

**POLICY**  
**Conflict of Individual Interest in Research**  
**Rush University Medical Center**

**Introduction**

Institutions in which faculty, staff, or students conduct research involving human subjects must ensure that the safety and welfare of those subjects and the integrity of the research are never subordinated to, or compromised by, financial interests or the pursuit of personal gain.

Financial interests in human subjects research are distinct from other interests inherent in academic life that might impart bias or induce improper behavior, because financial interests are discretionary, and because the perception is widespread that they may entail special risks. Specifically, opportunities to profit from research may affect -- or appear to affect -- a researcher's judgements about which subjects to enroll, the clinical care provided to subjects, even the proper use of subjects' confidential health information. Financial interests also threaten scientific integrity when they foster real or apparent biases in study design, data collection and analysis, adverse event reporting, or the presentation and publication of research findings.

The opportunity for researchers to receive financial rewards from these endeavors is not intrinsically unacceptable, as long as this opportunity does not adversely influence scientific or clinical decision-making. Importantly, however, though a researcher may strive to insulate his or her decision-making from bias, the mere appearance of a conflict between financial interests and professional responsibilities may weaken public confidence in the researcher's objectivity. The real and apparent risks posed by financial interests likewise have the potential to threaten public support for the research mission of academic institutions.

**Preamble**

As a starting point, we do not assume that financial interests in human subjects research are categorically improper, or that those who hold such interests cannot conduct research with the requisite scientific objectivity and integrity or protect the welfare of human research subjects. Recognizing, however, that research with human subjects is a privilege that imposes unique obligations, the following principles are the basis for the following institutional policies concerning financial interests in such research:

- A. With the welfare of research subjects always of foremost concern, Rush University Medical Center regards all significant financial interests in human subjects research as potentially problematic and, therefore, as requiring close scrutiny. ***This policy establishes the rebuttable presumption that an individual who holds a significant financial interest in research involving human subjects may not conduct such research.*** The intent is not to suggest that every financial interest jeopardizes the welfare of human subjects or the integrity of research, but rather to ensure that institutions systematically review any financial interest that might give rise to the perception of a conflict of interest, and further, that they limit the conduct of human subjects research by financially interested individuals to those situations in which the circumstances are compelling. The presumption against significant financial interests in human subjects research should apply whether the research is funded by a public agency, a non-profit entity, or a commercial sponsor, and wherever the research may be carried out.
  
- B. ***In the event of compelling circumstances, an individual holding significant financial interests in human subjects research may be permitted to conduct the research.*** Whether the circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, and the degree to which the interest may be affected by the research. When the financial interest is directly related to the research and may be substantially affected by it, (e.g., an equity interest in a start-up company that manufactures the investigational product) the risk is greatest and the bar must be high; however, even direct and potentially lucrative financial interests may be justified in some circumstances. For example, when the individual holding

such interests is uniquely qualified by virtue of expertise and experience and the research could not otherwise be conducted as safely or effectively without that individual, he or she should be permitted the opportunity to rebut the presumption against financial interests by demonstrating these facts to the satisfaction of Rush's Conflict of Individual Interest in Research (COIIR) Committee. The COIIR Committee might approve the involvement of such an individual in the research, subject to conditions that ensure effective management of the conflict and credible oversight of the research.<sup>1</sup>

- C. ***This policy requires full prior reporting of each covered individual's significant financial interests that would reasonably appear to be affected by the individual's research, updated reporting of any relevant change in financial circumstances, and review of any significant financial interests in a research project by the COIIR Committee prior to final Rush IRB approval of the research. COIIR Committee findings and determinations should inform the Rush IRB's review of any research protocol or proposal, although the Rush IRB may require additional safeguards or demand reduction or elimination of the financial interest.*** Between the COIIR Committee and the Rush IRB, the more stringent determination should prevail.
- D. ***Transparency is the watchword for the oversight of financial interests.*** Transparency is achieved through full and ongoing internal reporting and external disclosure of significant financial interests that would reasonably appear to affect the welfare of subjects or the conduct or communication of research.
- E. Transparency, though necessary to sustain public confidence in academic research, is not sufficient to protect human subjects. ***When Rush finds that financial interests in human subjects research are justified by compelling circumstances, those interests and the research in question must be managed through rigorous, effective, and disinterested monitoring undertaken by individuals with no financial or professional ties to the research or direct reporting relationships to the researchers.*** Approaches to monitoring might include the following: regular audits of the informed consent and enrollment process, the involvement of a patient representative or ombudsman when subjects are recruited and informed consent is obtained, a requirement to escrow the financial interest until the investigational product has been approved and on the market for a specified time period, and the use of data safety monitoring boards. In some circumstances monitoring boards might be composed wholly of institutional representatives; however, when the institution itself holds a financial interest in the research, disinterested monitoring might require the participation of individuals from outside the institution.
- F. ***Rush University Medical Center and its individual faculty, staff, employees, students, fellows, and trainees bear a shared responsibility for the oversight of financial interests in human subjects research, yet each remains accountable for the effectiveness of the oversight system.*** Individuals who conduct human subjects research under Rush's auspices must familiarize themselves with the Rush COIIR policies and act diligently to fulfil the requirements imposed by these policies.
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<sup>1</sup> To illustrate, the inventor of an implantable medical device, who under the Bayh-Dole Act might receive royalty income, and who might also be compensated by the device manufacturer for training other physicians to use the device, may also be the individual who is best qualified to implant the device in human subjects safely under experimental conditions. The COIIR Committee might, at its discretion, agree to permit this financially-interested inventor to participate in a clinical study of the device at the institution, subject to management conditions crafted to minimize the potential conflict of interest. These conditions could include, in addition to full disclosure of the interest (to research subjects and others as described in this guidance), requirements that informed consent be obtained by a clinician with no financial ties to the research, and that the research be overseen by a monitoring board.

## **POLICY**

### **A. Definitions**

**Compelling Circumstances** are those facts that convince the Rush COIR committee that a financially interested individual should be permitted to conduct human subjects research. When considering a request by a financially-interested individual to conduct human subjects research, the circumstances that the COIR Committee should evaluate include the nature of the research, the magnitude of the interest and the degree to which it is related to the research, the extent to which the interest could be directly and substantially affected by the research, and the degree of risk to the human subjects involved that is inherent in the research protocol. The Committee should also consider the extent to which the interest is amenable to effective oversight and management.

**Conducting Research** means, with respect to a research protocol, designing research, directing research or serving as the principal investigator, enrolling research subjects (including obtaining subjects' informed consent) or making decisions related to eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication.

**Covered Individual** includes any faculty (fully-, partially-, or non-salaried) or faculty agent, staff, student, fellow, trainee, or administrator who, under the aegis of Rush University Medical Center or pursuant to the review and approval of the Rush IRB, conducts research involving human subjects.

**Disclosure** means a release of relevant information about significant financial interests in human subjects research to parties outside Rush's COIR review and management processes (e.g., to research subjects or journal editors).

**Financially Interested Company** means a commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the research.<sup>2</sup> This term includes companies that compete with the sponsor of the research or the manufacturer of the investigational product, if the covered individual actually knows that the financial interests of such a company would reasonably appear to be affected by the research. This term also includes any entity acting as the agent of a financially interested company (e.g., a contract research organization)

**Financially Interested Individual** means a covered individual who holds a significant financial interest that would reasonably appear to be affected by the individual's human subjects research.

**Human Subjects Research** includes *all* research meeting the definition of "research" performed with "human subjects" as these terms are defined in the federal Common Rule (45 C.F.R. Part 46 and 21 C.F.R. Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation. In the event that the Common Rule definitions of "human subjects" or "research" are modified through rulemaking, any such revisions shall apply for the purposes of this guidance.

#### **Rebuttable Presumption Against Financial Interests in Human Subjects Research**

means Rush will presume, in order to assure that all potentially problematic circumstances are reviewed, that a financially interested individual may not conduct the human subjects research in question. This rule is not intended to be absolute: a financially interested individual may rebut the presumption by demonstrating facts that, in the opinion of the COIR Committee, constitute compelling circumstances. The individual would then be allowed to conduct the research under conditions specified by the COIR Committee and approved by the Rush IRB.

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<sup>2</sup> Under the standard articulated in the PHS regulations, institutions must solicit and review information about investigators' significant financial interests in any entity "whose financial interests would reasonably appear to be affected by the [PHS-funded] research." 42 C.F.R. §50.604(c)(1)(ii).

**Reporting** means the provision of information about significant financial interests in human subjects research by a covered individual to responsible institutional officials and to the Rush COIR committee, or the transmission of such information within institutional channels (e.g., from the COIR Committee to the Rush IRB).

**Responsible Institutional Officials** means the Provost and the Associate Dean for Research, who are responsible for the oversight of research programs within Rush University Medical Center.

**Responsible IRB** is any of the Rush institutional review boards with jurisdiction over the research as specified in the federal wide assurance (FWA) that Rush has provided to the U.S. Department of Health and Human Services.

**Significant Financial Interests in Research** includes the following remuneration received by a researcher from a firm or corporation directly involved in or affected by clinical or basic science research:

- salary, honoraria, or consulting fees that, when aggregated for the clinical investigator and the clinical investigator's spouse and dependent children, is expected to exceed an annual sum of \$10,000;
- stocks, stock options, or other ownership interests in a firm or corporation that, when aggregated for the clinical investigator and the clinical investigator's spouse and dependent children (i) exceed a dollar value of \$10,000, or (ii) represent a 5% or greater ownership interest in the firm or corporation, or (iii) any and all equity interests in entities whose value cannot readily be determined through reference to public prices; and
- patents, copyrights, or other intellectual property rights, and any royalties derived therefrom.

## **B. Scope and Substance of This Policy**

**1. Conflict of Individual Interest in Research (COIR) Officer and Committee.** Federal regulations require PHS-funded institutions to appoint a COIR officer to review financial interests in PHS-sponsored research.<sup>3</sup> The Associate Dean for Research shall appoint this COIR Officer.

The Rush COIR Committee membership shall consist of the entire membership of the Rush Scientific Integrity Committee<sup>4</sup> and

- the Director, Rush Office of Intellectual Property, and
- A liaison to/from the Rush IRB, drawn from the administrative staff of the Rush Human Subjects Protections Program, and appointed by the Associate Dean for Research.

The COIR Committee responsibilities include the following:

- Review* of any request by a financially interested individual to rebut the presumption that he or she may not conduct human subjects research.
- Documentation* of the Committee's findings and the bases for any recommendation to permit or to recommend against permitting a financially interested individual to conduct human subjects research. In either case the COIR Committee will prepare a summary report describing the nature and amount of the financial interest and the Committee's recommendations. This summary report shall be made available to the Rush IRB. When the COIR Committee has recommended that a financially interested individual be permitted to conduct human subjects research and the Rush IRB has approved the research and the individual's participation, the summary report should be provided to research subjects or the public, upon request.
- Management and oversight* when a financially interested individual is permitted to conduct human subjects research. As a first principle, the COIR Committee shall encourage the financially interested

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<sup>3</sup> 42 C.F.R. § 50.604(b).

<sup>4</sup> Membership of the Rush Scientific Integrity Committee consists of the Deans of the four Colleges, the Associate Dean for Research, the Director of Research Compliance, a representative of the Office of Legal Affairs as an ex officio member to give appropriate advice and consultation regarding legal matters, and four faculty members appointed by the President: a department chairperson with wide experience in research and publications, and three active investigators.

individual to minimize the potential for conflict of interest by reducing or eliminating the interest or the individual's direct involvement in the research. The COIIR Committee should specify the monitoring procedures or other conditions to be imposed when a financially interested individual will be permitted to conduct human subjects research. Such procedures may include: (i) public disclosure of the researcher's conflict, (ii) monitoring of a research's clinical or basic science studies, (iii) disqualification of a researcher from taking part in research, (iv) compelled divestiture of a researcher's ownership interest in an outside firm or corporation, or (v) severance of a researcher's business relationship with an outside firm or corporation.

- d. The COIIR shall notify each researcher within ten (10) business days of its findings with regard to the existence of a conflict of interest and the action it deems appropriate to manage, eliminate, or reduce the conflict of interest.
- e. *Appeal procedure for financially interested individual.* With regard to any finding or action of the COIIR, the COIIR shall afford the researcher the opportunity to petition for a reexamination and reassessment with ten (10) days of notification of the COIIR's findings. Such reexamination and reassessment shall take place in the context of a meeting of the COIIR, wherein the researcher shall have the opportunity to address the findings and concerns of the COIIR. Within a reasonable period of time following this meeting, the committee shall render its findings based on this reexamination and reassessment. Such findings shall be final and binding on the researcher.
- f. *Communication* to the Rush IRB, and to responsible institutional officials, of summary information about the nature and amount of any significant financial interest in human subjects research, along with the Committee's findings and recommendations concerning requests by financially interested individuals to conduct such research.

## **2. Process.**

- a. Each year, the COIIR Officer shall collect and maintain records of all financial disclosures in a format that is readily accessible to the COIIR Committee, the Director of the Sponsored Research Projects Office, and responsible institutional officials;
- b. The Rush IRB and responsible institutional officials shall be alerted whenever a financially interested individual proposes to conduct human subjects research;
- c. Prior to the Rush IRB's final approval (whether initial or continuing approval) of human subjects research, the COIIR Committee shall inform the Rush IRB and responsible institutional officials of any significant financial interests held by financially interested individuals who will conduct the research, as well as the COIIR Committee's findings and recommendations concerning the same;
- d. Financially interested individuals shall be provided an avenue for appealing decisions of the COIIR Committee; and
- e. When financially interested individuals are permitted to conduct human subjects research, the financial interests in question shall be disclosed in accordance with Rush's COIIR policies.
- f. The COIIR Officer shall maintain records of all financial disclosures and all actions taken by the institution with respect to any conflict of interest for at least three years from the date of submission of the final expenditures report (for each cited project), or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.

**3. Rebuttable Presumption that Financially Interested Individuals May Not Conduct Human Subjects Research.** This policy establishes the presumption that, in the absence of compelling circumstances, a financially interested individual may not conduct human subjects research. This presumption should be rebuttable when compelling circumstances exist.

- a. This policy allows the COIIR Committee, after it reviews the relevant facts and circumstances and documents the compelling circumstances, to recommend that a financially interested individual be permitted to conduct the research, and to make recommendations for appropriate monitoring and oversight.
- b. A summary report indicating the nature and amount of the financial interest and COIIR Committee recommendations shall be transmitted to the Rush IRB and to responsible institutional officials.

**4. Monitoring.** Procedures for internal, and, when deemed necessary, external monitoring when a financially interested individual is permitted to conduct human subjects research, include (but are not limited to):

- a. Assignment of a COIIR Committee member (or other disinterested and qualified individual) to monitor study implementation, analysis and reporting of findings, and financial management of the study and then make a written report back to the COIIR Committee at six-month intervals.
- b. Assignment of two or three COIIR Committee members (or other disinterested and qualified individuals) to monitor study implementation, analysis and reporting of findings, and financial management of the study and then make a written report back to the COIIR Committee at six-month intervals.
- c. Assignment of two COIIR Committee members (or other disinterested and qualified individuals) and at least one disinterested, qualified individual with no relationship to Rush University Medical Center, the study sponsors, or the study investigator -- to monitor study implementation, analysis and reporting of findings, and financial management of the study and then make a written report back to the COIIR Committee at six-month intervals.
- d. Assignment of one or more one disinterested, qualified individual with no relationship to Rush University Medical Center, the study sponsors, or the study investigator -- to monitor study implementation, analysis and reporting of findings, and financial management of the study and then make a written report back to the COIIR Committee at six-month intervals.

**5. Reporting by Covered Individuals.** This policy requires covered individuals to report to the COIIR Committee and/or the Rush IRB all significant financial interests that would reasonably appear to be affected by the individual's current or anticipated human subjects research. In making such reports, each covered individual is required to declare explicitly whether he or she does *or does not* have such financial interests; the failure to report is unacceptable.

- a. Reports are required at least annually, with prompt updating whenever there is an interim, material change in significant financial interests.
- b. Covered individuals shall indicate on the institutional face sheet accompanying the research proposal whether the researcher holds any significant financial interest in the research.

**6. Reporting to Chairman/Section Director.** When the COIIR Committee determines that a financially interested individual should be permitted to conduct human subjects research, a copy of the Committee's summary report describing the financial interest and any conditions to be imposed upon the research should be provided to the Department Chair in which the covered individual resides administratively (or to the Section Director, for the Department of Medicine), and to the responsible institutional officials who have institutional responsibility for monitoring the activities of the covered individual.

**7. Investigator Certification to IRB.** When a research proposal is submitted to the Rush IRB for review, including continuing review (where applicable), each covered individual who will conduct the research shall attest in writing to the Rush IRB that financial report information on file for that individual is current and will be updated promptly to reflect relevant changes in financial circumstances. The Rush IRB shall forward any information that it receives concerning a significant financial interest in human subjects research to the COIIR Committee.

**8. COIIR Committee Review of Significant Financial Interest Created by Licensing Agreements.** Prior to executing a technology licensing agreement, the Office of Intellectual Property must determine whether the agreement would create a significant individual financial interest in ongoing or proposed human subjects research, and if so, inform the Rush COIIR Committee of the proposed terms of the agreement. The COIIR Committee shall either approve the conduct of the research by the individual who will hold the financial interest, subject to an appropriate monitoring plan, or determine that the individual may not conduct the research if he or she wishes to retain the financial interest.

**9. Disclosure of Significant Financial Interests.**

- a. This policy shall require disclosure of the existence of significant financial interests in human subjects research as follows: to state and federal officials, as required by statute or regulation; to research

fundors or sponsors; to the editors of any publication to which a covered individual submits a manuscript concerning the research;<sup>5</sup> and in any substantive public communication of the research results, whether oral or written.

- b. If Rush as an institution participating in a multi-center trial has judged a financially interested individual eligible to conduct human subjects research at its site, that fact should be made known to the Principal Investigator or Sponsor, and to the IRBs of other institutions participating in the trial.
- c. Research consent forms should, as a matter of Rush's COIR policy, disclose the existence of any significant financial interest held by a covered individual who is conducting the human subjects research. The precise wording of disclosure in the consent form should be determined by the Rush IRB, but should include an explanation of the fact that the financial interest in question has been reviewed by the COIR Committee, approved subject to committee oversight, and determined by both the Committee and the Rush IRB not to pose any additional significant risk to the welfare of research subjects or the integrity of the research.
- d. If Rush's COIR Committee has authorized a financially interested individual to conduct human subjects research, the disclosure statement in the research consent form should indicate that additional information (to include the COIR summary report describing the nature and amount of the financial interest) will be provided to research subjects upon request.<sup>6</sup>

**10. Prohibition on Payments for Results.** This policy prohibits payments from Rush or the research sponsor to a covered individual, if such payments are conditioned upon a particular research result or are tied to successful research outcomes.

**11. Payments for Subject Enrollment or for Referral of Patients to Research.** Payments for subject enrollment or for referral of patients to research studies should be permitted only to the extent that such payments:

- a. Are reasonably related to costs incurred, as specified in the research agreement between the sponsor and Rush;
- b. Reflect the fair market value of services performed; and
- c. Are commensurate with the efforts of the individual(s) performing the research.

**12. Affirmation of Institutional Policies on Intellectual Property and Publication Rights.** This COIR policy affirms an investigator's accountability for the integrity of any publication that bears his or her name. This policy also affirms the right of a principal investigator to receive, analyze, and interpret all data generated in the research, and to publish the results, independent of the outcome of the research. Rush shall not enter, nor permit a covered individual to enter, research agreements that permit a sponsor or other financially interested company to require more than a reasonable period of pre-publication review,<sup>7</sup> or that interfere with an investigator's access to the data or ability to analyze the data independently.<sup>8</sup>

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<sup>5</sup> Disclosure to journal editors should take the form of an affirmative statement on behalf of each covered individual who conducted the research that he or she either does or does not hold significant financial interests in the research. This requirement is consistent with the recent uniform disclosure requirements published by a group of editors of major medical journals. F. Davidoff, C. D. DeAngelis, J.M. Drazen, et al. Sponsorship, authorship, and accountability. *JAMA*; 286;10:1232-1234.

<sup>6</sup> The National Human Research Protections Advisory Commission has recommended this approach to the disclosure of researchers' financial interests to research subjects. Letter from Mary Faith Marshall, Ph.D., Chair, NHRPAC, to Assistant Surgeon General/Acting Principal Deputy Assistant Secretary for Health Arthur J. Lawrence, Ph.D., dated August 23, 2001.

<sup>7</sup> For sponsored research, a reasonable period of review is no more than 90 days, unless both parties agree that extenuating circumstances require an extension of time. For research involving NIH-funded research tools, the NIH has stated that it would consider a 30-60 day review period to be reasonable. National Institutes of Health, Principles and Guidelines for Recipients of NIH Research Grants and Contract on Obtaining and Disseminating Biomedical Research Resources, 64 Fed. Reg. 246, 72090 (Dec. 23, 1999).

<sup>8</sup> When research involves more than one institution and numerous investigators (e.g., a multi-center trial), the investigators may delegate primary authorship to a subset who will take responsibility for the publication.

**13. Protection of Students and Trainees.** Commercially sponsored research may give rise to financial incentives that conflict with a supervising researcher’s responsibility to foster the academic development of students and trainees. Agreements with sponsors or financially interested companies that place restrictions on the activities of students or trainees or that bind students or trainees to non-disclosure provisions should ordinarily be prohibited. When deemed unavoidable, such agreements should be subjected to close scrutiny by the responsible university officials and the Rush COIR Committee, and should be fully disclosed to all students and trainees prior to their involvement in the research. Under no circumstance should a student or trainee be permitted to participate in research if the terms and conditions of participation would prevent him or her from meeting applicable institutional degree requirements (e.g., completion and public defense of a thesis or dissertation).

**14. Sanctions.**

a. *Range of possible sanctions* for noncompliance, up to and including dismissal:

- i. Verbal sanction.
- ii. Written sanction
- iii. Suspension of study.
- iv. Termination of study.
- v. Suspension of research privileges.
- vi. Termination of research privileges.
- vii. Dismissal

b. *Procedures to be followed for sanctioning violations.* Possible sanctions for noncompliance with this policy shall be discussed by the COIRR Committee and recommended by a majority vote to the responsible institutional officials (Associate Dean for Research and Provost) for affirmation and implementation.

c. *Procedures to be followed for appealing adverse determinations.* Faculty members and other employees sanctioned for noncompliance under these policies shall have the right to appeal the sanction action to the Management Committee of Rush University Medical Center.

Violations that appear to have resulted in a misrepresentation of research results or other unprofessional conduct should be handled according to Rush’s policies for dealing with allegations of misconduct in research; Rush’s Medical Staff policies; and/or Rush’s Human Resources policies. Violations of federal or state statutes and guidelines shall be handled consistent with federal and state laws and requirements. All decisions regarding violations and sanctions must be documented in writing.

**PROCEDURES**  
**Conflict of Individual Interest in Research**  
**Rush University Medical Center**

**RESPONSIBILITY**

**PROCEDURE**

Associate Dean for Research

1. The Associate Dean for Research shall appoint an institutional Conflict of Individual Interest in Research Officer who shall schedule meetings committee for the review of research conflicts of interest (“Conflict of Individual Interest in Research Committee”). This committee shall consist of the entire membership of the Rush Scientific Integrity Committee as well as the Director, Rush Office of Intellectual Property; and a liaison to/from the Rush IRB, drawn from the

administrative staff of the Rush Human Subjects Protections Program, and appointed by the Associate Dean for Research.

Conflict of Individual Interest in Research Officer

1. Each year, the Conflict of Individual Interest in Research Officer shall, on a form designed to indicate whether a researcher holds a Significant Financial Interest, solicit and review financial disclosure statements from each Principal Investigator.
2. The Conflict of Individual Interest in Research Officer shall maintain records of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for at least three years from the date of submission of the final expenditures report, or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.
3. The Conflict of Individual Interest in Research Officer shall provide the Director of the Sponsored Research Projects Office with access to an up-to-date listing of all investigators who have completed an annual financial disclosure report.
4. Prior to the institution's expenditure of any funds, the Conflict of Individual Interest in Research Officer shall report to the PHS Awarding Component or other relevant Sponsor the existence of a conflicting interest (but not the nature of the interest or other details) as found by the Research Conflict of Individual Interest Committee, and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations. Similarly, for any interest that the institution identifies as conflicting subsequent to the institution's initial report under the award, the Conflict of Individual Interest in Research Officer shall report the existence of a conflicting interest (but not the nature of the interest or other details) found by the Conflict of Individual Interest in Research Committee and assure that the interest has been managed, reduced, or eliminated in accordance with the regulations

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Principal Investigators

1. All Principal Investigators shall complete an annual financial disclosure listing the known Significant Financial Interests of the researcher and the researcher's spouse and dependent children. Following this annual disclosure, should the researcher become aware of any additional Significant Financial Interests, the researcher shall within a reasonable time amend the annual disclosure to include the additional Significant Financial Interests.

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Conflict of Individual Interest in Research Committee

1. The Research Conflict of Individual Interest Committee shall have the authority (a) to determine whether a disclosed Significant Financial Interest constitutes a conflict of interest, as defined in this policy, and (b) to take appropriate action to manage, reduce, or eliminate said conflict of interest.

2. In order to manage, reduce, or eliminate a researcher's conflict of interest, the Conflict of Individual Interest in Research Committee may take any appropriate action, including, without limitation: (a) public disclosure of a researcher's conflict, (b) monitoring of a researcher's clinical or basic science studies, (c) disqualification of a researcher from taking part in research, (d) compelled divestiture of a researcher's ownership interest in an outside firm or corporation, or (e) severance of a researcher's business relationship with an outside firm or corporation.
3. The Conflict of Individual Interest in Research Committee may from time to time establish threshold dollar amounts for Significant Financial Interests, above which a Significant Financial Interest will be presumed as a matter of Medical Center policy to constitute a conflict of interest. Notwithstanding the foregoing, the threshold dollar amounts for Significant Financial Interests will remain consistent with all applicable statutes.
4. The Research Conflict of Individual Interest Committee shall notify each researcher within ten (10) business days of its findings with regard to the existence of a conflict of interest and the action it deems appropriate to manage, eliminate, or reduce the conflict of interest.
5. With regard to any finding of the Conflict of Individual Interest in Research Committee as to the existence of a conflict of interest or the action appropriate to manage, eliminate, or reduce the conflict of interest, the Research Conflict of Individual Interest Committee shall afford researchers the opportunity to petition for a reexamination and reassessment within ten (10) days of notification of the Committee's finding(s). Such reexamination and reassessment shall take place in the context of a meeting of the Conflict of Individual Interest in Research Committee wherein the researcher shall have the opportunity to address the findings and concerns of the Committee. Within a reasonable period of time following this meeting, the Committee shall render its findings based on this reexamination and reassessment. Such findings shall be final and binding on the researcher.
6. The Research Conflict of Individual Interest Committee may modify the policies and procedures "as it deems appropriate" or "as necessary". Such modifications will be distributed upon approval from the Rush University Provost.

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Director, Sponsored Research  
Projects Office

1. With each new research application (regardless of funding sources), the Sponsored Research Projects Office will ascertain whether or not the investigator has completed an annual financial disclosure listing the known Significant Financial Interests of the researcher and the researcher's spouse and dependent children. This will be accomplished by

maintaining access to an up-to-date listing of all investigators who have completed an annual financial disclosure, as provided by the Research Conflict of Individual Interest Officer. For those new investigators who have not previously completed an annual financial disclosure, the Sponsored Research Projects Office will: (a) notify the Conflict of Individual Interest in Research Officer, and (b) not approve the research application until a financial disclosure is completed and submitted to the Conflict of Individual Interest in Research Officer.

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Director, Human Subjects  
Protection Office

1. When a research proposal is submitted to the Rush IRB for review, including continuing review, each Principal Investigator shall attest in writing to the Rush IRB that the financial report information on file for that individual is current and will be updated promptly to reflect relevant changes in financial circumstances. The Rush IRB shall forward any information that it receives concerning a significant financial interest in human subjects research to the COIIR Committee.
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Director Intellectual Property

1. Prior to executing a technology licensing agreement, the Office of Intellectual Property must determine whether the agreement would create a significant individual financial interest in ongoing or proposed human subjects research, and if so, inform the Rush COIIR Committee of the proposed terms of the agreement. The COIIR Committee shall either approve the conduct of the research by the individual who will hold the financial interest, subject to an appropriate monitoring plan, or determine that the individual may not conduct the research if he or she wishes to retain the financial interest.