

Conflict of Interest Policy for Officers of Instruction and Research

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I. Purpose of Policy

This policy is intended to educate the Brown academic community about Federal and University requirements on conflicts of interest. It outlines annual and transactional/*ad hoc* processes internal to the University for reporting apparent or potential conflicts of interest and for managing such conflicts. It supports the University's commitment to its core values:

- the education of undergraduates, graduate students, and trainees;
- academic freedom;
- the advancement of the range and depth of knowledge and understanding of the natural world and our human condition;
- the safety of patients under the care of University faculty and participants in research;
- open and timely communication and dissemination of knowledge; and
- the protection of the appearance and the actual integrity and objectivity of research, instruction, and public service.

A Changed Academic-Industry Relationship

Since the enactment of Bayh-Dole legislation in 1980, the academic community has played a broader role in translational research and the commercial development of technologies. Commercialization of inventions and discoveries through technology transfer brings the benefits of university research to the public good. The past thirty years have brought about a major cultural shift in research universities with respect to academic activities. "Where once the development of products for the market place was discouraged, investigators are now encouraged to share their expertise with industry through consulting, speaking, or

other arrangements, to collaborate with industry in product development, and to form their own companies. Deepened relationships with industry may involve financial linkages that are entirely benign but will in other cases carry the potential to create serious conflicts of interest.”¹

This policy addresses situations in which there may be a potential financial or personal conflict between a particular outside interest of a Brown faculty member or investigator and the professional commitment that person has made to Brown University. Such situations are not unusual; they do not imply wrong-doing or inappropriate activities. Rather, research universities encourage interactions and the establishment of relationships between academia and industry which can cause these conflicts to arise. The experience and knowledge gained through outside consulting and service on advisory committees is valued for its synergistic return to both research and student training.

The academic community often plays an important role in successful commercialization efforts as scientific consultants and in continuing research development projects. However, in a university setting, these relationships can compromise, or be perceived as compromising, important academic values, research integrity, or the university mission. Universities have an obligation to assure that all potential conflicts of interest are managed, reduced, or eliminated, as appropriate. The identification and management of conflicts of interest address the tension between the benefits of promoting the public good through the transfer of knowledge gained through University research to the private sector, and the primary responsibility of faculty and investigators to their University duties.

A conflict of interest generally arises when a faculty member or investigator has an outside financial interest that is closely related to his or her University responsibilities. An apparent financial conflict of interest exists when a faculty member’s or investigator’s outside financial interest could lead an independent observer to reasonably question whether the design, conduct, or reporting of research or the teaching or mentoring of students might be influenced by the potential for personal gain. The value of research lies in its objectivity or the absence of bias in the research process. Faculty and investigators in particular must be committed to conducting themselves and their research activities in accordance with the highest standards of integrity.

¹ A Report of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human Subjects Research *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*, (February 2008) p.8

The Management of Conflicts

Brown University is responsible for informing faculty and investigators about existing federal and institutional policies regarding reporting requirements and evaluation of reported information; determining whether a conflict or potential conflict of interest exists; and establishing mechanisms to manage, reduce, or eliminate real or apparent conflicts.

A frequently utilized mechanism for managing a conflict of interest is full and open disclosure of all outside financial interests and professional activities related to University duties. Sometimes additional safeguards and even prohibition of certain types of financial relationships may be required. Examples of other possible conditions or restrictions include the following:

- Monitoring of research by independent reviewer(s), or a conflict of interest oversight committee;
- Monitoring student activities;
- Modification of the research plan;
- Disqualification from participation in the portion of sponsor-funded research or the related business interest that would be affected by the significant financial interest;
- Divestiture of significant financial interest;
- Severance of relationships that create actual or potential conflicts.

Evaluation of reported information is a highly confidential and case-specific process. It is important to note that there is no formula that dictates which management methods “fit” which conflicts. When evaluating whether an outside financial interest constitutes a conflict and/or the appropriateness of certain management strategies, the faculty and staff who serve on the Conflict of Interest Review Board carefully consider the particular circumstances of the research endeavor. The Board considers the potential benefit of the project and the individual’s participation in it and the risks to integrity of research data, risk of bias, risks to human subject participants, and risk of the appearance of conflict. It poses such questions as the following:

- Is an open academic environment maintained?
- Do the conflicted individual and the institutional resources bring unique capabilities to the research?
- Is the research appropriate to Brown’s mission?
- Are there restrictions on publications and dissemination of research results?
- How great is the risk to human subjects?
- Are the roles of students, trainees, and junior faculty and staff appropriate and free from exploitation?

- Are there appropriate channels for communication and oversight of the research project?
- Are significant benefits to society likely to result from advancing the research?²

The Conflict of Interest Review Board identifies case specific management methods from a broad array of nationally recognized management methods that are applied to such cases. Management methods might include:

Management through disclosure of outside financial interests to one or more of the following:

- Human subject participants through IRB approved consent forms; editors of publications to which manuscripts are submitted; audiences of substantive oral or written public communications of research results; lay audiences and the press; funding institutions and sponsors; all of the researchers, research personnel, students and trainees working on the project; the conflicted individual's immediate supervisor; sponsors of multi-center trials and to IRBs of other participating institutions; relevant clinic or hospital administrators.

Measures to protect vulnerable members of the research team (students, trainees, staff, and junior faculty):

- Provide vulnerable research team members with access to faculty/staff who are not involved in the research to review questions and concerns about the research;
- Disclose the conflicted individual's outside commercial interest to research team;
- Provide a mechanism for outside review of academic decisions that involve vulnerable members of the research team;
- Restrict student, trainee, and junior faculty involvement in research projects conducted by conflicted individuals.

Measures to insure the integrity of the research:

- Independent data monitoring to ensure validity;
- Review the study design to address potential bias arising from the financial interest;
- Prohibit the involvement of a conflicted individual as PI, Co-PI, or investigator;
- Prohibit the involvement of a conflicted individual in data collection;
- Prohibit the involvement of a conflicted individual in data analysis;
- Review authorship status;
- Oversight of the research by an independent individual or group with sufficient expertise to evaluate the research and progress of the project.

² Ibid.p.24-25

Measures to reduce the conflicted individual's outside financial interests:

- Divestiture of outside interest;
- Reduction of the amount of the outside interest;
- Restrictions in exercising/trading stock options or stock;
- Deferral or waiver of royalty payments, research-related milestone payments, or related payments received in partial or full compensation for licensing of the technology that is the subject of research.

Measures to reduce the role of the conflicted individual in the outside entity when she or he is performing research related to that entity, especially a new or small entity. Potential management methods might include prohibitions against certain services such as:

- Board of Directors positions; Speakers Bureau activities; consulting; officer positions; scientific advisory board positions.

II. Types of Conflicts

Conflict of Commitment occurs when a faculty member's outside professional interests interfere with or compromise his/her full time obligation to the University. University policy permits faculty members who are full-time University employees to devote not more than one day per normal work week, on average, to outside professional interests.

An appointment as a full-time faculty member at Brown carries primary professional responsibility to the University, to its educational mission, and to its students. Full-time, regular faculty members are therefore not permitted to hold regular (tenured or tenure-track) positions elsewhere. It should be noted that the primary responsibility of regular faculty is the education of Brown students. Regular faculty members are not permitted to teach at other institutions during the academic year except under special circumstances and with the prior written permission of the Dean of the Faculty or the Dean of Biology and Medicine, as appropriate.

Conflict of Interest in Research refers to situations in which outside financial interests may compromise, or have the appearance of compromising, a faculty member's or an investigator's professional judgment in designing, conducting or reporting research. The bias such conflicts may conceivably impart not only affects collection, analysis, and interpretation of data, but also other activities such as the hiring of staff, teaching and mentoring of students and junior faculty, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods.

III. Conflict of Interest Definitions

Financial interest means anything of monetary value, including but not limited to, salary or other payments or services (i.e., consulting fees or honoraria); equity interests (i.e., stocks, stock options, deferred benefits, or other ownership interests); intellectual property rights (i.e., named inventor on a patent and/or patent assignee, royalties, copyrighted material and benefits accruing from such rights); and gifts.

A *Conflict of Interest* within the scope of this policy refers to situations in which outside financial interests may compromise, or have the appearance of compromising, a faculty member's or an investigator's professional judgment in designing, conducting, or reporting research and/or in the teaching and mentoring of students.

Investigator includes faculty, staff, students, and trainees who are responsible for the design, conduct, or reporting of sponsored research. For the purpose of identifying financial conflicts or potential conflicts, investigator includes the spouse, domestic partner, and dependent children of the investigator.

Assurance of Compliance is the electronic certification by which faculty and investigators acknowledge that they have read this policy and are in compliance with internal reporting requirements.

Reporting refers to the annual and transactional/*ad hoc* processes and forms by which faculty and investigators submit to the University information on an outside financial interest (i.e., an investigator "reports" an outside financial interest on the Reporting of Outside Financial Interests and Professional Activities form).

Transactional or *Ad hoc* reporting is when a faculty member or investigator submits an assurance of compliance or reporting form outside of the *annual* reporting process.

Ad hoc reporting occurs when a faculty member or investigator updates an assurance or reports a new outside financial interest that has emerged after the annual assurance process, or was previously unreported.

Transactional reporting occurs when a faculty member, student, staff, adjunct, or post doctoral investigator submits a sponsored research proposal and has not completed an assurance of compliance in the previous 12 months; or an investigator submits a sponsored research proposal and indicates the presence of an outside financial interest that is directly or indirectly related to the proposed research.

Conflict of Interest Review Board is the University entity that is responsible for reviewing the Annual Reporting forms; the Review Board determines whether an outside financial interest constitutes a conflict of interest. Once a conflict of interest has been identified, the Review Board develops a management plan and mechanisms to implement the plan.

Disclosure is a method of managing a financial conflict of interest or potential conflict of interest by means of the release of relevant information about outside financial interests to parties outside Brown's Conflict of Interest Review Board. It may include public disclosure of a faculty member's or investigator's outside financial interest in relevant publications and presentations, disclosure to co-investigators, members of the laboratory and research group and students or trainees, and disclosure on human subject consent forms.

IV. To whom does this Policy Apply?

Brown-Employed Faculty and Investigators with Appointments Greater than 50%

All Brown- employed faculty and investigators with appointments of greater than 50% (including faculty with administrative positions) must adhere to the annual reporting requirements policy as well as transactional and *ad hoc* reporting when appropriate.

Brown-Employed Faculty and Investigators with Appointments 50% or Less

All faculty members with appointments of 50% or less and all non-faculty investigators must adhere to transactional reporting requirements.

Hospital-Based Faculty

All full-time, hospital-based faculty in the Division of Biology and Medicine must comply with the Conflict of Interest policies of their employers and/or grantee institutions. If a hospital-based faculty member or investigator submits a sponsored project through Brown, he or she must comply with the University's transactional assurance and reporting process and management policies as appropriate.

Post doctoral and Non-Faculty Staff, Students, Fellows, Trainees, and Technicians

For each proposed research activity, Principal Investigators are responsible for determining which non faculty staff and students meet the definition of "investigator" defined above. Prior to submitting a grant proposal, named "investigators" are required to submit an Assurance of Compliance and if necessary, the Reporting form.

Emeriti Faculty must participate in the annual assurance/reporting process if conducting on-campus research funded through Brown University.

Off Campus Collaborators and Contractors

The Principal Investigator is responsible for each proposed Public Health Services (PHS) and the National Science Foundation (NSF) activity for determining which non-subrecipient collaborators and contractors meet the definition of “investigator.” Such collaborators and contractors must disclose all outside financial interests to the University. Brown will determine if a conflict exists and manage, reduce, or eliminate the conflict as appropriate. (Subrecipients see Section XI, Institutional Reporting Requirements)

V. Reporting Responsibilities and Procedures

Annual Process

Annually, Brown faculty members receive a request from the Vice President for Research to complete an Assurance of Compliance with Brown’s Conflict of Interest Policy. If the Assurance indicates the presence of an outside financial interest directly or indirectly related to University duties, the individual will be asked to complete a supplemental form, the Reporting of Outside Financial Interests and Professional Activities (Reporting form).

Financial interest means anything of monetary value, including but not limited to, salary or other payments or services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options, deferred benefits or other ownership interests); intellectual property rights (e.g. named inventor on a patent and/or patent assignee, copyright material and benefits accruing from such rights) and gifts.

Financial interests that do not have to be reported include:

- Service on boards and visiting committees of non-profit educational institutions or other nonprofit organizations.
- Service on government or nonprofit agencies scientific advisory committees or study sections

Faculty and investigators must report all outside financial interests directly or indirectly related to professional responsibilities at Brown.

Institutional Review Board (IRB)

Investigators involved in the design, conduct or reporting of studies involving human participants have a special obligation to avoid bias or the appearance of bias in the conduct of these studies. Of special interest are those clinical studies where a drug, device, or procedure has been invented or discovered by the investigator. All investigators must fully report any outside financial interest directly or indirectly related to any protocol under review to the IRB. The IRB will be apprised of management practices that the University has defined for the reported outside financial interest. The IRB shall determine what information relating to the financial interest should be included in the informed consent process or other appropriate protections for human subjects.

IRB Members

All IRB members must comply with University Conflict of Interest policies. In addition, IRB members must complete the relevant form upon their initial appointment to the IRB for evaluation and update the form when circumstances change. An IRB member may be recused from any deliberations relating to studies with which that IRB member has a potential conflict of interest.

VI. University Review and Management Responsibilities

The Provost has final authority for compliance with the University Conflict of Interest Policy. The Provost may make delegations consistent with this responsibility to the Vice President for Research and/or the Associate Vice President, Research Administration.

Pursuant to the delegation of authority by the Provost, The Vice President for Research shall be responsible for appointing the Conflict of Interest Review Board which will include at least five members of the faculty, the Director of Brown Technology Partnerships, the Director of the Office of Sponsored Projects, an ex officio representative of the Dean of Faculty, and an ex officio representative of the Dean of the Division of Biology and Medicine. The Committee will be chaired by the Associate Vice President, Research Administration, who shall convene the committee's meetings and provide guidance to the committee on issues of COI. The Chair shall have the authority to request additional information from faculty and investigators as necessary to enable the committee to discharge its duties and responsibilities. The Committee will review reported financial interests to determine the following:

- Whether financial interests on a submitted reporting form indicate(s) a potential conflict of interest
- Whether a reported financial interest is a real or apparent conflict and if so, whether the conflict requires a management plan or elimination.
- The effectiveness of mechanisms for managing, reducing, or eliminating the conflict as proposed by the Associate Vice President, Research Administration, and/or determining the feasibility for implementation of a decision regarding the individual conflict(s).
- The appropriate follow up mechanisms that the Associate Vice President, Research Administration should implement to assure continuing effectiveness of management plans and oversight committees.

The Associate Vice President, Research Administration, shall prepare a written report on each such matter reviewed reflecting the decisions made by the committee in accordance with the charge above for the Vice President of Research's approval or consideration. The Vice President of Research will consult with the Dean of the Division of Biology and Medicine or the Dean of Faculty as appropriate.

The IRB will be notified in those instances where the Review Board recommends management for faculty and investigators engaged in human subjects, or certain preclinical, research.

The University is responsible for notifying research sponsors of a conflict of interest when required under sponsors' regulations outlined in Section XI below.

VII. Prohibited Conflicts and Compelling Circumstances

Certain kinds of conflicts cannot be managed under any circumstance, while other conflicts require case-specific management *if* compelling circumstances are present. The following section describes prohibited conflicts, management of conflicts that involve the use of human subjects, and management of conflicts that arise when research is funded by a faculty member's or an investigator's start-up company.

A. Examples of Prohibited Conflicts

Certain activities result in conflicts that are not permitted *under any circumstances*. The following are examples of conflicts that are prohibited for all faculty and investigators:

1. Receipt of remuneration from Brown and an outside source for identical services or activities;
2. Authorizing a consulting agreement at Brown for one's spouse or domestic partner;
3. Authorizing University-paid travel for a spouse or domestic partner;
4. Voting on the award of University business to a vendor in which one has a financial interest or by which one is employed;
5. Solicitation for personal benefit of gratuities, favors or anything of monetary value from students, donors, vendors, or contractors of the University;
6. Serving on an organization's Board and authorizing a Brown donation to or purchase from that organization;
7. Investing personally or owning stock in privately held business ventures of their subordinates or students;
8. Using staff time and laboratory space for consulting or other non-university purposes;
9. Use of confidential information acquired through the conduct of university business or research for personal gain;
10. Making clinical referrals to a business in which the faculty member or investigator or his/her family member has financial interest other than Brown-affiliated institutions, e.g. hospitals, foundations, clinical laboratories, or practice plans;
11. Publishing or presenting research results or expert commentary without simultaneously disclosing any related financial relationship;
12. Solicitation or acceptance of any gratuities, favors, or anything of monetary value for personal benefit from contractors or parties to subagreements that are paid through direct or indirect funds awarded to Brown University.

B. Compelling Circumstances in Human Subjects Research

Research involving human subject participants is subject to a strong presumption against the participation of any Brown faculty or investigator holding a related conflict of interest particularly if the protocol involves more than minimal risk. There is a strong presumption against participation in human subjects research by a conflicted individual in the following situations:

- Accepting research sponsorship from a company in which the individual or his/her family members have a financial interest;
- Serving as a Principal Investigator on a federal grant/contract that involves the evaluation of products from companies in which the PI has a financial interest;
- Service on Boards of Directors or any other fiduciary role for a company that sponsors a faculty member's or investigator's research

Exceptions may be made in compelling circumstances which will depend in each case upon the nature of the science, the nature of the outside interest, how closely the interest is related to the research, and the degree to which the interest may be affected by the research. For example, when the individual 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 is permitted the opportunity to rebut the presumption against participation by demonstrating these facts to the satisfaction of the Conflict of Interest Review Board.

In addition to exceptions made for compelling circumstances, exceptions may also be made when the reported outside financial interest is less than

- \$10,000 in monetary value;
- 5% of total value of company or \$10,000 in a publicly traded company;

C. Compelling Circumstances in Research Funding from a Non-Publicly Traded Company (No Human Subjects Involved)

There is a strong presumption against participation in University research sponsored by a start-up or non-publicly traded company in which a faculty member or investigator has a financial interest; or in which the faculty member's or investigator's research assistants (i.e., undergraduate and graduate students, trainees, and post docs) are involved.

Certain compelling circumstances may allow the faculty member or investigator to participate in such sponsored research if:

- The research is fundamental or basic in nature, and if there are no multiple entanglements (i.e., faculty is on Board and/or consults for the company);
- The individual's equity interest is so diluted that control over the company's decisions are negligible;
- The research is essential to maintain the continuity of research effort related to licensed IP during a short interval of time (normally under six months) and during this time it is subject to appropriate oversight by the Conflict of Interest Review Board.

VIII. Issues of Concern and University Responsibilities

Technology Transfer and Financial Conflicts of Interest- Conflicts of interest often arise at the intersection of two fundamental missions: to push the boundaries of knowledge and to transfer that knowledge to the private sector for the benefit of the public. With pro-active technology transfer increasingly close relationships emerge between industry and university, which provide benefits but also increase the risk of academic research being compromised through either or both individual and institutional conflict of interest. There are, for example, significant personal financial advantages from outside consulting, patenting and licensing, stock options, or other business interests. The perception that such incentives might harm research or educational integrity, or diminish the protection of human subjects, students, or others whose work depends on the direction of the conflicted individual is sufficient to mandate that such conflicts be identified, then managed, reduced, or eliminated.

Conflict with Educational/Research Obligations - Consideration of personal gain related to activities outside the University must not influence the decisions or actions of individuals in carrying out their University responsibilities. Such outside activities conflict with obligations to the University when they involve excessive commitments of time, when they bias the nature and direction of scholarly research, or when they influence a faculty member's or investigator's decision or behavior with respect to teaching and student affairs, appointments and promotions of faculty, purchasing of equipment or medical devices, or other matters of interest to the University. The potential problems arising from conflicts between faculty and investigators' obligations to the University and outside professional and commercial activities are numerous and sometimes subtle. A conflict may arise out of a single transaction and should be addressed whenever possible before that transaction is undertaken.

Maintaining objectivity in research is the personal responsibility of each scholar. Faculty and investigators are obliged to assure that their research results are not subject to influence by third parties that may have financial interests in the research outcomes. This is particularly significant if a company has been the sponsor of the research or if a company's product is involved in the research, directly or indirectly.

From the education, research, financial, and career status perspectives, there are many occasions in which outside financial interests might compromise or create the perception of compromising the student-faculty relationship. At the same time, involvement of students in projects of commercial interest, practical benefits from corporate work experience or internships, and potential career opportunities may benefit students. It is incumbent upon faculty and on any Conflict of Interest management plan, to assure that their advice and guidance should always be governed by the student's best interest and should not become entangled with the personal financial interests of faculty who are in positions of authority over the students. Occasions where a faculty member's outside financial interest could compromise the publication rights and research data derived from a student's work should be explicitly avoided.

Approval must be obtained before a faculty member may involve students whom he or she directly supervises or advises, in business activities outside the University in which the faculty member has a financial interest or officer /director role. The Vice President for Research in consultation with the Conflict of Interest Review Board will review such requests. If approved, the arrangement will be subject to a conflict management plan.

Publication and presentation of research results are the hallmark of academic freedom. Faculty and investigators are expected to disclose relevant consulting or other outside financial interests in any publication or public presentation of the research. Faculty and investigators should not participate in nor accept sponsor conditions that preclude dissemination of research results or otherwise compromise academic freedom.

Conflict with the Business Interests of the University- Faculty may be privy to certain confidential business decision making within the University, such as selection of equipment, services, educational materials, procurement of consultants, and acquisition of information or management systems. Faculty members who have a financial interest in an organization that either has Brown as a large customer or supports the individual's University activities must disclose their relationships to administrative and academic officers who need to assure that any purchase decision is free from bias or self-interest. A faculty member who has a personal interest, or who has an immediate family member who has a personal interest, in an organization engaged in negotiation of a contract between the University and the organization should not generally participate in the contract negotiation or attempt to influence the University's decision in favor of their

interest. Management, employment, consulting, or other contractual activities with, or ownership interest in, a business entity that competes with the University must be disclosed and is generally not permitted.

Faculty and investigators are prohibited from soliciting or accepting any gratuities, favors, or anything of monetary value from contractors or parties to subagreements or other research collaborations. All gifts must be routed through Brown's Gift Accounting Manager via the Corporate and Foundation Relations Office.

Appointments and Promotions - Junior faculty and developing independent investigators must be assured that their evaluations are based on the merits of their scholarship and contribution to the University's research and educational mission. Senior faculty and department chairs are required to exercise their recommendations and decisions concerning promotion and appointments in the absence of influence of benefit from personal commercial relationships.

University Contribution- Faculty and investigators' outside financial interests cannot interfere or compromise his/her full time obligation to the University's mission. Faculty must assure that their outside obligations are within the consulting privileges permitted under University policy, that their absence from campus does not preclude them from participation in the normal and productive interactions with colleagues and students in the affairs of the faculty member's department and the University, and that no intellectual property rights of the University are breached by agreements between the individual faculty member and the outside financial interest.

Office/Laboratory Space and other Resources - Faculty and investigators should not use the facilities and resources of the University for personal gain. Faculty and investigators should reimburse the University for any administrative costs (e.g. phones, use of office equipment, and computer services) used in the course of their consulting activities. If it is assumed that the consulting activity does not interfere with University obligations and operations, use of the individual's office is permissible. Use of University laboratory space by for-profit companies, especially those in which a faculty member or investigator has a financial interest, is permissible only under special conditions and requires prior written approval of the Chair, Dean of the Faculty or Dean of Medicine and Biological Sciences, and Provost. Approval is likely to be granted only in extraordinary circumstances and where the University is fully compensated for the use of the facilities and the research program is conducted in compliance with all University research policies.

Hiring Family Members for University Business - Faculty and investigators must not be in the position of hiring, supervising, directing, or setting the pay for one's spouse, domestic partner, children and/or relatives.

Service on University Committees - Faculty members may be asked to serve on University committees charged with purchasing of equipment, systems, or educational materials where the faculty member or their families may have relationships with outside vendors, suppliers or contractors. Faculty members are not automatically disqualified from serving on committees when potential conflicts appear, but early and full disclosure to the Chair of the Committee and the administrative officer overseeing the procurement activity, is critical. In most circumstances, it should be possible for the faculty member to continue to serve on the committee, but some conflicts may be so obvious and severe that they are resolvable only if the faculty member resigns from the committee.

IX. Right to Appeal

If a faculty member or investigator believes that a determination made by the Conflict of Interest Review Board in a specific case is not appropriate or is based on erroneous information, the individual may request additional Board review by submitting a written request to the Vice President for Research. If, after a second review by the Board, he or she still wishes to appeal, s/he may appeal to the University Provost. The decision of the Provost shall be final.

X. Failure to Comply with this Policy

Faculty and investigators found to be knowingly in violation of the policy may be subject to the ordinary disciplinary processes and penalties of the University if they are found to have failed to fully and truthfully disclose conflict of interest situations or failed to comply with any stipulated plan for managing the disclosed conflict. Among the penalties that could be applied include ineligibility to submit sponsored projects proposals, obtain IRB or IACUC approvals, or supervise graduate students. In particularly egregious cases the penalty could be non-renewal or termination of appointment or dismissal. The latter would proceed in accordance with the normal procedures for termination.

XI. Institutional Reporting Requirements for Federally Funded Research

This section describes the federal agency requirements and alerts investigators to the way in which Brown University will implement them. In addition, it informs investigators of Brown's requirement to notify agencies in the event a potential conflict is identified.

Brown University is required to incorporate the Public Health Service (PHS) regulation at 42 CFR Part 50, Subpart F for grants or cooperative agreements and 45 CFR Part 94 for research contracts into its policy and apply the regulation to any proposed or funded PHS project and National Science Foundation (NSF) regulations found in GPM 510 (July 2005). For those investigators whose pending or active research projects involve these sponsors, special attention to these requirements is necessary.

PHS and NSF require that for each proposal the PI certify that he or she has appropriately disclosed any significant financial interests related to that proposal. Before an award can be made, the University must determine how any potential conflict will be managed, reduced or eliminated. Prior to expenditure of any funds under the award, Brown is required to report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) and assure that the interest has been managed, reduced or eliminated. If a conflict is reported to Brown subsequent to the investigator's initial report under the award, Brown will notify the PHS Awarding Component of a conflict and that it has been managed, reduced, or eliminated, at least on an interim basis, within sixty days of that identification.

Subrecipients confirm their compliance with the Sponsor's conflict of interest policy upon execution and acceptance of the sub-award. Sub-recipients must report identified conflicts of interest to Brown prior to the expenditure of any sub-award funds. Brown is responsible for reporting to the National Institutes of Health (NIH) any conflicting interests it has identified, including those of its subrecipients, and assuring that the interest has been managed, reduced, or eliminated in accordance with the NIH regulation.

Notifications to NIH will be signed and transmitted by the Office of Sponsored Projects. A copy of the notification must be kept with the project records. This notification requirement applies only to the Public Health Service, including the (NIH).

PHS and NSF have defined "significant financial interest" as follows:

A financial interest is anything of monetary value, including but not limited to

- Salary or other payments for services (consulting fees or honoraria)
- Equity interests (e.g. stocks, stock options or other ownership interests)
- Intellectual property rights (e.g. patents, copyrights and royalties from such rights)

Such results become "significant" for PHS and NSF if, for any one enterprise, the interest has a value of \$10,000 or more or represents more than 5% ownership interest. Note that this threshold applies to the individual or aggregated interest of the PI, spouse or domestic partner, and dependent children.

The term “significant financial interest” does not include:

1. Salary, royalties, or other remuneration from the applicant institution;
2. Any ownership interests in an outside entity if the entity is a Phase 1 applicant under the Small Business Innovation Research (SBIR) or Small Business Technology Transfer Program (STTR); (*Note Brown University cannot be an applicant to the SBIR/STTR Program; a Brown University subaward under an SBIR/STTR proposal or award is not excluded from disclosure.)
3. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
4. Income from service on advisory committees or review panels for public or nonprofit entities;
5. An equity interest, when aggregated for the Investigator and for the Investigator’s spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or
6. Salary, royalties, or other payments that, when aggregated for the Investigator and the Investigator’s spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

“Investigator” means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research. For the purposes of relating to financial interests, “investigator” includes the Investigator’s spouse and dependent children.

For every proposal (including continuations and renewals) submitted to either PHS or NSF, the following questions must be answered by the PI:

1. Have you filed the annual Assurance of Compliance form and if necessary, a disclosure as required by the University’s Conflict of Interest Policy for Officers of Instruction and Research?
2. Do you have a significant financial interest that is related to this research project?
3. Are any other individuals involved in this project considered “investigators” as defined above? If yes, please identify the individuals considered to be “investigators.”

Each named “investigator” must complete the University’s Conflict of Interest Additional Investigator form (http://research.brown.edu/pdf/PHS-NSF_Coi.doc).

Review of Disclosures: Any investigator who is required to assure compliance with PHS and NSF policies must comply with this policy. The Office of Vice President for Research shall determine management of any disclosed conflict pertaining to a PHS or NSF proposal or award.

If an investigator's non-compliance with this policy results in the bias of the design, conduct or reporting of the PHS-funded research, Brown is required to notify the PHS Awarding Component of the corrective action taken or to be taken.

Record Retention

Federal regulations mandate that for research contracts each Institution maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for three years after the final payment, or where applicable, for the other time periods specified in 48 CFR Part 4, Subpart 4.7.

For grants and cooperative agreements, the Institution must 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 submissions of the final expenditures report or, where applicable from other dates specified in 45 CFR 74.53 (b) for different situations.

Section XI will be updated as Federal regulations mandate.

Approved by the Brown Corporation May 22, 2009