

Requests for Division of Biology & Medicine Facilities Use Research Agreements (FURA)

Introduction: The Division of Biology and Medicine may make its research facilities available for a limited time to private parties, including University-affiliated faculty members, to provide opportunities for advancing the University's mission. The procedures which follow provide guidelines to help insure private use of Division research facilities is properly managed, potential conflicts of interest minimized and Division resources not misused.

Scope: Define the parameters for use of the Division of Biology and Medicine's unique facilities by external researchers from other universities, industry, or affiliated hospitals when not in use by Brown researchers. Outside organizations may rent facilities for their research when not being fully utilized by the Division. Facilities are defined as Division research space, instruments, and laboratories. Such use needs to be reviewed, approved and documented by a Brown University Facilities and Use Research Agreement (FURA). The FURA defines the general purpose, period, conditions of the facility use, the cost for use, and any additional requirements. Requests for use of Division facilities will be evaluated on a case-by-case basis and approved by senior administration. 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. The following are among the factors to be considered in determining if a facilities agreement is required.

Does the Use Advance University Research, Education, or Public Service Efforts? There must be a direct benefit of the use of the particular facility use to specific, clearly identifiable objectives of the university's mission of teaching, research and public service. The nature and purpose of use of the space or equipment must advance Brown's primary purpose of scientific or technical activity related to basic research. If proposed facility use is non-academic in nature contact Technology Ventures Office (TVO) for a Contract Research Agreement (TVO_patents@brown.edu or 401-863-7499).

What is the Duration and Scope of the Use? Is the facility use for less than twelve months and is fair market value being charged for the use? Use of Division facilities is intended for short-term projects, such as the simple test of an idea. A long-term project (for example, a process development project which requires extensive or prolonged use of analytical services) is not appropriate. Private use of a facility on a long-term or permanent basis may not be permitted due to legal restrictions imposed by the tax-exempt status of Brown University.

Does Use of Space Generate Expenses? Will the use of the space require expenses related to shipping, refrigerated storage, gases, hazardous material, clean room, etc.?

What is the Role of Responsible Brown Contact? The individual from the department initiating the request is responsible for monitoring revenue/expenses, compliance with terms and conditions of agreement and timely

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processing of FUAR renewal, if necessary. Renewal requests must be made 60 days prior to end date of existing agreement.

Does Use Involve a Relative of a Brown employee or Business Controlled by a Brown Employee or Relative?

If the Brown University party to the FURA is associated with the outside user, approval is not likely. Please see Financial Conflict of Interest (FCOI) policy found here and Attachment I:

<http://www.brown.edu/research/compliance-education-training/research-compliance/conflict-interest/conflict-interest>

Is the Facility Use for Research Sponsored by Private (Nongovernmental) Parties? Such use is considered sponsored research and must be handled by BMRA & OSP.

Does Use Involve Brown Affiliated Institutions? In the course of sponsored research, opportunities may arise for researchers from Brown affiliated institutions to work side by side with Brown campus-based colleagues. These researchers are considered Visitors working at Brown and must obtain an academic Visiting Scholar appointment through the Bio Med Faculty Affairs Office. Visitors may also be governed by Brown University's Patent and Invention policy, and must take required safety training provided by Environmental Health and Safety Office (EH&S).

Does Use Involve Brown Personnel? If use of facility involves Brown University faculty, post docs, students or staff, then such use is considered sponsored research and must be handled by BMRA and Office of Sponsored Projects (OSP). (Exception may be Animal Care Facility agreements where minimal ACF staff will assist with approved protocol activities).

Submission of Request for Facility Use Needs Department Chair, Associate Dean of Biology and Executive Dean for Administration Review

When submitting a request for outside facility use the following is needed:

- Preliminary Facility Use Information Form (<http://biomed.brown.edu/bmra/>)

What is the Process Once Approved? If a request is approved, use of the facility by or for the benefit of the outside user may not commence, or continue, until a written FURA is signed by the user and the duly authorized representatives of the university (Provost, Dean, Ex Dean Administration, Ass Dean Biology & Chair, Office General Counsel). Office of General Counsel may review the agreement and request additional information

Standard facility use agreement and Preliminary Use form are available on the following web sites:

**Facilities Planning and Operations
Finance and Planning
Research Administration
Executive Dean, Office of the**

Researchers may not make use of facilities if any commercial analytical or service organization offers essentially the same service.

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Examples of when FURA is needed for research and service-center facilities by an outside organization:

- Animal Care Facility
- Magnetic Resonance Imaging Research Facility
- Rhode Island BioBank
- Structural Biology Facility
- Bio Med Laboratory Space

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Attachment I

Conflict of Interest Policy for Officers of Instruction and Research

- I. Purpose of Policy
 - II. Conflict of Interest Definitions
 - III. To Whom Does the Policy Apply?
 - IV. Reporting Responsibilities and Procedures
 - V. University Review and Management Responsibilities
 - VI. Prohibited Conflicts and Compelling Circumstances
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- I. Purpose of Policy

In the last decade, “Brown has been on a challenging, illuminating path defined by expansive creativity – emerging stronger in research, richer in intellectual inquiry, and more engaged with the world than ever before in its long history... Brown’s profound commitment to growth in research and teaching has elevated its work in the laboratory, in the classroom, and in the marketplace of ideas and commerce.”¹ Researcher partnerships with industry and the increased commercialization of technologies resulting from research supported by federal, corporate, and private funding bring the benefits of University research to the public through the marketplace. As researchers, scientific consultants, inventors, and founders of companies, members of the academic community contribute to successful technology transfer. While the academic community often plays an important role in successful commercialization efforts in a university setting, these relationships can compromise, or be perceived as compromising, important academic values, research integrity, or the university mission. Researcher financial relationships with the private sector may result in financial conflicts of interest (FCOI) that could result in a breach of public trust and confidence in the researcher, the research enterprise, or research outcomes. FCOI emerge at the intersection of fundamental University goals: to push the boundaries of knowledge and to transfer that knowledge for the public benefit – in many cases the public is best served when that new knowledge or technology is transferred to the private sector. Specifically, an FCOI may arise when a faculty member or investigator has a significant outside financial interest that is closely related to his or her University responsibilities or professional expertise. An apparent FCOI exists when a faculty member or investigator’s significant 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 and trainees, or faculty service or professional practice might be influenced by the potential for personal gain. Universities have an obligation to assure that FCOI are managed or eliminated. The identification and management of FCOI can 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 commitment of faculty and investigators to their University responsibilities. An FCOI is not unusual; it does not imply wrong-doing or inappropriate activities. Rather, research universities encourage interactions and the establishment of relationships between academia and industry which can cause FCOI to arise. This policy addresses situations in which there may be a real or apparent conflict between an outside financial interest of a Brown faculty member or investigator and the professional commitment that person has made to Brown University. It is intended to educate the Brown academic community about Federal and University requirements on conflicts of commitment and FCOI. It outlines processes internal to the University for reporting financial interests that are related to University responsibilities and professional expertise; and for identifying and managing an FCOI. The policy supports the University’s commitment to its core values:

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- 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.

II. Conflict of Interest Definitions

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 educational and research mission, clinical care, and University service activities. 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 responsibilities of regular faculty are the education of Brown students and University scholarship. 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.

Financial interest means anything of monetary value whether or not the value is readily ascertainable. A financial interest includes, but is not limited to, payments or fees for services outside of University compensation including:

- any form of compensation;
- consulting, honoraria, or expert testimony;
- equity interests such as stocks, stock options, deferred benefits or other ownership interests;
- intellectual property rights including named inventor on a patent or patent assignee, copyrighted material and benefits accruing from such rights; royalty or milestone payments from Brown or an outside entity; and
- gifts.

Significant financial interest means an investigator's financial interest (and those of the investigator's spouse and dependent children) that is directly or indirectly related to the investigator's University responsibilities or professional expertise, when:

- (1) the aggregated value of any equity interest in and remuneration received from a *publicly traded entity* in the preceding twelve months exceeds \$5,000; or
- (2) the aggregated value of any remuneration received from a *non - publicly traded entity* in the preceding 12 months exceeds \$5,000; or
- (3) the investigator (or the investigator's spouse or dependent children) owns *any* equity interest in a non-publicly traded entity; or
- (4) the income received from intellectual property rights and interests (e.g., patents, copyrights) from Brown or another entity in the preceding twelve months exceeds \$5,000.

Faculty and investigators must report all significant financial interests directly or indirectly related to their University responsibilities and professional expertise except:

- 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.

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Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. ²

Financial conflict of interest means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

Investigator means the project director or principal investigator and any other person regardless of title or position (e.g. a full or part-time faculty member, staff member, student, trainee, collaborator, or consultant) who is *responsible* for the design, conduct, or reporting of sponsored research.

Institutional (University) Responsibilities means a faculty member or investigator's professional responsibilities on behalf of the University including teaching, research, University service, and clinical care.

Assurance of Compliance is the annual 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 information on a significant financial interest to the University. An investigator "reports" a significant financial interest on the Reporting of Outside Financial Interests and Professional Activities form (Reporting form).

²These exclusions only apply to a United States (U.S.) Institution of higher education or a federal, state or local government agency within the U.S.

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 reports a new significant financial interest that has emerged after the annual assurance process. Transactional reporting occurs when an investigator submits a sponsored research proposal and has not completed an assurance of compliance in the previous 12 months.

Conflict of Interest Review Board (Review Board) is the University entity that is responsible for reviewing Reporting forms; the Review Board determines whether a significant financial interest is related to the investigator's Brown research and whether it constitutes an FCOI. Once an FCOI has been identified, the Review Board recommends to the Vice President for Research a management plan and mechanisms to implement and monitor the plan.

Disclosure is a method of managing a real or apparent FCOI by means of the release of relevant information about a significant financial interest to parties outside Brown's Review Board. It may include public disclosure of a faculty member or investigator's significant financial interest in relevant publications and presentations, disclosure to coinvestigators, members of the laboratory and research group and students or trainees, and disclosure on human subject consent forms.

III. 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

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For each proposed research activity, Principal Investigators are responsible for determining which faculty, staff, students, and trainees meet the definition of “investigator” defined above. When 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 research funded through Brown University.

Off Campus Collaborators and Contractors

Subrecipients The University will establish by written agreement with each subrecipient whether the financial conflict of interest policy of the University or the subrecipient will apply to the subrecipient’s investigators (Section X and XI of this policy). Non-subrecipient Collaborators and Consultants For each proposed Public Health Services (PHS) activity the Principal Investigator is responsible for identifying which non-subrecipient collaborators and consultants meet the definition of “investigator.” All such investigators are required to submit an annual assurance of compliance form and if necessary, a reporting form, prior to proposal submission, and will be subject to Brown’s Conflict of Interest policy.

IV. Reporting Responsibilities and Procedures

Annual Process

Annually, Brown faculty members and other Brown researchers who have been identified as investigators 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 of Compliance indicates the presence of a significant financial interest that directly or indirectly relates to University responsibilities and professional expertise, the individual will be required to submit additional information about the significant financial interest via the Reporting form. Faculty and investigators must report all significant financial interests directly or indirectly related to their University responsibilities. If a faculty member or investigator discovers or acquires a new significant financial interest (e.g., through purchase, marriage, or inheritance) between the annual reporting process and the time of proposal submission or award, or, during the period of the award, the individual is required to update his/her Reporting form within 30 days of the change.

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 significant financial interest directly or indirectly related to any protocol under review to the IRB. The IRB will be apprised when an FCOI has been identified for any investigator who conducts research involving human participants or certain pre-clinical research. The IRB shall determine what information relating to the significant financial interest should be included in the informed consent process or other appropriate protections for human subjects. Specific Federal agency requirements are detailed at the end of this policy.

V. 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 for Research. 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, 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 Review Board will be chaired by the Associate Vice President for Research who shall convene meetings and provide guidance to the Review Board on issues of FCOI. 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 Review Board will evaluate reported significant financial interests to determine the following:

- Whether a significant financial interest is related to an investigator’s Brown research.
- Whether a significant financial interest is an FCOI and if so, whether the FCOI requires a management plan or elimination.

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- The most appropriate mechanism for managing the identified FCOI.
- The appropriate follow-up mechanisms that the chair should implement to assure continuing effectiveness of the management plan.

The chair of the Review Board 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 for Research's approval or consideration. The Vice President for Research will consult with the Dean of the Division of Biology and Medicine or the Dean of Faculty as appropriate.

Management of Financial Conflicts of Interests

A frequently utilized mechanism for managing an FCOI is full and open disclosure of significant financial interests that are related to University responsibilities and professional expertise. Sometimes additional safeguards and even prohibitions of certain types of financial relationships may be required. Examples of possible conditions or restrictions include the following:

- Monitoring of research by independent reviewer(s), or a conflict of interest management committee;
- Monitoring student activities and providing measures to protect vulnerable members of the research team;
- Modification of the research plan or other measures to ensure the integrity of the research;
- 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 a significant financial interest or other measures to reduce the significant financial interest;
- Severance of relationships that create an FCOI.

When evaluating whether a significant financial interest constitutes an FCOI and/or the appropriateness of certain management strategies, the faculty and staff who serve on the Review Board carefully consider the particular circumstances of the research endeavor. The Review Board considers the potential benefit of the project and the investigator's participation in it and the risks to integrity of research data and student training, risk of bias, risks to human subject participants, and risk of the appearance of a conflict. It is important to note that there is no one formula that dictates which management methods "fit" which conflict. The confidential evaluation of reported financial information is a case-specific process.

Notifications

The University is responsible for notifying research sponsors of an FCOI and implementing public accessibility processes when required under sponsors' regulations outlined in Sections X and XI below.

VI. Prohibited Conflicts and Compelling Circumstances

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

A. Prohibited Conflicts

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

1. Voting on the award of University business to a vendor in which one has a financial interest or by which one is employed;
2. Use of confidential information acquired through the conduct of University business or research for personal gain;
3. Solicitation for personal benefit of gratuities, favors or anything of monetary value from students, donors, vendors, or contractors of the University;
4. Using staff time and laboratory space for consulting or other non-University purposes;
5. Publishing or presenting research results or expert commentary without simultaneously disclosing any related significant financial interest;

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6. Receipt of remuneration from Brown and an outside source for identical services or activities;
7. Authorizing a consulting agreement at Brown for one's spouse or domestic partner;
8. Authorizing University-paid travel for a spouse or domestic partner;
9. Serving on an organization's Board and authorizing a Brown donation to or purchase from that organization;
10. Investing personally or owning stock in privately held business ventures of their subordinates or students;
11. 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);
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 significant financial interest, particularly if the protocol involves more than minimal risk. There is a strong presumption against participation in human subjects research by an investigator in the following situations:

- Accepting research sponsorship from a company in which the investigator, or his/her spouse or dependent children, have a significant financial interest;
- Serving as a Principal Investigator on any sponsored project that involves the evaluation of products from companies in which the PI has a significant financial interest;
- Service on Boards of Directors or any other fiduciary role for a company that sponsors a faculty member 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 significant financial 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 investigator is uniquely qualified by virtue of expertise and experience and the research could not otherwise be conducted as safely or effectively without that investigator, he or she is permitted the opportunity to rebut the presumption against participation by demonstrating these facts to the satisfaction of the Review Board.

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 an investigator has a significant financial interest; or in which the investigator's research assistants (i.e., undergraduate and graduate students, trainees, and post doctoral researchers) are involved. Exceptions may be made in compelling circumstances which will depend in each case upon the nature of the science, the nature of the significant financial 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 investigator is uniquely qualified by virtue of expertise and experience and the research could not otherwise be conducted as safely or effectively without that investigator, he or she is permitted the opportunity to rebut the presumption against participation by demonstrating these facts to the satisfaction of the Review Board. Other compelling circumstances might include:

- The research is fundamental or basic in nature, and if there are no multiple entanglements (i.e., the investigator serves on the Board and/or consults for the company);
- The investigator'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 Review Board. Phase I SBIRs and STTR's are exceptions to this presumption and the compelling circumstance requirement; in such cases however, the Review Board will normally recommend management of a real or apparent FCOI that may arise with Phase I SBIRs and STTRs.

VII. Issues of Concern and University Responsibilities

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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 or investigator's decision or behavior with respect to teaching and student affairs, appointments and promotions of faculty, clinical care, purchasing of equipment or medical devices, or other matters of interest to the University. From the education, research, financial, and career status perspectives, there are many occasions in which significant 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 FCOI management plan, to assure that faculty 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 significant financial interest could compromise the publication rights and research data derived from a student's work must be explicitly avoided. Publication and presentation of research results are the hallmark of academic freedom. Faculty and investigators are expected to disclose relevant significant financial interests in any publication or public presentation of the research.

Involvement of Students or Trainees in a Faculty Member's Significant Financial Interest Approval must be obtained before a faculty member or investigator may involve students whom he or she directly supervises or advises, in a privately owned entity outside the University in which the faculty member or investigator has a significant financial interest or officer /director role. The Vice President for Research in consultation with the Review Board will review such requests. If approved, the arrangement will be subject to a management plan.

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.

Gifts - 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.

Full-time Commitment to the University - A faculty member's significant financial interest 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 may 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

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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 FCOI may be so obvious and severe that they are resolvable only if the faculty member resigns from the committee.

VIII. Right to Appeal

If a faculty member or investigator believes that a determination made by the Review Board in a specific case is not appropriate or is based on erroneous information, the individual may request additional Review Board evaluation 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.

IX. Failure to Comply with this Policy

Faculty and investigators found to be 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 significant financial interests related to University responsibilities 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.

X. PHS - Specific Requirements

This section describes additional FCOI requirements that are specific to PHS; it will be updated as Federal regulations mandate. For PHS sponsored research, prior to expenditure of any funds under the award, the University must determine whether a significant financial interest is related to the proposed project, whether an FCOI exists, how the FCOI will be managed or eliminated, and how the management plan will be monitored. An investigator's significant financial interest is related to PHS-funded research when the University reasonably determines that the significant financial interest could affect the PHS-funded research; or is in an entity whose financial interest could be affected by the research. For all PHS/NIH awards, prior to expenditure of any funds under the award, the University is required to report to the PHS Awarding Component the existence of a FCOI and submit an FCOI report. The report must contain:

- The project number, name of investigator, nature of the financial interest, and value of the financial interest (dollar range);
- A description of how the financial interest relates to the PHS-funded research and the basis for the determination that the financial interest conflicts with the research;
- The role and principal duties of the conflicted investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;

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- Confirmation of the investigator's agreement to the management plan; and
- How the management plan will be monitored to ensure investigator compliance.

The University is responsible for submitting FCOI reports to NIH initially and annually during the award period, and within 60 days of any subsequently identified FCOI.

Subrecipients

When proposed University research is to be carried out through a subrecipient, the University will establish in writing, at the time of proposal submission, whether the University's conflict of interest policy or that of the subrecipient will apply to the subrecipient's investigators. FCOI reports will be provided to the PHS Awarding Component regarding all identified FCOI prior to expenditure of funds and within 60 days of subsequently identified FCOI.

Sponsored or Reimbursed Travel

On an annual basis, investigators with PHS awards are required to report to the University the occurrence of any reimbursed travel 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 institutional responsibilities *except* when travel is reimbursed 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 institution that is affiliated with an institution of higher education. Investigators must provide information on the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

Conflict of Interest Training

Each investigator is required to complete conflict of interest training prior to engaging in any Brown PHS-funded research and at least every four years. Additional training will be required if the University revises its conflict of interest policy, or when an investigator fails to comply with this policy.

Public Accessibility

In those situations in which the University identifies an FCOI for Senior/ key personnel on a NIH award, prior to the expenditure of any funds, the University will ensure public accessibility of information concerning the significant financial interests of the Senior/key personnel. Senior/key personnel means the Project Director/Principal Investigator and any other person identified as Senior/key personnel by the University in a grant application, progress report, or any other report submitted to the PHS by the University. The information provided must include the investigator's name, title, and role with respect to the research project, and:

- Name of the entity in which the significant financial interest is held;
- Nature of the significant financial interest;
- Approximate dollar value (e.g. dollar ranges) 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.

Failure to Comply with PHS Requirements

In the event of failure to meet PHS regulations, including an FCOI that is not identified in a timely manner; University failure to review or manage such a FCOI; or investigator failure to comply with a FCOI management plan, the University is required to complete a retrospective review of the investigator's activities and the PHS or NIH-funded research project within 120 days to determine any bias in the design, conduct or reporting of research. If bias is found, the University will notify NIH, develop and implement a mitigation plan, and submit the PHS-required mitigation report.

XI. Institutional Reporting Requirements for Federally Funded Research

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This section describes PHS and the National Science Foundation (NSF) institutional reporting requirements and informs investigators of Brown University implementation processes; it will be updated as Federal regulations mandate. Brown University is required to incorporate the PHS regulation at 42 CFR Part 50, Subpart F (revised August 2011) for grants or cooperative agreements and 45 CFR Part 94 (revised August 2011) for research contracts into its policy and apply the regulation to any proposed or funded PHS project. The University is required to incorporate NSF regulations found in GPM 510 (July 2005) in its policy and apply the regulation to any proposed or funded NSF project. For those investigators whose pending or active research projects involve these sponsors, special attention to these requirements is necessary. This includes research funding from a PHS Awarding Component through a grant or cooperative agreement such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award. For both PHS and NSF proposals, the University will review investigator significant financial interests to determine if an FCOI is present and determine appropriate management mechanisms prior to award expenditure, and conform to agency specific reporting requirements. (See Section II above for the definition of significant financial interest.) If the investigator discovers or acquires a new significant financial interest (e.g., through purchase, marriage, or inheritance) between the annual reporting process and the time of proposal submission or award, or, during the period of the award, the investigator is required to update his/her Reporting form within 30 days of the change. The University is required to notify NSF of an identified FCOI if the University determines that an identified FCOI is unmanageable.

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 submission of the final expenditures report or, where applicable from other dates specified in 45 CFR 74.53 (b) for different situations.

Effective date: 8/24/2012

Approved by the Brown University Corporation: 5/26/2012

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Attachment II

Brown University Patent and Invention Policy and Copyright Policy

The Corporation of Brown University approved and adopted the Brown University Patent and Invention Policy and Copyright Policy on May 27, 2005. In so doing, the Corporation affirmed and reserved the right to revoke or amend the Policy. The Policy, effective immediately, replaces the University Patent and Invention Policy approved and adopted May 30, 1981.

Guiding Principles

Brown University's Patent and Invention Policy and Copyright Policy are intended to further the University's central missions of education and the production, preservation and dissemination of knowledge. These Policies are designed to maintain the University's general philosophy regarding the open dissemination of research results and the encouragement of research and scholarship without regard to potential financial gain, while recognizing that commercialization of intellectual property is the means to achieve the maximal benefit to society of certain research. These Policies aim to assure faculty, students, and staff of fair treatment and appropriate sharing in any financial return.

1.0 The Patent and Invention Policy

1.1 Relationship between the University and Faculty, Students and Employees

1.1.0 Applicability

This policy applies¹ to faculty, postdoctoral associates, graduate students, employees, visitors and consultants, whether paid or not, who create or make any discovery or invention conceived during or developed from research conducted as a part of their University Duties, or in which all or part of the cost is paid from University funds or from funds administered by the University, or which has been developed in whole or in part through the more than incidental use of University resources. For convenience, such a person is termed a "Covered Individual." This policy will also apply to undergraduate students who are receiving sponsored research funding and/or working collaboratively with faculty who are Covered Individuals under the policy. If more than one organization claims rights to inventions by a Covered Individual (*e.g.*, a visiting scholar at Brown, or a Brown scholar on sabbatical at another institution), Brown will consult with such organization to arrive at a mutually satisfactory division of rights and responsibilities. "University Duties" include teaching, mentoring of students, the conduct of scholarly research and service on university committees consistent with the furtherance of knowledge and its dissemination. A faculty member's University Duties are those that are customarily performed by those holding the position held by the faculty member as well as those that are assigned by the University. It is understood that research and intellectual endeavors of University faculty are not static, but rather are dynamic and subject to change and evolution, and therefore it is not possible to specifically demarcate when an invention or discovery might be covered by this policy without, in some cases, an examination of the facts and circumstances surrounding the development of the invention or discovery. This examination, when warranted, will be conducted by the Standing Appeals Committee which will make its recommendation to the Vice President for Research, the Provost and the President.

1.1.1 Ownership

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The University shall own, on a worldwide basis, all rights in any discovery or invention created or made in the course of research carried out by a Covered Individual as defined in Section 1.1.0 above. The University shall not assert ownership rights in any discovery or invention not falling within the coverage delineated in Section 1.1.0.

† The new policy will apply to those covered by the existing policy with some individual exceptions – see FAQ’s.

1.1.1(i) Consulting

An invention made by a Covered Individual in the course of a written consulting agreement with an outside third party arising from work not performed at a Brown facility may be assigned to the outside third party, so long as doing so is consistent with the University’s policies on Conflict of Interest and Conflict of Commitment, the invention was not made or conceived under circumstances involving more than incidental use of University facilities or resources, and the invention does not compromise Brown University’s Intellectual Property Rights. If the consulting relationship does involve the use of Brown Intellectual Property, disclosure should be made to BTP who will provide assistance regarding making licensing or other arrangements for the use of the Intellectual Property in the consulting relationship with the outside third party.

1.1.1(ii) Sabbatical

Sabbaticals are granted in recognition of notable service through teaching and scholarly contributions and as an aid and inspiration to future achievement. They are intended to provide faculty opportunities for scholarly development, which contribute to their professional effectiveness and to the value of their future services to Brown University. Accordingly, faculty on sabbatical are included in this policy.

1.1.2 Disclosure

All discoveries or inventions that might be patentable must be disclosed in writing (a “Disclosure”) to the Office of Brown Technology Partnerships as soon as practicable.

1.1.3 Invention Evaluation

The University, through the Office of Brown Technology Partnerships, shall evaluate Disclosures. Within three months of the receipt of a completed Disclosure, Brown Technology Partnerships will determine if it intends to apply for patent protection. If Brown Technology Partnerships determines that (i) the University has no legal obligation to participate in the licensing or patenting of an invention and (ii) the University does not desire to participate in the licensing or patenting of an invention, the University will release to the inventor(s) the University’s interest in the invention as permitted by law. This release will be confirmed in writing. If there is more than one inventor, the University shall treat all inventors equally, except as otherwise determined under Section 1.1.3(i) below.

1.1.3(i) Inventive Contribution Apportionment

Inventorship, in the first instance, shall be equally apportioned among the named inventors as to each patent. If any named inventor makes a written request for a non-equal inventorship apportionment and the named inventors cannot agree on such non-equal apportionment, a binding determination on apportionment shall be made by the Standing Appeals Committee. (See Section 1.5.1 below.)

1.1.4 Inventorship Evaluation

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Inventorship is a legal determination which shall be made in the first instance by University's patent counsel, taking into consideration the comments of potential inventors and/or patent counsel retained by such inventor(s). In the event that agreement is not reached between counsels, inventorship will be bindingly decided by a mutually acceptable patent attorney. It is noted that inventorship is subject to change based on the subject matter ultimately issuing as a patent. Changes in inventorship shall be determined in the same manner as the initial determination of inventorship.

1.2 Licensing of Inventions

If the University decides to participate in the licensing of an invention, the Office of Brown Technology Partnerships, on behalf of the University, will seek to enter into appropriate business arrangements to commercialize the invention, taking into consideration the comments and concerns of the inventors. Exclusive licenses will be granted if it appears to the Office of Brown Technology Partnerships that this is the most effective way of ensuring development of the invention so that the public will benefit. Any exclusive license agreement will be drafted so as to protect against failure of the licensee to carry out effective development and marketing within a specified time frame.

1.3 Division of Royalties

1.3.1 Definition

For purposes of this policy, "Royalties" shall include running royalties, advances against running royalties, license fees, milestone payments, shares of stock or other securities issued by the licensee, and any other payments received by the University under a license agreement in consideration for licensing an invention. Royalties shall not include funds directed to additional research or governmental grants.

1.3.2 Recovery of Expenses and Support of Licensing Efforts

The Office of Brown Technology Partnerships will deduct 15% of the gross Royalties it receives as a contribution towards the costs of operating the Office for the University. After this deduction, remaining Royalties shall be used first to offset costs directly attributable to the protection of rights to the intellectual property and to the licensing of rights. Such fees are anticipated to include fees paid or attributable to legal services, consulting services, licensing organizations and out-of-pocket costs incurred by the University. The University may also retain reasonable Royalties as a reserve against anticipated future costs expected to be incurred that are directly associated with the invention.

1.3.3 Distribution of Net Royalties

After recovery of these expenses (see Section 1.3.2 above), the remaining Net Royalties shall be divided as follows:
Inventor(s) Share PI's Laboratory (ies)² and Department(s)³ Share(s) University Share⁴ Royalty Share after deduction of BTP fees and expenses (per Section 1.3.2 above)

1/3 1/3

Distributed as follows: 50%:50% PIL:DEP until PIL has achieved a cumulative and thence capped income of \$2,000,000 (two million) per license. At this point, the DEP receives the full 1/3 until DEP has achieved a cumulative and thence capped income of \$10,000,000 (ten million) per license. At this point, the 1/3 income is transferred to the University to be added to its 1/3 share 1/3

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1.4 Equity

Brown University may at times accept equity as part of a licensing agreement. Net Equity, that is the value of equity after the deduction of 15% to support the Office of Brown Technology Partnerships and any further deduction for reimbursement of expenses, will be shared between the University, the inventor(s) and the inventor(s) laboratory(s) and department(s) in accordance with Section 1.3.3 above. Any equity received by the University under a license agreement will be held and managed by Brown Technology Partnerships. Brown Technology Partnerships will promptly distribute the inventor(s) shares to the inventor(s), when permitted under applicable securities laws and not otherwise prohibited by contractual restriction.

² PIL = Principal Investigator Laboratory. This term embraces a single Covered Individual (“CI”) and a laboratory in which a CI is a member. The intent of the PIL share is to reward the inventor(s) by distributing funds back into the research of the CI(s). If a CI does not have a laboratory, the share distribution will be made by mutual agreement. If an agreement cannot be reached, a determination will be made by the Standing Appeals Committee, and the Committee will make recommendations to the Vice President for Research, the Provost and the President.

³ DEP = the Department(s) in which the CI(s) are members.

⁴ When the invention originates in the Division of Biology & Medicine, the Provost, in consultation with the Dean of Biology & Medicine, will determine the portion of the University’s 1/3 share to be allocated to the Division.

1.5 The Office of the Vice President for Research

The Research Advisory Board (“RAB”) for the Office of the Vice President for Research (“OVPR”) or its appointed working party or sub-committee will periodically review and update the Patent and Invention Policy. Considered in this review will be the policies of peer institutions and changes in law and regulation. The RAB or its appointed working party or sub-committee will make recommendations to modify the Policies to the Vice President for Research, the Provost and the President, including recommendations to modify the levels at which distributions are made and capped to take into account the impact of inflation as well as changes in law and regulation.

1.5.1 The Standing Appeals Committee

The OVPR, through the offices of its RAB or its elected working party or subcommittee and in consultation with the Faculty Executive Committee, will recommend a list of faculty for selection to the Standing Appeals Committee (“SAC”). The members of the SAC, with an initial membership of five, will be selected by the Provost. The SAC shall examine disputed matters pertaining to the Patent and Invention Policy and make its recommendations to the Vice President for Research, the Provost and the President. The SAC shall work in consultation with the Office of Brown Technology Partnerships and the Office of the General Counsel.

2.0 The Copyright Policy

2.1 Applicability

This policy applies to faculty, students, employees, visitors and consultants, whether paid or not, who create copyrightable materials under University auspices or using University facilities.

2.2 Copyright Policy

It is the policy of Brown University that ownership of the copyright in a work shall belong to the author or authors of the work, with certain, stated exceptions. (See I. – VIII. below.) For cases in which ownership of the copyright vests in the author or authors of the work, assignment of the copyright in such work need not be approved by the University.

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The exceptions to this policy that shall vest ownership of the copyright in a work with Brown University, rather than with the author or authors of the work, are:

- I. if the work is a Work Made for Hires as defined by United States copyright law;
- II. if the work is defined as an “Institutional Work” under Section 2.4 below;
- III. if there is an intent to commercialize the copyrighted material on the part of the copyright owner or owners in an industrial application (*e.g.*, commercial data management and analysis products and services);
- IV. if the work was “Significantly Derived from University Resources” under Section 2.5 below;
- V. if the work is an audio, video, photographic or any form of digital reproduction of a class, course or presentation made by Brown faculty, staff or students;
- VI. if the work includes images of Brown University-owned facilities, buildings or property for purposes other than scholarly research and publication;
- VII. if the work includes rare Brown University holdings or unique data sets that are periodically employed by faculty or students other than the author or authors of the work; or
- VIII. if the work includes the name or insignia of Brown University as an endorsement, enhancement or sanction for a product or service.

With respect to the foregoing works, Brown University shall be the owner of the copyright in the work. As such, the University may decide to assign its copyright to the author or authors of the work on a case by case basis.

⁵For guidance on the definition of “work made for hire,” see Section 2.3 below and additional guidelines provided at <http://www.brown.edu/Administration/Copyright/glossary.html>.

For cases in which ownership in the copyright of a work vests in the University as a result of a grant or contract, the University shall, if permitted by the grant or contract, assign the copyright to the author or authors if necessary to comply with the requirements of scholarly publications.

2.3 Work Made for Hire

A “Work Made for Hire” is a work created in the course of the author’s employment. For example, works created by writers of university publications or by staff programmers would be considered Works Made for Hire and are the property of the University. Copyrightable works of scholarly research, course materials or artistic works made by faculty members would not be considered Works Made for Hire and are the property of the author or authors.

2.4 Institutional Works

The copyright in Institutional Works shall be owned by the University. Institutional Works are defined as works that are supported by a specific allocation of University funds or created at the direction of the University for a specific University purpose. Institutional Works also include works whose authorship cannot be attributed to one or a discrete number of authors, but rather result from simultaneous or sequential contributions over time by multiple authors. For example, software tools developed and improved over time by multiple faculty and students, where authorship is not appropriately

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attributed to a single or defined group, would constitute an Institutional Work. The mere fact that multiple individuals have contributed to the creation of a work shall not cause the work to constitute an Institutional Work.

2.5 Works Significantly Derived from University Resources

The copyright in Works Significantly Derived from University Resources shall be owned by the University. Works Significantly Derived from University Resources are defined as works created using expert University services, extensive use of the University computer infrastructure, equipment, use of the services of University nonfaculty employees working within the scope of their employment, or extensive use of other University resources that exceeds the level of support that is commonly and customarily accessed by faculty. Any question as to whether a work is Significantly Derived from University Resources can be brought to and addressed by the Standing Appeals Committee at any time, i.e., at the beginning, during the course of, or at the completion of the work. The ordinary use of University resources, including the use of desktop computers, the University computer infrastructure, secretarial staff and supplies, one's office and the University libraries, constitutes the customary use of University resources. The copyright in works created using such resources vests in the author and not in the University.

2.6 Other University Rights

When copyrighted material is developed in conjunction with an author's University activities and responsibilities, or using University facilities or equipment, or with the involvement of faculty, employees or students, the University shall retain the right to use such material for its own educational and research purposes, even though it does not claim ownership of the materials under Section 2.2 above. The foregoing right does not include a royalty-free license to use or to reproduce a published textbook for classroom or library use.

2.7 Disclosure

All copyrightable materials owned by the University must be disclosed in writing by the author(s) to the Office of Brown Technology Partnerships.

2.8 Distribution of Net Income from University-Owned Copyrights

The University agrees to share with the author(s) any net income received from the commercialization or exploitation of University-owned copyrighted material using the same formula for Net Royalties as for licensed patents as described in Section 1.3.3 above.

2.9 Works of Non-Employees

Under the United States Copyright Act, works of non-employees, such as consultants and independent contractors, are owned by the author and not by the University, unless there is a written agreement to the contrary. As it is Brown's general policy that the University shall own such works, Brown will typically require a written agreement from non-employees that ownership of such works will be assigned to the University.

Examples of works which the University may retain non-employees to prepare are:

- Reports by consultants or subcontractors;
- Computer software;

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- Architectural or engineering drawings;
- Illustrations or designs; or
- Artistic works.

2.10 Distribution of Computer Software

The distribution of University-owned computer software to others for external research purposes must be coordinated with the Office of Brown Technology Partnerships if the software has potential commercial value or if it is subject to the terms of a sponsored research agreement. The Office of Brown Technology Partnerships will provide appropriate wording for the distribution agreement and will arrange for copyright registration. Distribution for internal, Brown University, purposes need not be coordinated with the Office of Brown Technology Partnerships and is permissible with the approval of the author of the work and the Department Head.

2.11 Electronic Distribution of Copyright Material

To the extent that this Policy does not fully address distance learning, recordation, broadcast, narrowcast, and methods and electronic means of use and dissemination of copyright materials created under University auspices or using University facilities, the University shall create a policy on such rights by a joint Faculty and Administration committee to be created for this purpose.

2.12 The Office of the Vice President for Research

The Research Advisory Board (“RAB”) for the Office of the Vice President for Research (“OVPR”) or its appointed working party or sub-committee will periodically review and update the Copyright Policy. Considered in this review will be the policies of peer institutions and changes in law and regulation. The RAB or its appointed working party or sub-committee will make recommendations to modify the Policies to the Vice President for Research, the Provost and the President including recommendations to modify the levels at which distributions are made and capped to take into account the impact of inflation as well as changes in law and regulation.

2.12.1 The Standing Appeals Committee

The OVPR, through the offices of its RAB or its elected working party or subcommittee in consultation with the Faculty Executive Committee, will recommend a list of faculty for selection to the Standing Appeals Committee (“SAC”). The members of the SAC, with an initial membership of five, will be selected by the Provost. The SAC shall examine disputed matters pertaining to the Copyright Policy and make its recommendations to the Vice President for Research, the Provost and the President. The SAC shall work in consultation with the Office of Brown Technology Partnerships and the Office of the General Counsel.