") is considered to be a clinical conflict of interest and **prohibited** unless an exception is granted by the Clinical Conflicts of Interest Committee (CCIC):

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);
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. Participating in Speakers' Bureaus or other events sponsored by commercial entities if the presentation, lecture or talk by the Person Subject to this Section of the 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 Section of the Policy is expected to disseminate company or product information on behalf of the commercial entity);
4. Accepting drug samples or coupons at RUMC/ROPH except in specified situations for patients who lack financial access to medications, as approved by the RUSH entity Chief Medical Officer. Accepting drug samples/coupons are managed by Care Management at RCMC.
5. 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 Section of the 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 directed by the CCIC;
6. Permitting sponsorship by a commercial entity of an educational event which does not comply with the Accreditation Council for Continuing Medical Education (ACCME) 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;
7. Accepting funds or contributions from a commercial entity earmarked for specific recipients or to support specific projects which have not been approved by the RUSH entity Department Chairperson and which do not comply with Section V ("Educational Grants and Donations") of the Vendor Guidelines;



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8. Accepting financial support or other personal or financial benefit from a commercial entity for the training of clinical trainees on medical devices unless the RUSH entity 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);
9. Accepting promotional items from a commercial entity for use or display in offices or elsewhere on the RUSH campuses 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;
10. Permitting sales representatives of commercial entities to come on the RUSH campus without an invitation or appointment. Representatives must register at the RUMC security desk on the 4th floor of the Atrium Building or at other designated registration sites (at ROPH/RCMC) and all meetings with sales representatives must occur in non-patient care areas;
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).

C. Procedure for Clinical COI: RUSH requires the following steps to avoid, reduce or manage clinical conflicts:

1. Persons Subject to this Section of the Policy, specifically Physician and Health Professionals are required to make a clear disclosure of any potential, perceived or actual conflict of



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interest to their immediate supervisor. This must occur at the earliest possible opportunity before an arrangement is entered into which would result in a conflict or as soon thereafter as the individual becomes aware that such a conflict exists. Supervisors should consider whether the time requirements or nature of the activity could compromise the Physician and/or Health Professionals ability to fulfill their institutional responsibilities. In addition, supervisors should consider whether the activity adheres to RUSH’s Mission, Vision, and Values. Supervisors may consult with the COI Office to take action in addressing the disclosed activity consistent with RUSH Policies. Supervisors must review and provide written approval of the outside activity before it is carried out.

2. Annually and as new instances arise, Physicians and Health Professionals are required to disclose any financial/economic interests and/or “associational interests” and associated time and commitment related to disclosed interests and attest their understanding of and compliance with this Policy. Disclosures are completed and returned via the conflicts survey. In the event that an individual becomes aware of any additional interests after the submission of the disclosure of interests form, the individual must amend their annual disclosure of conflicts form to include the additional interest(s). Disclosures are transmitted to the COI Office for processing. An initial review will be undertaken by the COI Office, who will determine if an actual, potential, or perceived COI exists and make recommendations to the CCIC. The CCIC shall review such disclosures and recommendations and determine how best to avoid, reduce, or manage the clinical COI. The CCIC shall recommend and monitor clinical COI management plans.
3. Exceptional Circumstances: Committees, panels or groups within RUSH which develop Clinical Practice Guidelines (CPG) 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 COI. In the exceptional situation in which avoidance of members with COI is impossible because of the critical need for their expertise and where there has been a good faith effort to find experts without COI, then such committees, panels or groups should:
  - a. appoint a chair without a conflict of interest;
  - b. limit members with conflicting interests to a distinct minority of the membership;
  - c. exclude individuals who have a promotional relationship with the commercial entity whose product is being considered;
  - d. exclude panel members with conflicts from deliberating, drafting, or voting on recommendations concerning matters about which they have a conflict; and
  - e. publicly disclose any relevant COI of members. All committees, panels and groups are to report their handling of potential conflicts on a regular basis to the RUSH entity Chief Medical Officer except for RCMC whose CMO will receive reports for RCMC clinical conflicts





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4. The COI Office will submit reports to the Chairperson of the CCIC summarizing the implementation of the annual COI survey and will keep the Chairperson apprised of COI management issues. The COI Office will submit reports to the RUSH System Audit Committee of the Board and the Rush University Board of Governors. In addition, an annual report will be shared with the Performance Improvement Oversight Committee (PIOC) by the Chair of the CCIC. Lastly, to address the Liaison Committee on Medical Education (LCME) accreditation, summary reports related to issued management plans will be sent to the Dean and the Senior Associate Dean of RMC.

D. Compliance and Enforcement: A first violation of this Policy may require that the person who committed the violation receive counseling, training or education concerning this policy to prevent any further infraction subject to the CCIC and/or Human Resources. Physicians and Health Professionals who fail to comply with this Policy, including failure to disclose or submission of an erroneous, misleading, or incomplete disclosure as required by this Policy, or failure to comply with a Clinical management plan, may be subject to disciplinary action, up to and including termination of employment and/or medical staff privileges.

RUSH reserves the right to check the accuracy of the annual COI disclosure forms.

E. Moonlighting: Moonlighting is outside professional work for compensation; the first obligation of members of the employed medical staff and employed RMC faculty is the preparation for and carrying out of official RUSH duties and are subject to this Policy. Subject to approval in advance, and within certain guidelines, RMC faculty, residents and fellows may moonlight for compensation outside of RUMC/ROPH. Residents and Fellows on J-1 visas are not permitted to moonlight. Residents and Fellows on H-1B visas are not permitted to moonlight without authorization from RUSH Legal. These requests will be processed on a case-by-case basis. Any and all professional work performed for any type of compensation from a non-RUSH entity requires approval from the immediate supervisor. The following requirements must be met for those individuals who have their primary employment at RUSH:

1. The outside activity does not impact regularly scheduled work through RUSH (teaching or other duties);
2. The outside activity does not exceed 10% of Full Time Effort (FTE) over the course of a Fiscal Year (FY);
3. Moonlighting at a RUSH entity will result in compensation prorated based on employment.

The following moonlighting requirements must be met for those individuals who do not have their primary employment at RUSH (**external**) and based on the criteria below, are not subject to this Policy:



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May be recused from completing an annual COI disclosure, if meets **all** of the following requirements

- Primary employment is not at RUSH
- Performs clinical service only
- Devotion of time is not to exceed 20% FTE based over the course of a Fiscal Year
- Is not on faculty at Rush University
- Does not have authority to be a decision maker on behalf of RUSH

### III. Research Conflicts

The term “conflict of interest (COI) in research” refers to situations in which financial or other personal considerations may compromise or have the appearance of compromising an investigator’s professional judgment in conducting or reporting research. A COI depends on the situation and not on the actions or character of an individual investigator. Please refer to the expanded policy on Research COI titled, *External Relationships and Financial Conflicts of Interest in Research* (for RUMC/ROPH).

This Policy applies to any individual who, regardless of title or position, is independently responsible for the design, conduct, or reporting of research at RUMC/ROPH, which includes, but may not be limited to, a principal investigator, project director, co-investigator and key personnel. The principal investigator/project director is responsible for making the determination of any other individuals who meet this definition. Examples include Trainees, Medical/Nursing/Clinical Staff, Collaborators, Consultants and Private Practice Physicians.

- A. A Conflict of Interest may exist when an investigator has a significant financial interest or an external professional relationship which could directly and significantly affect or bias the design, conduct, or reporting of a research project.
- B. The following conduct on the part of members of the RUSH medical, clinical, and nursing staffs, and/or faculty members and students of Rush University and any employee engaged in RUMC/ROPH research in the basic or clinical sciences is considered a research conflict of interest and is **prohibited** unless an exception is granted by the Conflict of Individual and Institutional Interest in Research (COIIR) Committee:
  1. Accepting a financial interest in an entity or receiving a benefit from an entity through oneself or one's family that could influence how he/she/they designs, conducts or reports any research in which he/she/they are 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, technology or product).



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- 3. Accepting a personal or financial benefit from an entity engaged in research or a research sponsor without providing reciprocal professional service of fair market value.
- 4. **Additional examples related to the context of research listed in section II, B, 1-12 of this policy are also included for this section of the policy.**

C. Procedures for Research Conflict of Interest: RUMC/ROPH requires the following steps to avoid, reduce or manage research conflicts. All significant financial relationships will be reviewed in order to eliminate, reduce or manage research conflicts:

- 1. Researchers subject to this policy are required to make a clear disclosure of any potential, perceived or actual conflict of interest to their immediate supervisor. This must occur at the earliest possible opportunity before an arrangement is entered into which would result in a conflict or as soon thereafter as the individual becomes aware that such a conflict exists. Supervisors should consider whether the time requirements or nature of the activity could compromise the researchers ability to fulfill their institutional responsibilities. In addition, supervisors should consider whether the activity adheres to RUSH’s Mission, Vision and Values. Supervisors may consult with the COI Office in Corporate Compliance to take any action in addressing the disclosed activity consistent with RUMC/ROPH Policies. Supervisors must review and provide written approval of the outside activity before it is carried out.
- 2. Annually and as new instances arise, researchers are required to disclose any financial/economic interest and/or “associational interests” and associated time and commitment related to disclosed interests and attest their understanding of and compliance with RUSH’s policies on Conflict of Interest. Disclosures are completed and returned via the conflicts survey. In the event that an individual becomes aware of any additional interests after the submission of the disclosure of interest form, the individual must amend his/her/they annual disclosure of conflicts form to include the additional interests(s) within thirty (30) days of when the activity took place.
- 3. Transactional disclosures are required with each proposal also known as Protocol Specific COI (PSCOI). Researchers must complete a disclosure prior to protocol submission. Examples include (but are not limited to) Institutional Review Board (IRB) submissions, federal funded grant submissions, technology licensing arrangements, laboratory animal research, and certain procurement activities.
- 4. Disclosures are transmitted to the COI Office, Corporate Compliance for processing. An initial review will be undertaken by the COI Office, and determine if an actual, potential, or perceived COI exists and make recommendations to the COIIR Committee. The COIIR Committee shall review such disclosures and recommendations and determine how best to avoid, reduce, or manage research COI. The COIIR Committee shall recommend and monitor research management plans.
- 5. The COIIR Committee may require such action be taken as deemed appropriate to eliminate, reduce or manage a researcher’s COI, including without limitation:
  - a. Publicly disclosing the researcher’s conflict



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- b. Monitoring and managing the investigators research
  - c. Disqualifying the researcher from taking part in the relevant sponsored research
  - d. Compelling the divestiture of the researcher’s ownership interest in an entity, or severance of the researcher’s business relationship with an entity while conducting research
  - e. Restricting conflicted individual from participation in certain aspects of the research
  - f. Involving independent third parties in validation of data and/or data analysis
6. The COIIR Committee shall notify the conflicted individual of its findings with regard to the existence of a COI and the action it deems appropriate to eliminate, reduce or manage the COI.
  7. The COI Office in conjunction with the Vice Provost for Research may perform items 4-6 above in situations where the disclosure is identical to situations presented to the Committee previously and “Committee Precedent” has been established. This review process is considered *Expedited Review*. All expedited reviews will be presented, reviewed, and ratified at the next convened COIIR Committee meeting.
  8. Exceptional Circumstances: When a COI is determined and required action must be taken, the COIIR Committee will provide the affected researcher the opportunity to petition for a re-examination and assessment of the decision or action within ten (10) days of notification of the COIIR Committee’s findings. Such re-examination and assessment 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 the updated fact pattern and reassessment. Such findings shall be final and binding to the conflicted researcher. Conditions for exceptions include 1) the conflicted researchers participation is integral for the conduct of the research; and the Committee 2) approves an effective mechanism for managing the conflict and protecting the integrity of the research.

The COI Office in Corporate Compliance will submit reports to the Deans of each college to which faculty who have a primary appointment have a COI. In addition, annual summary reports of key performance indicators will be provided to the system audit committee of the board and the Rush University board of governors.

- D. Compliance and Enforcement: Violation of this policy may require that the person who committed the violation receive counseling, training or education concerning this policy to prevent any further infraction subject to the COIIR Committee and/or Human Resources. Researchers who fail to comply with this Policy, including failure to disclose or submission of an erroneous, misleading, or incomplete disclosure as required by this Policy, or failure to comply with a Research management plan, may be subject to disciplinary action, up to and including termination of employment.

RUSH reserves the right to check the accuracy of the annual COI disclosure forms.



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#### IV. Conflict of Commitment

RUSH employees and Rush University faculty members owe their primary professional allegiance to RUSH and its academic enterprise, Rush University. Their primary commitment of time and intellectual energies should be to the care delivery, education, research, and scholarship programs of the institution. The specific responsibilities and professional activities that constitute an appropriate and primary commitment will differ across employed and private physicians, schools, and departments, but they should be based on a general understanding between the employee and/or faculty member and their supervisor. While employees can engage in outside activities in the area of their RUSH responsibilities, those activities should not impinge on the employee’s ability to perform their professional duties and should not perceive or directly interfere with or detract from their institutional responsibilities.

Even with such understandings in place, however, attempts to balance RUSH responsibilities with external activities such as consulting, public service or pro bono work can result in conflicts regarding allocation of time and energies. Conflicts of Commitment usually involve issues of time allocation. Whenever an individual’s outside professional activities exceed the permitted limit of 10% effort, or whenever an employee’s primary professional loyalty is not to RUSH, a conflict of commitment exists. Conflicts of commitment generally develop when an employee’s outside activities impose excessive demands on their time and/or when an employee enters into a fiduciary relationship with an outside entity.

In a situation that raises questions of a possible Conflict of Commitment, individuals should discuss the situation with their supervisor, department chair or school dean, or the COI Office. The commitment limit does not apply to non-employed faculty members.

The following conduct on the part of RUSH corporate officers and executives, employees, faculty, and members of RUSH’s medical, nursing, professional and technical staffs (employees) is considered to be a conflict of commitment:

1. For officers/executives and employees (with the exception of part time 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.

See sections I, II, and III of this Policy, to avoid, reduce or manage Conflicts of Commitment.



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## V. COI Policy Review and Approval Process

RUSH’s COI Office, in coordination with the Conflict of Interest Committees and under the oversight of the RUSH System Audit Committee of the Board, is responsible for the administration and oversight of this Policy.

A. Approval and Amendment: This Policy shall be approved and may be amended from time to time by the RUSH System Audit Committee of the Board.

B. COI Committees:

**Institutional Conflicts of Interest (ICOI) Committee:** The Rush System CEO in conjunction with the Rush System Chief Legal Officer appoints the Committee members who are comprised of legal, compliance, members of the clinical and research COI Committees and others as necessary. Decisions of the Committee shall be by majority vote of members present. Committee members must recuse themselves from any discussion and deliberation at a Committee meeting on a particular matter under the following conditions:

- The individual has a personal or outside interest in the matter or,
- The individual has a personal or outside interest because of particular relationships involved in the matter (*e.g.*, spouse, collaborator).

The Committee may, at its discretion, invite a conflicted member to stay for the discussion of an issue, but not vote.

**Clinical Conflict of Interest Committee (CCIC):** The Chief Executive Officer (CEO) of Rush University Medical Center and the President of Rush University appoint the CCIC members who are comprised of faculty, administrators and clinicians as well as the following ex-officio, non-voting members: The Senior Vice President/General Counsel or designee; and a Corporate Compliance representative. Any CCIC voting member who makes a disclosure will recuse themselves for the discussion and the vote on their disclosure.

The CCIC may, at its discretion, invite a conflicted member to stay for the discussion of an issue, but not vote.

**Conflict of Individual and Institutional Interest in Research Committee (COIIR):** The President of Rush University appoints the COIIR members that are composed of faculty, researchers, and deans from each of the four (4) colleges (or their designee) and representatives from RUSH Legal and the following ex-officio, non-voting members: the AVP of Research Compliance; an Intellectual Property/Technology Transfer representative; and a RUMC/ROPH IRB Chairperson as a liaison to/from the RUMC/ROPH IRB.



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The President will appoint at their discretion ad-hoc members if further faculty representation or non-RUSH staff is desired.

In the instance of a tie vote, the Chairperson of the Committee is permitted to vote to carry *or* strike down the motion. COIIR members must recuse themselves from any discussion and deliberation at a Committee meeting on a particular matter under the following conditions:

- The individual has a personal or outside interest in the matter, or
- The individual has a personal or outside interest because of particular relationships involved in the matter (*e.g.*, spouse, collaborator).

The COIIR may, at its discretion, invite a conflicted member to stay for the discussion of an issue, but not vote.

## VI. 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 and Executive:** A president, executive vice president, senior vice president, vice president, associate vice president or assistant vice president.



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**Covered Person: Any Officer, Senior Executive Officer, President, key person, member of the Board, or other person with substantial fiduciary obligations and/or influence or authority within RUSH. Please refer to *External Relationships and Financial Conflicts of Interest in Research* for definition of *Covered Person* in research.**

**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:** 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.

**Health Professionals:** means RUSH registered nurses, nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, occupational therapists, respiratory therapists, audiologists, perfusionists, physical therapists and pharmacists. See Physician definition below.





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**Institutional Conflicts:** Such conflicts arise when an institution's own financial interests or those of its board members/executives, 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 this Policy.

**Physicians:** any physician who has a full or part-time appointment on RUMC/ROPH/RCMC medical staffs. Any physician with a faculty appointment at Rush University.

**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 University, including but not limited to, research that requires approval by the RUMC/ROPH 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 are not limited to, principal investigators, co-investigators or any other person responsible for the design, conduct or reporting of 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.



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**VII. Procedure**

n/a

**VIII. Attachments**

[Vendor Guidelines.pdf](#)

**IX. Related Policies or Clinical Resources**

- External Relationships and Financial Conflicts of Interest in Research
- Disclosure and Management of Conflicts of Interest by IRB Members
- Prevention of Conflicts in Assessment and Promotion (Rush Medical College)
- Procurement for Non-Capital Goods and Services
- Competitive Bidding and Request for Proposal Policy

**X. References and Regulatory References**

- 45 CFR part 46
- 21 CFR parts 50, 56

**Policy Approval History**

Approved by the Board of Trustees, September 9, 2009