



## Policy

<b>Title</b>	<b>External Relationships and Financial Conflicts of Interest in Research</b>
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PolicyType	Research Affairs
Category	Research Compliance
Subcategory1	
Subcategory2	
Subcategory3	
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Contact	Stephanie Guzik
Applies To	All Research Personnel Engaged in the Design, Conduct or Reporting of Research Including Trainees, Medical/Nursing/Clinical Staff, Collaborators, Consultants, and Private Practice Physicians.  All Covered Officials.
Purpose	This Policy expands upon the leadership policy <u>OP-0359 "Conflicts of Interest and Commitment"</u> ; section III Conflicts of Interest in Research. This policy covers both individual and institutional Conflicts of Interest in research.
Executive Summary	<p>Rationale</p> <p>Establish a consistent report and review process to collect professional external activities to determine financial conflicts of interests (FCOI) in research from: (1) all research personnel engaged in the design, conduct, and reporting of research and to oversee and manage significant financial interests in research, in accord with 42 CFR 50, Subpart F, 21 CFR 54, and 45 CFR 94 which address perceived, potential or actual conflicts in research; and (2) all Covered Officials and Covered Offices, in order to identify business relationships to assess institutional financial relationships that may compromise research objectivity at Rush.</p> <p>Background</p> <p>Rush University Medical Center (Rush) depends on its ability to maintain the public's trust. To ensure adherence to the highest professional standards our research activities cannot be compromised by or perceived as biased by financial and/or business relationships.</p>
Definitions	

**"Conflict of Interest"** may exist when an investigator (defined below) 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.

**"Conflict of Individual and Institutional Interest in Research (COIIR) Committee"** refers to the Rush Committee that advises the Provost on conflict of interest matters in research. The Provost appoints the faculty Committee members and the ex-officio members (non-voting). The Provost will appoint at his/her discretion ad hoc members if further faculty representation or non-Rush staff is desired. For Public Health Service (PHS) funded research, the COIIR acts as the designated official(s) to review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest prior to the Rush's expenditure of any funds under a PHS-funded research project. The Director of the Office of Research Compliance serves as the FCOI Officer and is responsible for communicating these decisions to the NIH through eRA Commons.

**"Contractor"** refers to an entity that provides property or services "under contract" for the direct benefit or use of the Federal Government (for Public Health Service research).

**"Covered Officials"** means the members of the Board of Trustees, the President, the Provost and vice provosts, corporate officers, deans and associate deans and other institutional administrators, particularly insofar as the individuals have oversight of research, with special attention to human subjects research, conducted by, through, or at Rush. The responsibilities/procedures relating to Institutional COI in Research set forth below applies to such Covered Officials. This policy will also require review of actual or potential conflicts of interest involving department chairs, division chiefs, institute and center directors, Institutional Review Board (IRB) chairs, and the Conflict of Individual and Institutional Interest in Research (COIIR) chair.

**"Covered Offices"** means those offices at Rush, including the Intellectual Property and Technology Transfer Office, the Office of Legal Affairs, the Office of Research Affairs and others that may be involved in relationships with business entities or other interests on behalf of Rush and must report information about potential Institutional Conflicts of Interest in Research accordance with this Policy.

**"Disclosure of Significant Financial Interests"** means an investigator's disclosure of significant financial interests to the institution (Rush).

**"FCOI Training"** applies to PHS-funded investigators and requires them to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

(1) The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

(2) An Investigator is new to an Institution; or

(3) An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

**"Institutional Conflict of Interest in Research:"** An Institutional Conflict of Interest (COI) in Research may occur whenever the financial interests of the institution, or of an institutional official who has authority to act on behalf of the institution (i.e., a Covered Official), might affect, or reasonably appear to affect, institutional processes for the design, conduct, reporting, review, or oversight of research.

**"Institutional responsibilities"** refer to an investigator's professional responsibility on behalf of the institution including, but not limited to activities such as research, research consultation, teaching, professional practice, institutional Committee memberships, and service on panels such as Institutional Review Boards or on Data and Safety Monitoring Boards.

**"Investigator(s)"** refers to the principal investigator or project director (PI/PD), co-investigator (Co-I) and any other person(s) (e.g., faculty, staff, post-doctoral fellows, senior scientists, graduate students, nursing students, consultants and/or collaborators) and for PHS-funded research, "senior/key personnel" responsible for the, design, conduct, or reporting of sponsored research. For disclosure purposes, investigator(s) completing the disclosure survey also must disclose interests of immediate family members: his/her spouse, domestic partner, and dependent children in accord with 42 CFR 50.63; 45 CFR 94.3; and OP-0359.

**"Procurement Activities"** means goods and services that support federally funded research and charged to federal awards.

**"Procurement COI":** A conflict of interest would arise when the Rush employee, officer, faculty or agent, and/or any member of his or her immediate family, his or her partner, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract that involves federal awards. Rush officers, faculty, employees, and agents may neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts for federal awards. No employee, officer, faculty or agent may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest.

**"Senior/key personnel"** means the Project Director (PD)/ Principal Investigator (PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution.

**"Significant Financial Interest"** with respect to an individual, refers to a financial interest consisting of one or more of the following interests of the Investigator that reasonably appears to be related to the Investigator's institutional responsibilities:

(1) 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 (12) 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 of fair market value.

(2) 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 (12) 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 option, or other ownership interest); or

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

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. For PHS-funded Investigators, a disclosure will include reimbursed travel and at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Further information may be needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

**"Significant Financial Interest"** (institutional or imputed institutional): With respect to the assessment of Institutional COIs, or Imputed Institutional COIs, a "Significant Financial Interest" means:

(1) Royalties: Institutional COI may be present when the institution has agreements to receive milestone payments and/or royalties from the sales of an investigational product that is the subject of the research;

(2) Intellectual property (IP): Rush may license and/or receive equity in a company as a result of a licensing agreement for Rush IP; receive royalties or other fees as compensation for the use of that IP; and/or may receive equity or other financial interest as part of a co-investment in a licensee or related company;

(3) Non-publicly traded equity: When, through its technology licensing activities or investments related to such activities, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded company that is: i) the sponsor of research at the institution, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the institution;

(4) Publicly traded equity: When, through technology licensing activities or investments related to such activities, the institution has obtained an ownership interest or an entitlement to equity (including options or warrants) exceeding \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a publicly traded company that is i) the sponsor of research at the institution, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the institution;

(5) Gifts from sponsors: When the institution has received substantial gifts (including gifts in kind) from a potential commercial sponsor of research or a company that owns or controls products being studied or tested, or an individual affiliated with these companies.

Equipment

Information

Policy

Outcome

Guidelines

Responsibility and Procedure

**A. Disclosure of Financial Interests and Assessment of Individual Conflicts of Interest**

**B The annual Conflict of Interest (COI) survey will collect Investigator disclosures at the end of the fiscal year.**

**Investigators engaged in research are required to complete the COI annual survey to report on activities related to their institutional activities for which they have received external compensation. The disclosure report will include an accounting of any payments received. If an amount in excess of \$5,000 is reported (pursuant to 42 CFR 50, Subpart F) it is considered a SFI.**

**Annual disclosures are reviewed for the twelve (12) months prior to the end of the reporting period and the twelve (12) months subsequent to the period. Protocol-specific disclosures are reviewed and acted upon at time of submission for prospective management.**

**Protocol-specific disclosures will be required at the time an investigator initiates a new IRB study, submits a grant/contract for basic research, and/or any time a change in financial status occurs. Such disclosures will be reported in the Rush Research Portal (RRP).**

**The Office of Research Compliance (ORC) will collect, review and assess annual and protocol-specific disclosures of external relationships and financial interests in research.**

**In the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project is required to disclose any significant financial interests. For existing Investigators, disclosures of new significant financial interests should be made to the ORC through the RRP within 30 days. At which time the ORC will communicate the SFI to the COIIR and will within sixty days review the disclosure of the significant**

financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflicts of interest. Based on guidance and precedent established by the COIIR Committee, the ORC will perform an expedited review and assessment with the Vice Provost for Research who serves as the COIIR Chairperson. All expedited reviews will be reviewed by the COIIR Committee during the annual Fiscal Year review for its review and assessment of the appropriate management of the conflict. If a conflict of interest is identified by the COIIR, the COIIR will take such actions as necessary to eliminate, or to appropriately manage, such conflicts, including the creation of management plans. ORC, on behalf of the COIIR Committee, will transmit recommended actions and/or management plans, as applicable, for research involving human subjects to the Institutional Review Boards for consideration and overall approval of the human subject research.

The COIIR through the ORC will maintain records (e.g., COIIR meeting minutes, reports) relating to all PHS Investigator disclosures of financial interests and the Institution's review and assessment of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a financial conflict of interest) and all actions under this policy or retrospective review, if applicable, for at least three years from the date of the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

#### **Disclosure of Financial Interests and Determination of Institutional Conflicts of Interest**

Each year, the Annual FY Conflict of Interest (COI) Survey requests information from the following Covered Offices in order to identify: (1) financial relationships Rush has with business entities that could compromise the integrity of Rush's research, teaching activities; and (2) any individual interests of any Covered Officials that can be "imputed" to the institution because of that Covered Official's decision-making authority and influence over certain of the Institution's research affairs.

- Intellectual Property and Technology Transfer Office
- Office of Legal Affairs
- Office of Research Affairs
- Covered Officials, Principal Investigators and Key Personnel

To the best of their knowledge, Investigators shall identify the use of Rush Intellectual Property in Human Subject Research in the Annual Fiscal Year COI Survey and on the IRB application (if applicable). Those protocols shall be forwarded to the Office of Research Compliance for assessment by the COIIR.

In cases of Rush License or Option Agreements, the Intellectual Property and Technology Transfer Office will notify the Office of Research Compliance (ORC) when it executes a license or option agreement with a business entity whose commercial interests may be affected by research conducted at Rush. Additionally, the Intellectual Property and Technology Transfer Office will compile a list of all Rush License/IP annually and forward to the ORC for assignment and assessment by the COIIR.

The following significant financial and fiduciary interests of the Institution warrant formal review by the COIIR for potential Institutional COI with respect to research and should assess the potential for conflict and weigh the magnitude of any risk to the research's integrity:

- Significant financial interests for the institution.
- Significant financial interests on the part of covered officials responsible for the oversight of research.

(1) When Rush itself has a significant financial interest (an Institutional Interest):

**Human Subjects Research:** There is a "rebuttable presumption" that human subjects research should not be carried out at Rush when the institution has a significant financial interest that is determined to be a COI. In those situations where Rush faculty have unique capabilities, or where there are unique resources at the institution, the research may be performed at Rush after the establishment of a formal institutional management plan by the COIIR.

**Non-Human Subjects Research:** Because research subject safety is not an issue in the case of non-human subjects research, the primary reasons to manage Institutional COI focus on protection of the integrity of the Rush's research and educational missions. If a decision is made by the COIIR that the potential value of a line of research exceeds the potential risks related to Institutional COI, the management plan created by the COIIR may include some form of additional oversight. The level of oversight should be proportional to the risk to Rush's reputation and/or educational mission.

(2) When an individual in a supervisory administrative role has an Imputed Institutional or Individual COI:

**Human Subjects Research:** In this situation, there is not the same "rebuttable presumption" made that the work cannot be performed, since in most cases alternative supervision can be arranged. The COIIR should review the administrator's role in relation to the research and to the researchers, the nature of the administrator's conflict of interest, and should then formulate a plan so that an appropriately objective administrator can oversee the research for the institution.

**Non-Human Subjects Research:** In most cases for this circumstance, an alternative administrator should be identified, and the conflicted administrator should voluntarily recuse themselves. The situation should be

reviewed by the COIIR to be certain no bias will be introduced that could affect the research, the researchers, or any students working on the research project. If there is potential for bias or pressures, particularly in the case of a student, alternative supervision should be suggested by the Committee.

#### **Procurement Standards for Federally Funded Awards**

No employee, officer, or agent of Rush may participate in the selection, award, or administration of a contract supported by a Federal award if he or she has a real or apparent conflict of interest. Such a conflict of interest would arise when the employee, officer, or agent, any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract. The officers, employees, and agents of Rush may neither solicit nor accept gratuities, favors, or anything of monetary value from contractors or parties to subcontracts. To comply with University Purchasing Policy and Uniform Guidance Section: 200.318, 200.319 & 200.320, completion of the Purchasing Checklist Form is required for all transactions \$10,000 or greater.

#### **Management of Individual Conflicts of Interest Management Plan**

Disclosures of investigator financial relationships that constitute a significant financial relationship and that are identified as giving rise to a Conflict of Interest, require development of an appropriate management strategy, endorsed by the institution and reviewed and accepted by the IRB. The plans focus on the management, reduction, modification, elimination or divestiture of the significant financial interests. Management plans are developed on a case by case basis, but adhere to COIIR Committee precedent where applicable, and may include, but are not limited to, some or all of the following actions:

- Disclosure of the relationship in the informed consent and in any subsequent written or oral presentations or publications;
- Disclosure to all participating Investigators and members of the research team in multi-site trials and as otherwise appropriate; removing the Investigator as principal investigator, or restricting of the Investigator from a part of or the entire research project, such as precluding his/her participation in the informed consent process, data analysis, or a specific procedure;
- Eliminating the interest completely or permitting the investigator to withdraw from participation in the research;
- Reducing the amount of remuneration allowable for services provided to the entity;
- Monitoring research by independent reviewers.

When a SFI exists that has been identified as giving rise to a conflict of interest, and there are compelling circumstances, which warrant continued



participation of the conflicted individual in the study, the COIIR Committee may recommend a Conflict of Interest Management Plan (MP).

The COI determination and plan is developed after discussion by the COIIR Committee and transmitted to the IRB, when human subjects are involved. The ORC is responsible for administering the final management plan communicated to and acknowledged by the IRB (human subjects research) or the COIIR Committee for non-human subjects research or to others as deemed necessary (e.g., IACUC).

The following steps are required:

**(1) Assurance of Disclosure**

The Investigator affirms in the RRP that his/her disclosure is up to date, at least once a year and is required to update the disclosure within 30 days of discovering or acquiring (e.g., through purchase, marriage or inheritance) a new significant financial interest.

**(2) Notification of Changes**

The investigator is responsible for notifying the Office of Research Compliance through the RRP of any changes in his/her financial interests or relationships within thirty (30) days of the change, so it can be determined whether further management is necessary.

For PHS-funded research projects of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the PI and COIIR as required by this policy, the COIIR will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations. In addition ORC will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project. Affected individuals will be required to demonstrate acceptance of issued management plans.

**Appeal**

Individuals have the right to appeal. Any Investigator may appeal the COIIR Committee determination. If an individual is dissatisfied with his/her appeal outcome they may appeal to the Provost.

**Non-Compliance and Sanctions**

Covered Employees and faculty are subject to the ordinary disciplinary process of Rush if they fail to fully and truthfully disclose activities or relationships that could reasonably be viewed as conflict of interest situations or fail to comply with any stipulated plan for managing the disclosed conflict.

Other potential actions include, but are not limited to:

- Inclusion in Rush's faculty, medical staff member or employee file of a letter from the appropriate university or hospital official(s) indicating that the individual's good standing has been called into question;
- Determination that the individual is precluded from conducting research, teaching or organizing Continuing Education programs, IRB or Institutional Animal Care and Use Committee (IACUC) approval, or supervising graduate students;
- Non-renewal of appointment;
- Dismissal from the college where the individual holds an academic appointment or termination of Rush's employees, medical/hospital and/or nursing staff;
- Failure to disclose known financial conflicts of interests or to follow an appropriate prescribed management plan may be a serious breach of this process and may itself be considered ethical misconduct or professional dishonesty; and/or detrimental research practices.

Allegations against an employee for breach of this process should be reported confidentially, in writing to the employee's supervisor and/or the Rush Research Integrity Officer (RIO).

In addition, whenever a financial conflict of interest is not identified or managed in a timely manner, including: (a) failure by the Investigator to disclose a significant financial interest that is determined by the COIIR to constitute a financial conflict of interest; (b) failure by Rush to review or manage such a financial conflict of interest; or (c) failure by the Investigator to comply with a financial conflict of interest management plan, Rush will, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The ORC will document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;

(5) Name of the entity with which the Investigator has a financial conflict of interest;

(6) Reason(s) for the retrospective review;

(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(8) Findings of the review; and

(9) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, Rush will update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

If bias is found, Rush notifies the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and Rush's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, Rush will submit FCOI reports annually.

If Investigators fail to disclose their significant financial interests (initially or provide timely updates) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest, the ORC will investigate and complete a retrospective review of the Investigator's activities for Public Health Service (PHS) funded research conducted during the time period of the noncompliance. The COIIR Committee will determine if any PHS research was biased in the design, conduct or reporting of such research. The outcome and determination from a non-compliance investigation will be reported to the PHS awarding component/agency. Mitigation reports and/or corrective action plans may be issued.

#### **Management of Institutional Conflicts of Interest**

COIIR Committee's purpose in reviewing and managing Institutional conflicts of interest is to maintain the highest possible standards in research; adhere to all applicable federal and state regulations; promote objectivity in research and protect the reputation and credibility of Rush, its faculty and staff.

Criteria for Evaluating an Institutional Financial Conflict of Interest are:

- Reviewing the nature of the research, current phase of development and intentions for subsequent phases

- Magnitude of potential risks to human subjects inherent in the research, and how those risks could be affected as a result of the Institutional COI
- Degree to which the Institutional Financial Interest could be directly and substantially affected by the research
- Whether the studies involve Rush Intellectual Property that is used as a platform technology or a generic method used broadly
- Likelihood that a societally important development project will be substantially impeded if the research is not performed at Rush
- The effectiveness of managing, reducing or eliminating the Significant Institutional Financial Interest through recusal, divestiture, or independent oversight of the affected research
- The degree of risk to the human subjects involved that is inherent in the research protocol

In cases where an Institutional Financial Interest involves a Covered Official and gives rise to an Imputed Institutional Conflict with regard to that Covered Official, the following shall also be considered; the degree of direct and immediate authority that Covered Official has over the research and the people involved in the performance and reporting of the research. Also, whether a plan for separation of oversight of the faculty/staff conducting the human subject research by the Covered Official with the conflict can be implemented that is both practical and effective while the Covered Official remains in the assigned leadership position.

If the COIIR Committee determines that a Significant Institutional Financial Interest exists and may be managed, the Committee must include in its finding a justification as to why Rush and/or its Investigator must be involved in the research despite the COI. Management tools that may be used to minimize the risk to Rush and its subjects may include:

- Transparency to the public and to subjects
- Referral of the protocol to an external IRB for review and monitoring
- An independent monitoring mechanism to be established, which could include any of the following: data safety monitoring board, independent monitor, or independent reviewer
- Permitting the research to proceed subject to a plan of divestiture of financial interests
- Permitting only certain procedures and analysis to occur at Rush
- Key members of the COIIR Committee also are members of the Intellectual Property (IP) Committee to assure communication. The ORC facilitates communication between, IRB, COIIR and the IP Committees about Institutional COI through issued Management Plans.

**Confidentiality**

All information disclosed by an employee for the purpose of financial disclosure and management, and all official records of disclosure and management shall be deemed confidential to the extent possible. Any information disclosed by an employee as required by this process shall be used solely for the purpose of administering and/or executing this policy and may not be disclosed or used for any other purpose unless required by law. Unauthorized disclosure of any such information shall be deemed to be unethical behavior and a violation of this policy and subject to appropriate disciplinary action.

### **Training**

Conflict of Interest training is required for all research personnel and is accessible through [www.citiprogram.org](http://www.citiprogram.org). Federally funded investigators are required to take FCOI training as specified in the definitions section of this policy.

### **Sub-recipient assurances**

When Rush carries out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), Rush takes reasonable steps to ensure that any subrecipient Investigator complies with this policy by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with 42 CFR 50.604(c). If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to Rush's financial conflicts of interest policy and are responsible for disclosing significant financial interests that are directly related to the subrecipient's work for Rush ;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to Rush . Such time period(s) shall be sufficient to enable Rush to provide timely FCOI reports, as necessary, to the PHS awarding component.

(iii) Alternatively, if the subrecipient's Investigators must comply with Rush's Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to Rush. Such

time period(s) shall be sufficient to enable Rush to comply timely with its review, management, and reporting obligations.

(Rush will provide FCOI reports to the PHS awarding component regarding all FCOI's of all subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI).

(2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this subpart, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

## Regulatory Elements

The 2011 US Public Health Service regulations state:

The primary goals of the federal regulations are to manage, reduce, or eliminate financial conflicts of interest (FCOI).

The institution has primary responsibility for developing internal policies and procedures related to COI. The institution designates an official to review disclosures of significant financial interests and to manage conflicts of interest.

Investigators must disclose any "significant financial interest" to the institution.

The institution must report to the federal government funders if it believes an investigator's significant financial interest could affect the research.

The institution has the responsibility to make its COI policy available via a publically accessible web site.

Prior to the expenditure of funds, make certain information concerning COIs held by investigators are available via a publicly accessible web site.

Significant financial interest means anything of monetary value that appears to be related to the Investigator's institutional responsibilities including, but not limited to:

- Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); when aggregated over the next twelve (12) months, are expected to exceed \$5,000;
- Any equity interest including stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value with regard to any non-publicly traded entity; any remuneration (e.g., estimated value) received from the entity in the twelve (12) 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 option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests;
- Reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/organizer,

destination and duration).

The term does not include the following:

- Salary, royalties, or other remuneration from Rush;
- Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- Reimbursed travel or sponsored travel that is reimbursed or sponsored by a federal, state or local government agency, an institution of higher education (e.g., academic teaching hospital, medical center or research institute affiliated with higher education);
- Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights;
- Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization.

The principal investigator/project director is responsible for:

- Each proposed activity,
- Determining who meets the definition of investigator,
- Ensuring and certifying that each investigator or relevant research personnel has submitted a current COI Survey in the RRP.

Each Investigator must complete training prior to engaging in research related to any NIH-funded grant annually and every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to an institution
- An institution finds an Investigator noncompliant with institution's FCOI policy or management plan

#### Public Accessibility

For affected PHS-funded researchers, Rush makes its policy available via its [website](#).

PHS regulations require that, prior to Rush's expenditure of any funds under a PHS-funded research project, that Rush ensure the public can access certain information by submitting a written request for information

concerning any significant financial interest disclosed to Rush that meets the following three criteria

1. The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the PHS-funded research project identified by Rush in the grant application, progress report, or any other required report submitted to the NIH;
2. Rush determines that the Significant Financial Interest is related to the NIH-funded research; and
3. The Institution determines that the Significant Financial Interest is a Financial Conflict of Interest.

If you would like to request information on a FCOI identified on or after 8/24/12 related to a Senior/Key investigator associated with a Public Health Service (PHS) funded award, then please submit a request to [stephanie\\_guzik@rush.edu](mailto:stephanie_guzik@rush.edu) (link sends e-mail), and ensure to include the following information in the request:

- Your email address
- The PHS Project Title
- The PHS Award Number
- The Senior/Key Investigator's First and Last Name

Within 5 business days, ORC will provide a response that will include the following information:

- Senior/Key Investigator's name;
- Senior/Key Investigator's title and role with respect to the research project;
- Name of the entity in which the Significant Financial Interest is held;
- Nature of the Significant Financial Interest; and
- Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Related Policies	OP-0359 "Conflicts of Interest and Commitment", Section III
Reference	42 CFR Part 50 Subpart F (grants and cooperative agreements) 45 CFR Part 94 (contracts) 42 CFR 50
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