



# OLD DOMINION UNIVERSITY

## University Policy

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### Policy # 5201

### RESEARCH CONFLICT OF INTERESTS

**Responsible Oversight Executive:** Provost and Vice President for Academic Affairs  
**Date of Current Revision or Creation:** August 2, 2012

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#### A. PURPOSE

The purpose of this policy is to address the potential for research conflicts of interests by defining the process for identifying, reporting, evaluating and managing potential conflicts of interests to ensure that they do not threaten the integrity of the University's scholarship, research, sponsored programs, evaluation, and administration.

#### B. AUTHORITY

[Code of Virginia Section 23.1-1301, as amended](#), grants authority to the Board of Visitors to make rules and policies concerning the institution. Section 6.01(a)(6) of the [Board of Visitors Bylaws](#) grants authority to the President to implement the policies and procedures of the Board relating to University operations.

[Board of Visitors Policy 1424, Policy on Intellectual Property](#), governs the use and sale of intellectual property.

#### C. DEFINITIONS

Center Grant - Funding for a research center or a larger project in which there is one Principal Investigator listed for the funding but that Principal Investigator may or may not be involved in specific projects being conducted with the support of the funding mechanism.

Co-Investigator (Co-I) - A previously approved individual who participates in the design, conduct, and reporting of research.

Co-Principal Investigator (Co-PI) – Co-Principal Investigators are key personnel who have responsibilities similar to that of a PI on research projects. While the PI has ultimate responsibility for the conduct of a research project, the Co-PI is also obligated to ensure the project is conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.

Data and Safety Monitoring Board – An independent group of experts tasked with oversight of a research project to ensure that study guidelines are being followed and to make decisions regarding study continuation based upon the existence of adverse events during the study. This

board has the power to stop a study based upon pre-determined criteria for study integrity not being met.

Data Stewardship Committee – Committee tasked with review of the data produced from a research activity to ensure that the data was collected and analyzed in accordance with the standards of the academic discipline.

Licensed Start-up Company - A licensed start-up company has the following characteristics: (1) a license or an option for a license for University or Old Dominion University Research Foundation (ODURF) intellectual property; (2) is not publicly traded; and (3) equity or an equity option is held by the University, by a University employee or student, by a member of the employee's or student's immediate family, or in trust for any employee's or student's immediate family. Excluded from this definition are companies that license only technology released by the University to the researcher/inventor or technology to which the University has no claim.

Immediate Family Member - A spouse and any other person residing in the same household as the officer or employee who is a dependent of the officer or employee or of whom the officer or employee is a dependent.

PI Exclusion Rule – Standard for service as a Principal Investigator on a human clinical trial research project. Investigators with a significant financial interest in the study cannot serve as a PI unless a waiver is obtained.

Principal Investigator (PI) – An employee who is responsible for the design, conduct, and reporting of research. The PI for any research activity conducted at a University facility must be a University employee or Old Dominion University Research Foundation (ODURF) employee, or, under appropriate circumstances, a student.

Research Conflict of Interests (COI) - A potential or actual Research Conflict of Interests (COI) exists when commitments and obligations to the University or to widely-recognized professional standards are likely to be compromised, or perceived to be compromised, by a person's outside interests or commitments, especially financial.

Research Conflict of Interests Committee (COIC) - The COIC is responsible for the oversight and management of potential conflicts of interests on the part of the University's employees and the institution itself related to this policy, and it reviews conflicts related to technology transfer activities involving Licensed start-up companies.

Research Review Boards - Any and all Boards and Committees included under the [Policy on Research Review Boards](#) to regulate research at the University: Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), Radiation Safety Committee (RSC), and individual college Human Subject Review Committees.

Significant Financial Interest (SFI) - A significant financial interest (SFI) includes an interest owned by the individual or immediate family members in an outside entity whose financial interests would reasonably appear to be affected by the individual's research and/or administrative activities and means anything of monetary value, including but not limited to:

- Any equity interest, including stock options in a non-publicly-traded company held by an individual and immediate family members;

- Any equity interest, including stock options in a publicly-traded company held by an individual and immediate family members, that exceeds 5% ownership interest or a current value of \$5,000, as determined through reference to public prices, recent financing events, or other reasonable measures of fair market value;
- Salary, consulting fees, honoraria, royalties, and milestone fees and other licensing proceeds received directly from a single outside entity that, when aggregated for the individual and immediate family members, are expected to exceed \$5,000 in a 12-month period;
- Any sponsored or reimbursed travel related to institutional responsibilities, regardless of dollar amount.

The term SFI does not include:

- Salary or supplementary payments from the University or its affiliates;
- Income from seminars, lectures, or non-promotional engagements sponsored by governmental or non-profit entities;
- Income from service on advisory committees or review panels for governmental or non-profit entities;
- Royalties, milestone payments, or licensing fees paid through the University or its affiliates.

Study Evaluation Committee – Committee tasked with review of study results to ensure objective analysis and interpretation of the research data. The PI may serve as a member of this committee, but should not chair.

#### **D. SCOPE**

This policy applies to all employees, students, volunteers, employees of affiliated organizations who are paid through the University, and visitors to the institution who are directly or indirectly involved in research activities, whether publicly, privately or internally supported. Employees include all staff, administrators, faculty, full- or part-time, and classified or non-classified persons who are paid by the University. Students include all persons admitted to the University who have not completed a program of study for which they were enrolled; student status continues whether or not the University's programs are in session. Affiliated organizations are separate entities that exist for the benefit of the University through an operating agreement and include the Foundations, the Community Development Corporation, and the Alumni Association. Visitors include vendors and their employees, parents of students, volunteers, guests, uninvited guests and all other persons located on property owned, leased, or otherwise controlled by the University.

#### **E. POLICY STATEMENT**

Old Dominion University requires disclosure and management of outside relationships and organizational commitments of its faculty, scholars, investigators, and research staff/coordinators. This assures that the advantages of associations between academe and industry are being realized without the loss of the fundamental values of objectivity and freedom of inquiry in research and scholarship; that the University's research programs and reputation are not compromised by even the appearance of a lack of concern about this matter; and that no one will unfairly benefit from the University's public trust or reputation.

The University's Research Conflict of Interests Policy complies with Federal regulations related to financial conflicts of interests in research and will be subject to any appropriate modifications in order to conform to regulations of any Federal agency sponsoring the research in question.

Individuals involved in research activities must devote their primary professional efforts to the University to the extent required by their appointments. Other activities or commitments must be arranged so as not to conflict with or dilute this commitment. While time devoted to employment outside the contract period (i.e., for those on less than 12-month appointments) may not represent a conflict of commitment, it may represent a Research Conflict of Interests (COI).

Potential COIs must be disclosed fully and accurately in all formal communications that may be impacted by the financial interest, including abstracts, publications, presentations, press releases, and applications or proposals for research funding.

Disclosure by University employees of financial, personal, or professional relationships that raise a potential COI or its perception is at the heart of the University's COI policy and is a prerequisite for determining whether a conflict, once recognized, can be managed or reduced or, in some cases, eliminated. Moreover, the policy assures confidentiality in order to encourage full disclosure of potential conflicts without unduly intruding on the privacy of University personnel or their families.

The enforcement of this policy rests with the academic unit where the research is conducted, and, if not the same, the unit where the researcher has his/her primary appointment. The immediate supervisor of the individual involved in research activities should be cognizant of the activities taking place in the unit and should monitor the research as to potential and actual COIs.

#### EXAMPLES OF RESEARCH CONFLICTS OF INTERESTS

The following examples illustrate potential or actual COIs. They are by no means exhaustive but are illustrative of potential COIs that must be disclosed, avoided, or otherwise managed, reduced, or eliminated.

- Accepting gifts, gratuities, or special favors related to University research;
- Giving remunerated lectures for or on behalf of companies or organizations whose economic or political interests are affected or perceived to be affected by an investigator's scholarly work;
- Entering into a paid consultancy with an entity that has an interest in the consultant's University-based research;
- Commenting directly or indirectly to investors or investment analysts about unpublished research results that may affect the value of the shares of a for-profit company;
- Providing privileged access to information (particularly unpublished research results) developed with University resources or supported by independent sponsors to any external entity other than the sponsor;
- Engaging in the purchase or sale of securities of a company while possessing information on unpublished research results that may affect the value of the shares;

- Undertaking evaluative research when the investigator or the investigator’s immediate family member has a financial, managerial, or ownership interest in the sponsoring company or in the company producing the product being tested;
- Using students or employees of the University to perform services for a company in which an individual involved in research activities has an ownership interest or from which he/she receives any type of remuneration;
- Accepting support for research under terms that require results to be held confidential, unpublished, or significantly delayed in publication;
- Purchasing equipment, instruments, or supplies for research or teaching, or contracting services from a firm in which the individual involved in research activities has a financial or other interest;
- Influencing the negotiation of contracts between the University and outside organizations in which an individual involved in research activities has a financial interest or other relationship;
- Influencing the sub-contracting of Federally funded University research to an entity in which the individual involved in research activities has an interest;
- Receiving royalties or non-royalty payments related to ongoing research.

## **F. PROCEDURES**

### **1. GENERAL RESEARCH CONFLICT OF INTERESTS POLICY AND COI MANAGEMENT**

The Research Conflict of Interests Policy outlines the requirements for disclosure, oversight, and management of potential and actual research conflicts of interests.

The Research Conflict of Interests Committee (COIC) is responsible for the oversight and management of potential conflicts of interests on the part of the University’s employees and the institution itself related to this policy, and it reviews conflicts related to technology transfer activities involving Licensed start-up companies. Members of the COIC and the chair are appointed by the Provost. Membership consists of a broad spectrum of University faculty, staff members, and students involved in a cross-section of research disciplines, including two members proposed by the Faculty Senate, and administrators responsible for purchasing. The COIC also includes representation from the University Office of Research, and the non-University community. Representatives from the Old Dominion University Research Foundation (ODURF) and the Office of University Counsel serve as *ex officio*, non-voting members. Voting membership of the Committee shall not exceed 15, and a quorum shall consist of 50% of the total voting membership. The COIC reports through its chair to the Provost and Vice President for Research.

#### **a. Responsibilities of Investigators and Scholars**

##### **i. COI Policy**

Individuals involved in research activities must withdraw from decisions or the exertion of influence concerning any decisions by the University regarding any

relationship affecting a company in which they or immediate family members have a significant financial interest (SFI).

Collegial communication among colleagues involving research information (such as sharing preliminary and unconfirmed results) is to be encouraged in an academic setting; in those few cases where exceptions to such an approach are unavoidable, the scope of the project must be defined so as to permit the exchange of as much information as possible. All research results must be submitted for publication or publicly disclosed unless specifically prohibited by a sponsor agreement.

Unpublished research results may not be disclosed to investors or investment analysts and should not be disclosed otherwise, except as permitted by the Patents and Licensing Office in the Office of Research, in order to avoid potential or actual research conflicts of interests.

When consistent with the terms of their University appointments, students or visiting scholars may be employed by companies in which their supervisors or advisers have an SFI only with the prior approval of their department chairs or deans and informed consent by the student or visiting scholar. It is the responsibility of the faculty member to ensure that their students are informed of their responsibilities under this policy.

The Policy on Faculty Research and Development Assignments addresses the issue of faculty leave of absence. The pursuit of entrepreneurial endeavors is an acceptable reason to be cited in a request for a faculty research or development leave. A faculty member on research or development leave may be exempted by the COIC from restrictions on holding equity or a management role only for the period of the research or development leave.

ii. Disclosure

All individuals involved in research activities must submit a [Research Conflict of Interests Disclosure Form](#) upon appointment, and annually thereafter, on or before April 15, and at any time when the outside interests related to their research responsibilities change. The forms must be submitted to the individual's supervisor (e.g., department chair, dean, or division head, as appropriate).

iii. Prior Approval

As required by [Board of Visitors Policy 1421, Outside Employment](#), individuals involved in research activities must seek prior approval from their supervisors for any planned outside interests and activities that are, or could appear to be, in conflict with their commitments to the University for the purpose of managing, reducing, or eliminating potential or actual conflict.

Consulting contracts shall not convey ownership of intellectual property that is subject to the University's [Board of Visitors Policy 1424, Policy on Intellectual Property](#).

b. Responsibilities of Department Chairs, Division Heads, and Deans

i. Review

The department chairs, division heads, or deans, as appropriate, shall:

- a. Keep confidential all COI disclosures submitted to them by individuals involved in research activities, except to provide institutional or internal oversight as authorized by this policy and to comply with requests from Federal, State, and Foundation funding agencies as required under terms of a grant, contract, or cooperative agreement;
- b. Review promptly the COI disclosures for existing or potential conflicts of interests and request and document additional details, including precise dollar figures or percentages for ownership interests or remuneration, if such details appear necessary to determine whether there is an impermissible conflict of interests;
- c. In all cases notify their supervisors of these outside interests disclosed when a COI has been determined to exist;
- d. Notify the employees that the supervisors will be reviewing the disclosures of COIs submitted as a matter of routine;
- e. Disqualify themselves and request that the review be done by their supervisors if they have a conflict of interests in reviewing disclosed information.

ii. COI Management

Upon review of the disclosures of their employees, first-line supervisors shall meet with the employee individually and, as appropriate, discuss how potential or actual conflicts will be managed, reduced, or eliminated and recommend and initiate actions to do so, or they may refer the matter to the next higher administrative level.

Examples of appropriate actions to resolve COIs include:

- a. Public disclosure of SFIs in abstracts, publications, presentations, press releases, and applications or proposals for research funding;
- b. Monitoring of research by independent reviewers or an oversight committee;
- c. Selection of a non-conflicted PI;
- d. Disqualification from participation in all or a portion of the funded research;
- e. Divestiture of SFIs;
- f. Severance of relationships that create actual or potential conflicts;

- g. Prospective discussions with supervisors of the time involved in any planned outside activities that may have the potential to conflict with, or appear to conflict with, commitments to the University;
  - h. Refusal by the University to enter into a research agreement if a COI cannot be managed effectively;
  - i. Participation of one or more non-conflicted persons in the evaluation of research data and/or preparation of manuscripts;
  - j. Partition a graduate student's work when that student is funded by a sponsor where the student's advisor has an economic interest
- iii. Additional Actions by First-line Supervisors
- a. Supervisors must inform the chair of the Research Conflict of Interests Committee (COIC) that a management plan has been developed prior to the expenditure of research funds, or, if the conflict is not disclosed prior to the beginning of research, no later than 30 days after learning of the conflict.
  - b. The chair will notify the Vice President for Research that COIs involving Federal agency sponsors are being managed. The same process applies if a conflict develops after the April 15 disclosure deadline.
  - c. For each individual who discloses outside conflicting interests, supervisors must submit a management plan for review by the dean (as appropriate), Provost, and Vice President for Research by May 15.
  - d. Possible additional actions
    - Recommend and initiate actions leading to sanctions for non-compliance with this policy or the approved management plan;
    - Seek the advice of the COIC.
- iv. [Annual Data Summary Report](#)
- a. The department chairs, deans, or other administrators reporting to the Provost or the Vice President for Research must submit to their respective supervisors annual statistical reports for their units that will summarize the COI disclosures, including the number of department employees whose conflicts were resolved or were not managed, reduced, or eliminated.
  - b. Each dean of an academic college shall prepare an [Annual Data Summary Report](#) for the entire college and submit it to both the Provost and the Vice President for Research.
- v. Disclosure of Outside Income

The University requires the reporting of an SFI. Some units, however, may require disclosure of the actual dollar amount.



c. Responsibilities of the Provost and the Vice President for Research

- i. Both the Provost and the Vice President for Research receive the management plans that address reported outside interests and the Annual Data Summary Reports from the deans.
- ii. Both the Provost and the Vice President for Research have the discretionary authority to review plans to prevent or manage COIs and to approve sanctions for non-compliance.
- iii. Both the Provost and the Vice President for Research may request the assistance of the COIC in dealing with individual cases.
- iv. The recommendation of the COIC, if any, will be conveyed to the Provost, who will take such recommendation under consideration.
- v. The Provost's ruling on any COI issue will be final.

d. Sanctions

Sanctions may be applied for non-compliance with the requirements of this policy or with management plans in the same way as for non-compliance with any other University policy, including a letter of reprimand, special monitoring of future work, removal from the particular project, probation, suspension, salary reduction, or initiation of steps leading to possible reduction in rank or termination of employment.

e. Data Retention

Conflict of interests records relating to research activities, including disclosures and conflict management plans, must be retained for a period of three years after submission of the investigator's filing of the final project report, or longer if required by the relevant funding agency.

**2. COI POLICY AND COI MANAGEMENT RELATED TO SPECIFICALLY REGULATED RESEARCH**

a. COI Policy

For all cases involving researchers who have an SFI impacting specifically regulated research, the COIC or its designated subcommittee will submit a conflict management plan to the Provost, Vice President for Research, the PI, the investigator with the SFI, and his/her department chair and dean. In the event of discrepancies, the funding agency's regulations addressing COI shall take precedence over the provisions of this policy.

This section does not apply to the overall PI of a multi-task project, such as one supported by a program project of a Center Grant, although it does apply to the PIs of the independent sections of such projects. There are two alternative ways of addressing a conflict related to an SFI held by the proposed PI:

- i. In regard to human clinical trials, an investigator with an SFI should not serve as PI (this is known as the "PI exclusion rule"), and a non-conflicted PI should be sought to conduct the research. This alternate PI should have the necessary background

and skills to conduct the project and should be scientifically and administratively independent of the conflicted investigator. The conflicted individual may be a co-investigator on the project, subject to some restrictions on the research role detailed in a conflict management plan developed by the COIC. In the case of research overseen by IACUC involving an investigator whose only SFI is in intellectual property rights, the applicability of the PI exclusion rule may be determined on a case-by-case basis.

- ii. If a suitable non-conflicted PI cannot be found for human clinical trials, the conflicted investigator may ask for a waiver of the PI-exclusion rule if a case can be made for the existence of compelling circumstances. A request for such a waiver must be submitted, through the COI Committee to the Vice President for Research in the case of research overseen by the IRB.
- iii. Compensation arrangements for support of human research studies shall not affect the conduct or influence the outcome of such research.
- iv. In instances not involving human clinical trials, an investigator with an SFI may serve as PI only when a COI management plan has been approved by the employee's first-line supervisor and department chair.

b. COI Management Plan

Any management plan must include the following:

- i. Disclosure
  - a. At the time of initial protocol submission, and at any time during the conduct of the research study when new interests are accrued, the PI must disclose to the relevant Vice President any SFIs of the individuals involved in research activities that may be affected, or perceived to be affected, by the outcome of the research study.
  - b. In the case of research that is considered a "clinical investigation" under the U.S. Food and Drug Administration (FDA) regulations, investigators must also disclose: 1) any proprietary interest in the tested product (including, but not limited to, a patent, trademark, copyright, or a licensing agreement) and 2) all payments made by the sponsor of a covered study to the investigator or the institution to support activities of the investigator that have a monetary value of more than \$25,000 (exclusive of the costs of conducting the clinical study or other clinical studies – e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for one year following the completion of the study.
  - c. All participants in the project, including students, postdoctoral fellows, employees and human subjects, must be informed of the existence of a conflict.
  - d. The existence of the conflict must be disclosed in all abstracts, publications, presentations, press releases, and applications or proposals for research funding related to research in which an investigator has a financial interest.

ii. Exceptions

Requests for exceptions to a management plan not related to PI exclusion (e.g., to add/remove elements to/from the plan) shall be communicated to the Office of Research.

The request will then be forwarded to the COIC for deliberation. The results of these deliberations will be reported to the Provost, Vice President for Research and the investigator with the SFI within two weeks of receiving the request and to the COIC at its next meeting.

If an exception is granted allowing a conflicted investigator to be PI, the management plan must include at least these additional elements:

- a. A Data Stewardship Committee (referred to below as the Committee) must be formed, appointed by the PI's immediate academic supervisors together with the chair of the COIC. The chair of the Committee shall be an Associate Professor or Professor at Old Dominion University, or a person of comparable standing from outside the University, who has adequate knowledge to scrutinize the data issuing from the project. This person must not have the same primary departmental affiliation as the PI, a financial conflict with the research project, or have had joint publications or grant support with the PI within the previous five years. There shall be at least two additional members of the Committee, all free of financial conflicts with respect to the research in question. One of these persons shall be a voting member of the COIC. The major criteria for appointment to the Committee are independence from the PI and sufficient background to understand the data from the study. In the case of a University conflict in the form of equity in the entity sponsoring the research, at least one member of the Committee shall be from outside the University.
- b. The Committee shall meet at least once a year and shall have the opportunity to meet individually with members of the research team. The Committee must have access to such information deemed sufficient and necessary to ensure that data are interpreted in accordance with standards appropriate to the discipline.
- c. After each of its meetings, the Committee shall report in writing to the chair of the PI's department and to the COIC, attesting to its opinion about the integrity and interpretation of the data.
- d. The PI may not be the only person involved in interpretation of study results but may be involved as part of a committee that evaluates study results. This Study Evaluation Committee, comprised of predominantly non-conflicted individuals, is not necessarily the same as the data stewardship committee.
- e. The following additional provisions shall apply in the case of human subject research:
  - i. The PI may identify possible subjects for the protocol but may not participate in enrollment.
  - ii. The PI may not administer the informed consent.

- iii. The informed consent document shall include a disclosure of the existence of the PI's financial interest, in a form approved by the IRB.
  - iv. The PI will not be involved in subjective assessments of eligibility criteria and intervention outcomes.
  - v. There shall be an independent and conflict-free Data and Safety Monitoring Board for any study considered by the IRB to involve more than minimal risk. This Board shall function under general guidelines from the Office of Research.
  - vi. In the unlikely event that the IRB is not in agreement with the proposed COI management plan and an agreement cannot be reached following the above procedures, the decision to grant approval of the protocol remains with the IRB.
- f. The following additional provisions shall apply in the case of research using vertebrate animals:
- i. A formal plan shall be devised in cooperation with the attending veterinarian for provision of "enhanced" veterinary oversight for the animals that serve as subjects for the project. As with all animal studies at the University, the attending veterinarian has the discretion to provide treatments to and/or humanely euthanize any research animals that may be deemed to be in pain or distress beyond that approved in the research protocol. Such actions shall be reported to the COIC by the attending veterinarian.
  - ii. The Data Stewardship Committee defined in [F.2.b.ii.a.](#), above, shall meet at least semi-annually.
- g. Any costs connected with the operation of the Data Stewardship Committee, a Data and Safety Monitoring Board, or "enhanced" veterinary oversight must be budgeted to the research project.

c. Sanction

The COIC will report any known violations of this policy to both the Provost and the Vice President for Research who, in turn, are responsible for invoking any sanctions they determine appropriate (e.g., suspension of human subject or animal enrollment, suspension of the research study) for non-compliance with COI management plans. Sanctions are invoked in cooperation with the investigator's department chair and dean for violations of this policy or for non-compliance with the management plan.

### 3. COI POLICY AND COI MANAGEMENT RELATED TO LICENSED START-UP COMPANIES

a. COI Policy

i. Disclosure and Approvals

- a. The relationship of all individuals involved in research activities and immediate family members to the company, including the holding of equity, must be disclosed to, and reviewed and approved by, the department chair or dean, and the COIC.

- b. Individuals involved in research activities must submit their financial disclosures at least annually, and as relationships change, to their department chairs or deans and the Vice President for Research.
- c. The individual's research conflict, potential or actual, must be disclosed in abstracts, publications, presentations, press releases, and applications or proposals for research funding when the described research involves matters that may be of interest to the licensed start-up company.
- d. Individuals involved in research activities must sign a [Licensed Start-up Company Policy Compliance Statement](#) that certifies that they understand applicable policies and agree to cooperate in their implementation.

ii. Equity

a. Institutional Equity

The University or ODURF may, in some circumstances, take stock in licensed start-up companies that do not have the financial resources to make full license payments in cash. In such cases licensed start-up companies should normally be required to pay for out-of-pocket patenting and related expenses. Equity shall not be held in sufficient amounts to confer management power, which generally would limit ownership to no more than 49% of closely held voting stock or 20% of publically held voting stock. Review and approval of stock acquisitions shall be provided by the COIC as to COI matters.

The Office of Research determines the amount and form of equity to accept, subject to the approval of the ODURF Board and the Vice President for Research, as noted above. The ODURF Board merely holds the shares, once taken, and ensures that legal restrictions on transfer are observed up to and including the date when the shares are sold. When it receives equity security in exchange for intellectual property of the University, it is the policy of the ODURF Board to liquidate that security as soon as it is legally tradable and in a manner that allows for an orderly sale, consistent with market conditions. This policy holds regardless of the research activity that may be occurring at the University or elsewhere. By selling equity securities as soon as legal restrictions on transfer are lifted and market conditions permit, the ODURF Board makes no judgment whether to hold or sell an equity position in a company and is not influenced by other potential financial interests of the University or faculty who may be shareholders in the company.

Decisions on acquisition of company stocks for the University's endowment are made by a third party investment manager having no connection with research administration or oversight.

b. Individually Held Equity

With the prior approval of the COIC, equity may be issued to inventors whose technology is being licensed and to other faculty, staff, and students, provided that a 49% ownership cap is placed on the aggregated stock and/or stock options held by the University or affiliates, its employees, students, and

immediate family members, so long as their aggregated ownership interests do not constitute a controlling interest in the company.

iii. Offices and Positions

Individuals involved in research activities may not hold management or operating positions in the company (e.g., officer of the company, member of the board of directors, chief scientific officer), although membership or chairmanship of the scientific advisory board is allowed.

iv. Consulting on behalf of companies in which individuals involved in research activities have an interest:

- a. Consulting, in accordance with [Board of Visitors Policy 1421, Remunerative Outside Employment](#), may be undertaken, provided there is prior approval from the department chair or dean and the COIC.
- b. Consultants shall not use University resources for purposes other than University business.
- c. The University may claim rights to intellectual property developed by its employees in consulting arrangements in accordance with [Board of Visitors Policy 1424, Policy on Intellectual Property](#).
- d. Full-time University faculty may not provide any research effort to the company, whether compensated or not, other than through a Sponsored Research Agreement (SRA) with ODURF.

v. Research Grants and Contracts

- a. Research grants and contracts, service agreements, and other contracts between the ODURF and the licensed start-up company shall be negotiated on behalf of the University by the Office of Research, not by individuals involved in research activities.
- b. Financial relationships must be disclosed in applications and proposals for research funding.
- c. Individuals involved in research activities may not receive remuneration directly from a company for work subcontracted to that company by the University.

vi. Research Sponsored by a Licensed Start-up Company

Research sponsored by a licensed start-up company should generally be permitted in University laboratories provided that:

- a. Proposals are reviewed by the COIC prior to approval;
- b. Reports to the COIC on the sponsored activity are provided at least annually;
- c. An investigator with an SFI in the company may not serve as PI;

- d. In the case of Small Business Innovation Research (SBIR) or Small Business Technology Transfer Program STTR grants not involving research regulated by the IRB or IACUC, the Investigator with the outside interest may be the PI;
- e. Participation as a researcher in a company's SBIR or STTR program is limited to the sub-contract to the University or to the portion of the award made directly to the University;
- f. Individuals involved in research activities who participate in company research, whether at University or company facilities, do so under SRAs negotiated by the Office of Research and not through consultancies;
- g. Prior approval is obtained from the department chair or dean on the use of graduate and undergraduate students on such research;
- h. The study's budget includes application of the University's full indirect cost rate and all costs associated with the research study are borne by the company.

Any exception to the PI exclusion rule or request for an exception must be approved by the Vice President for Research upon the recommendation of the COIC; in case an exception is granted, the management plan indicated in section IV.B. applies.

vii. Licensing of University Technology

- a. The Office of Research undertakes broad marketing and utilizes a common format for optioning or licensing a specified technology to either a licensed start-up company or an existing company. A comprehensive grant of future rights to all technologies from a research laboratory will not be allowed.

viii. Product Liability

- a. In order to control the risk of product liability, a disclaimer of warranties to the licensed start-up company, along with comprehensive insurance, is required. Automatic indemnification of the University by the licensed start-up company also is required.

b. Review by the COIC

i. Initial Submission of Proposed Equity Ownership

The initial submission to the COIC shall be made on the [Proposed Equity Ownership Form](#). This form requests, among other items, identification of individuals involved in research activities and immediate family members involved in the creation of the licensed start-up company, the products or services to be developed, ownership interests, any intended SRAs between the company and the University, and funding.

ii. Initial Review

The initial review will consider the proposed relationships among individuals involved in research activities, administrative and other University personnel, the licensed start-up company, and the University. The COIC may accept the proposed relationship with or without stated conditions, request additional information, or reject the proposed relationship.

Other forms required for an initial submission

- a. [Licensed Start-up Company Policy Compliance Statement](#)
- b. [Approval of a Licensed Start-up Company by Chair/Dean](#)
- c. [Notification to Students/Staff of Financial Interest in a Company](#) (if applicable)

iii. Subsequent Review

Review will be required annually, upon the occurrence of changes in any elements of the initial submission, and upon the occurrence of specified triggering events. Changes in relationships with the University or with the licensed start-up company also will be reviewed.

iv. Conflict of Interests Committee (COIC)

To promote awareness and understanding of COI issues and their importance to the University's mission and research integrity, the COIC and the Office of Research also fulfill an educational function, providing resources and training for the University community on these subjects. Examples of such resources include:

- a. Working with department chairs, deans, and division heads, as requested, encouraging them to:
  - Disseminate COI information (policy, procedures, etc.) to individuals involved in research activities at departmental meetings, at the time of annual performance reviews, and during orientation programs for new employees; and
  - Adhere to consistent and equitable COI policies and procedures.
- b. Presentations to academic units upon request.
- c. Providing the University community with policy updates.
- d. Preparation of updates to the material contained in web-based COI training modules.

If the failure of a researcher to comply with the University's COI policy has biased the design, conduct, or reporting of Federally-funded research, the Provost or the Vice President for Research will conduct a retrospective review and promptly submit a mitigation report to notify the sponsoring agency of the corrective action taken or to be taken.



**G. RECORDS RETENTION**

Applicable records must be retained and then destroyed in accordance with the [Commonwealth's Records Retention Schedules](#).

**H. RESPONSIBLE OFFICER**

Director of Research Compliance

**I. RELATED INFORMATION**

[Board of Visitors Policy 1426 - Policy, Procedures and Timeline for Responding to Allegations of Misconduct in Scientific Research and Scholarly Activity](#)  
[Policy on Financial Interests in Sponsored Programs](#)

**POLICY HISTORY**

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**Policy Formulation Committee (PFC) & Responsible Officer Approval to Proceed:**

<u>/s/ Adam Rubenstein</u>	<u>July 9, 2012</u>
Responsible Officer	Date

**Policy Review Committee (PRC) Approval to Proceed:**

<u>/s/ Donna W.Meeks</u>	<u>March 27, 2012</u>
Chair, Policy Review Committee (PRC)	Date

**Executive Policy Review Committee (EPRC) Approval to Proceed:**

<u>/s/ Carol Simpson</u>	<u>July 23, 2012</u>
Responsible Oversight Executive	Date

**University Counsel Approval to Proceed:**

<u>/s/ R. Earl Nance</u>	<u>August 1, 2012</u>
University Counsel	Date

**Presidential Approval:**

<u>/s/ John R. Broderick</u>	<u>August 2, 2012</u>
President	Date

**Policy Revision Dates:** August 2, 2012

**Scheduled Review Date:** August 2, 2017