

**VCU Office of Research - Policy Update**  
***Executive Summary***  
**VCU Board of Visitors, May 14-15, 2009**

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**POLICY ON CORPORATE SPONSORED RESEARCH AGREEMENTS:**

*New Policy:* This policy was drafted to detail requirements for appropriate execution of research agreements with corporate sponsors. Corporate-sponsored research must be consistent with VCU's comprehensive mission.

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**RESPONSIBLE CONDUCT IN RESEARCH AND SCHOLARSHIP POLICY:**

*New Policy:* This policy was drafted to articulate University requirements and guidance which apply to responsible conduct in research and scholarly activities, including: Ensuring research subject protection, research integrity, environmental health and safety, fiscal accountability, and a broad range of educational opportunities that support these principles.

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**INTELLECTUAL PROPERTY POLICY:**

*Revised Policy:* This document establishes a policy for Virginia Commonwealth University with respect to Intellectual Property developed by members of the University community. The University shall retain all rights, title, and interest in any and all Intellectual Property generated, created, or developed in facilities operated or controlled by the University, supported by funds administered by the University, and/or performed in the course of regular duties by University Members, unless exempted by other provisions of this policy.

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**RESEARCHER CONFLICTS OF INTEREST POLICY:**

*Revised Policy:* This policy defines the process for identifying, reporting, evaluating, and managing investigators' financial relationships that have or may have an impact on the objectivity and integrity of research conducted at Virginia Commonwealth University

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**RESEARCH DATA OWNERSHIP, RETENTION, AND ACCESS:**

*Revised Policy:* This policy asserts and protects the rights of Virginia Commonwealth University, and its Member researchers, in regard to ownership and retention of research data and related records.

## **Timeline**

### **Report of the VCU Task Force on Corporate-Sponsored Research**

(Note: The Report was comprised of recommendations that mandated the creation of a Policy on Corporate-Sponsored Research and a Responsible Conduct of Research and Scholarship Policy. The Report's recommendations also necessitated revising the Researcher Conflict of Interest Policy, the Intellectual Property Policy, and the Research Data Ownership, Retention, and Access Policy. Activities listed below from October to November involved just the Report of the VCU Task Force on Corporate-Sponsored Research. Those activities described in the period of February through May involved all of the new and revised policies mandated by the Report.)

|                                 |                                                                                                                     |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------|
| October 1, 2008                 | Final report submitted to President Trani                                                                           |
| October 6, 2008                 | President and Vice Presidents Reviewed and Approved                                                                 |
| October 7, 2008                 | Council of Deans Reviewed and Approved                                                                              |
| October 7, 2008                 | Faculty Senate Reviewed and Endorsed                                                                                |
| October 16, 2008                | University Council Reviewed and Approved                                                                            |
| November 19, 2008               | Board of Visitors: Academic and Health Affairs Policy Committee [for information]                                   |
| December 2008-<br>February 2009 | Policy Writing and Revision by OVPR staff with VCU Research Development Advisory Council consultation               |
| February 16-<br>March 3, 2009   | Draft Policies Policies posted for VCU Community review and comment                                                 |
| February 23, 2009               | Review of VCU Corporate-Sponsored Research Policy and Related Policies by Presidents and Vice Presidents (approved) |
| March 3, 2009                   | Council of Deans (reviewed and approved)                                                                            |
| March 5, 2009                   | University Council (approved by vote of UC)                                                                         |
| March 3, 2009                   | Faculty Senate (presented and discussed)                                                                            |
| March 17, 2009                  | Faculty Senate Leadership Committee (reviewed and approved)                                                         |
| April 7, 2009                   | Faculty Senate vote (voted to endorse all policies)                                                                 |
| May 16, 2009                    | Board of Visitors (Academic and Health Affairs Policy Committee and Full Board [for approval])                      |
| June 1, 2009                    | VCU Corporate-Sponsored Research Policy and Related Policies Implemented, pending BoV approval                      |

## **Policy on Corporate-Sponsored Research Agreements**

**Responsible Office:**  
Office of Research

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### **POLICY STATEMENT AND PURPOSE**

To establish a policy that details requirements to appropriately execute research agreements with Corporate Sponsors.

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### **WHO SHOULD READ THIS POLICY**

All University Members involved in corporate-sponsored research should read and comply with this policy.

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### **RELATED DOCUMENTS**

[Policy on Research Data Ownership, Retention and Access](#)

[Conflict of Interest Policy](#)

[Intellectual Property Policy](#)

Responsible Conduct in Research Policy

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### **CONTACTS**

[VCU Office of Research](#) officially interprets this policy and will prepare revisions, as needed, to meet the changing needs of Virginia Commonwealth University. All revisions shall be subject to University Board of Visitors approval following review by university leadership (Vice Presidents, Council of Deans, University Council, and Faculty Senate).

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## **DEFINITIONS**

**Agreement:** Generic name for grant, contract or other written arrangement which is enforceable by law, and which must be executed for VCU by an authorized official.

**Award:** Funds that have been obligated by a funding agency for a particular project, or the document memorializing this transaction.

**Clinical Trial:** A clinical trial is a study designed to assess in humans the safety, efficacy, benefits, adverse reactions, and/or other outcomes of drugs, devices, diagnostics, treatments, procedures, medical evaluations, monitoring, or preventive measures. Preclinical laboratory studies or studies in animals are not included under the term clinical trial.

**Clinical Trial Agreement:** A legally binding agreement that manages the relationship between the parties conducting a clinical trial.

**Contract:** A mechanism for procurement of a product or service with specific obligations for both the sponsor and recipient. Each contract document contains a statement of work or services to be performed (scope of work) and represents a legal obligation by the contractor. Since a contract is a purchase or procurement, there will always be a deliverable.

**Copyright:** Intellectual Property protection for a "writing," which protects the specific expression. A copyright may be registered, but registration is not needed for protection. All materials to be copyrighted by VCU should be marked "Copyright © [date of publication], Virginia Commonwealth University."

**Corporate Sponsor:** A for-profit organization providing financial support for a research project.

**Data:** Research Data means 1) recorded information, regardless of form or the media in which it may be recorded, which constitute the original observations and methods of a study, 2) the analyses of these original data that are necessary for reconstruction and, 3) evaluation of the report(s) of a study made by one or more Investigators. Research Data also includes all such recorded information gathered in anticipation of a report. Research Data differ among disciplines. The term may include but is not limited to: technical information, computer software, laboratory and other notebooks, printouts, worksheets, other media, survey instruments, memoranda, evaluations, notes, databases, clinical case history records, study protocols, statistics, findings,

conclusions, samples, physical collections, other supporting materials created or gathered in the course of the Research, tangible research products, unique research resources such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA as well as genetic sequences and mapping information, crystallographic coordinates, plants, animals and spectroscopic data, other compilations formed by selecting and assembling preexisting materials in a unique way. The term does not include information incidental to administration, such as financial, administrative, cost or pricing, or management information.

**Facilities and Administrative (F&A) Costs:** Costs related to expenses incurred in conducting or supporting research or other externally-funded activities but not directly attributable to a specific project. General categories of indirect costs include general administration (accounting, payroll, purchasing, etc.), sponsored project administration, plant operation and maintenance, library expenses, departmental administration expenses, depreciation or use allowance for buildings and equipment, and student administration and services. F&A Costs are synonymous with Indirect Costs, and are sometimes called "overhead."

**Facilities and Administration (F&A) Rate:** The rate, expressed as a percentage of a base amount (Modified Total Direct Cost "MTDC" for most universities), established by negotiation with the cognizant federal agency on the basis of the institution's projected costs for the year and distributed as prescribed in OMB Circular A-21.

**Grant:** A type of financial assistance awarded to an organization for the conduct of research or other program as specified in an approved proposal. A federal Grant, as opposed to a federal Cooperative Agreement, is used whenever the awarding office anticipates no substantial programmatic involvement with the recipient during the performance of the activities. The Principal Investigator of a research grant has significantly greater flexibility in making changes to the research plan than the PI of a research contract. As with any Agreement, a Grant has terms and conditions which must be followed.

**Indirect Costs:** See Facilities and Administrative Costs

**Industry Sponsor:** See Corporate Sponsor

**Intellectual Property:** Anything developed by anyone covered by the [VCU Intellectual Property Policy](#) that fits, but is not limited to, one or more of the following categories:

- a) an Invention
- b) an issued Patent
- c) a Copyrighted work
- d) a legal right inherent in a Patent, Copyright, Trademark,
- e) know-how or trade secrets, or
- f) Tangible Research Property; including, but not limited to, compositions, biologicals, materials, illustrations and drawings, prototypes, devices, and equipment.

**Material Transfer Agreement:** A contract to provide or receive material, which will restrict the material's use, and therefore, liability associated with its use, and may contain language concerning rights to inventions made while using the material.

**Non-Disclosure Agreement:** A Non-Disclosure Agreement, Proprietary Agreement, and a Confidentiality Agreement are all the same thing. The purpose of this Agreement is generally to protect proprietary information regardless of whether it is technical, financial, business information, or any other item that the party is disclosing, that they do not want divulged beyond the parties signing the Agreement.

**Patent:** Intellectual property protection of the embodiment of an idea. A patent is the statutory monopoly property right granted by the government to prevent others from making, using or selling what was patented for a set period (commonly 20 years from the patent filing date) in exchange for making public the information in the patent document.

**Principal Investigator (PI):** a) The individual with final responsibility for the conduct of research or other activity described in a proposal or an award; b) the individual with fiduciary responsibility for an award's management. Usually these are the same individual. However, VCU has a requirement that the fiduciary responsibility vest in a VCU employee, so on occasion they may be different. A common example is that the recipient of a research fellowship is explicitly not an employee, so that person's major professor manages the award's account.

**Research Development Advisory Council (ReDAC):** Inaugurated in 2006, its members are Associate/Assistant Deans for Research or individuals who hold comparable responsibilities for research development within their respective College/School. Council members represent the research interests of each of the Schools and Colleges at VCU, and serve as a conduit of information from the Office of the Vice President for Research (OVPR) back to their constituencies. The Council meets regularly with the Vice President for Research and the Associate Vice President for Research Development to address topics of specific interest to the VCU research enterprise, and to identify resources and supports necessary for increasing the strength and competitiveness of VCU as a research university.

**Right to Publish:** University policy requires that the institution or PI retains the right to publish the results of a sponsored program, as it is part of our mission and obligation to disseminate knowledge and educate students. A short delay in publication for Intellectual Property protection, coordination with other publishers, or other good reason may be allowed.

**Sponsor:** The organization that funds a sponsored program received by the institution

**Sponsored Program:** A Grant, Contract or other Agreement awarded to accomplish a specific goal or project.

**Tangible Research Property:** Products of research that include, but are not limited to, compositions, biologics, materials, illustrations and drawings, prototypes, devices, and equipment.

**Trade Secret:** Information, including a formula, pattern, compilation, program device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

**University Member:** All VCU full-and part-time faculty, classified employees, administrative staff, paid student assistants, students, volunteers, fellows and trainees, visiting faculty and researchers, and those employees and visitors covered by sponsored program Agreements or other contractual arrangements are considered University Members for purposes of this Policy, and are subject to its terms.

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## **PRINCIPLES**

### **Diversity in the VCU Externally Supported Research Portfolio**

VCU encourages the development of relationships with government, industry, and not-for-profit organizations that enhance its research productivity, provide financial sustainability, and support its mission. VCU vigorously supports a comprehensive range of sponsored programs consistent with its mission of “[e]xpanding the boundaries of knowledge and understanding through research, scholarship and creative expression in the sciences, arts, humanities and professional disciplines.” (<http://www.vcu.edu/quality/mission.html>)

### **Compatibility with VCU’s Mission**

Corporate-sponsored research must be consistent with VCU’s [comprehensive mission](#), which bridges learning, teaching, research, creative expression, and public service. The University is committed to each of these areas, supported by specific goals and sustained by established core values.

Additionally, as a public institution and in stewardship of our resources, corporate sponsored research should be aimed at promoting the health and welfare of people and their communities, and/or providing meaningful public benefit through research outcomes, research training, or other benefits to the institution, faculty, students, and/or community.

Potential conflicts in commitment posed by corporate-sponsored research will be considered as part of the corporate-sponsored research review process.

### **Academic Freedom**

Corporate-sponsored Agreements must conform to VCU policies on conflicts of interest and academic freedom of the investigator. They must recognize and accommodate VCU's academic autonomy and integrity, financial commitments, reputation, and public trust.

### **Investigator Autonomy**

VCU affirms the right of faculty to undertake research with Corporate Sponsors, as long as the research is consistent with the mission of VCU and the research agreement conforms to the policies and procedures of the institution. No investigator shall be required to participate in corporate-sponsored research. Principal Investigators are free to accept or reject any Agreement from industry. If an Agreement is accepted, it must support the mission of VCU and conform to all other policies and procedures of the institution.

### **Intellectual Property**

Intellectual Property created solely by VCU Members during the conduct of corporate-sponsored research is the property of the institution. The financial proceeds resulting from commercialization of such VCU-created Intellectual Property shall be equitably distributed between the inventor and the institution according to institutional Intellectual Property policy.

### **Publication**

VCU affirms the right of investigators, faculty, students, and trainees to publish results of their research in a timely manner without constraint or interference from any party.

### **Trainee Research**

VCU recognizes that the involvement of students and/or trainees in corporate-sponsored research may be appropriate and supports the instructional mission of the university.

### **Responsible Conduct of Research**

Established principles and procedures related to ethics and scientific integrity of research apply to all corporate-sponsored research activity.

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## **POLICY**

### **Administration and Signature Authority**

Agreements for corporate-sponsored research are negotiated and administered by the Office of Sponsored Programs in the Office of Research. The designated signatory for



corporate-sponsored research Agreements is the Assistant Vice President for Research Administration.

### **Non-Disclosure and Confidentiality**

When Corporate Sponsors collaborate with public research universities to conduct innovative research through sponsored research Agreements, they usually require strict confidentiality from their academic collaborators in order to protect sensitive information that, if revealed, could put sponsors at a competitive disadvantage. However, this is often contrary to the interests of university researchers who want to advance science and benefit from these relationships. Thus, compromises have to be established that balance the university's need to disseminate knowledge and advance science with the sponsor's need to protect sensitive corporate information. Sponsored research activities may require access to information that is proprietary or might otherwise be considered by the sponsor or the principal investigator to be privileged and confidential. Related VCU requirements for handling non-disclosure and confidentiality in corporate-sponsored research include:

- Proprietary or confidential information must be appropriately marked and identified by the discloser when information is exchanged between the parties. If these criteria are met, such information may be received and maintained under a promise of confidentiality for a period of time, generally not to exceed five (5) years. This time period must be agreed upon by both the sponsor and the principal investigator.
- Periods of time during which confidentiality must be maintained that are greater than five (5) but less than seven (7) years must be approved by the Vice President for Research.
- Periods longer than seven (7) years in duration must be reviewed by the Research Development Advisory Council, whose recommendations will be provided to the Vice President for Research for final dispensation.
- As a public institution subject to the Virginia Freedom of Information Act, a confidentiality clause requiring that the Agreement, its existence, and/or its terms be kept confidential cannot be accepted by VCU.
- VCU will not accept Trade Secrets.
- The title of the study and the entity supporting the research must be publicly available on the VCU Office of Research web site.

### **Intellectual Property (IP) and Data Ownership**

VCU policies and practices related to identification, protection and ownership of Intellectual Property and Data are sufficient to protect the interests and values of VCU

in the conduct of corporate-sponsored research. At the same time, the policies and practices allow the University sufficient latitude to negotiate specific terms and conditions in individual Agreements to accommodate the legitimate ownership claims of the other parties to such Agreements.

In cases where Intellectual Property or Data are provided to the Principal Investigator by the Sponsor and specifically identified as such, they remain the property of the Sponsor. If there is any expectation by either party that Intellectual Property may be created jointly between a VCU Member and a Sponsor during the course of corporate-sponsored research, an appropriate clause reflecting this should be negotiated at the beginning of the work and included as part of the research Agreement.

### **Publication Rights**

University Members must be free to share, publish, or publicly present their research results. This freedom is essential if universities are to remain a source of new knowledge for society. Corporate-funded research Agreements with VCU must explicitly provide for the open communication of research results, and not be subject to the Sponsor's permission for publication. At the same time, good business practice requires that Sponsors protect their proprietary rights or other confidential information. VCU should allow a Corporate Sponsor to review research materials prior to publication in those cases where proprietary right may be involved or where the university has been provided a Sponsor's proprietary information.

- Any reviews by Corporate Sponsors must not delay submission for publication for more than thirty (30) days.
- If a Patent application must be filed, submission for publication may be delayed no more than an additional 30 days.
- The Vice President for Research may increase either of these delay periods for an additional 30 days. However, pre-publication corporate review of research should not exceed a total of 90 days.
- Pre-publication corporate review of research exceeding 90 days must be reviewed by the Research Development Advisory Council, whose recommendations will be provided to the Vice President for Research for final decision.
- Clinical Trial Agreements, especially multi-site Clinical Trial Agreements, may include publication delays not to exceed 18 months to permit data coordination among the multiple sites.

### **Research Agreement Mechanisms**

Appropriate mechanisms for corporate sponsored research are Contracts, Grants, Non-Disclosure Agreements, Clinical Trial Agreements, and Material Transfer Agreements.

## **Cost Recovery**

All corporate-sponsored research must recover the full costs (direct and facilities and administrative costs) of the project.

## **Ethical Issues**

### **Conflict of Interest Considerations**

Virginia Commonwealth University affirms that it operates under the aegis of state and federal law and institutional policy related to the identification, disclosure and management of conflict of interest issues. VCU requires strict adherence to these established policies in the proposing, performing, reviewing, and reporting of research.

### **Conflict of Commitment, Transparency, and Referral**

VCU asserts that every researcher is responsible for assessing the merits of his/her research and that deans and chairs are also responsible for reviewing the integrity of their faculties' research.

If any University Member believes that any proposed corporate-sponsored research Agreement has the potential to be in conflict with the mission and goals of the university or otherwise potentially negatively impact the university, he or she should submit a letter of concern to the research officer (e.g., research dean or similar office) of the respective school. The appointed research officer may request to have that potential project reviewed by the Vice President for Research and/or the ReDAC. Alternatively, University Members may contact the [Faculty/Staff Ombudsperson](#) and/or utilize the [VCU Ethics Helpline](#).

## **PROCEDURE**

The Office of Sponsored Programs will review and negotiate corporate sponsored research Agreements to ensure compliance with this policy.

The ReDAC will review corporate research Agreements that fall outside the norms in this policy and provide its recommendations to the Vice President for Research. The ReDAC has the right and responsibility to recruit and engage faculty experts in any review deliberations that fall outside the norms of this policy. The ReDAC will report to Faculty Senate on a regular basis concerning such review activities and decisions.

The Vice President for Research shall consider ReDAC recommendations but will make the final decision on acceptance or rejection of corporate-sponsored Agreements.

## **Responsible Conduct in Research and Scholarship Policy**

**Responsible Office:**  
Office of Research

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### POLICY STATEMENT AND PURPOSE

To articulate University requirements and guidance which apply to responsible conduct in research and scholarly activities.

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### WHO SHOULD READ THIS POLICY

All University Members who are engaged in research or the supervision of others engaged in research should read and comply with this policy.

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### RELATED DOCUMENTS

#### [VCU Code of Ethics](#)

Intellectual Property Policy (*link pending*)

[Policies and Procedures for Misconduct in Research and Scholarly Activities Policy](#)

Research Data Ownership, Retention, and Access (*link pending*)

[Outside Professional Activity and Employment, Research, and Continuing Education](#)

Researcher Conflict of Interest Policy (*link pending*)

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### CONTACTS

[VCU Office of Research](#) officially interprets this policy and will prepare revisions, as needed, to meet the changing needs of Virginia Commonwealth University. All revisions shall be subject to University Board of Visitors approval following review by university leadership (Vice Presidents, Council of Deans, University Council, and Faculty Senate).

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## DEFINITIONS

### **Misconduct in Research and or Scholarly Activities**

Misconduct in research and scholarly activities means fabrication, falsification, plagiarism or other similar activity in proposing, performing, or reviewing research, or in reporting research and scholarly activity results.

1. Fabrication is making up data or results and recording or reporting them.
2. Falsification is manipulating research or scholarly activity materials, equipment, or processes, or changing or omitting data or results such that the research or scholarly activity is not accurately represented in the record.
3. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate attribution or credit.
4. Misconduct in research and scholarly activities does not include honest error or differences of opinion.

**Fiscal Administrator** The individual that works with the Principal Investigator to ensure that administrative and financial requirements of awards are met.

**Principal Investigator (PI):** a) The individual with final responsibility for the conduct of research or other activity described in a proposal or an award; b) the individual with fiduciary responsibility for an award's management. Usually these are the same individual. However, VCU has a requirement that the fiduciary responsibility vest in a VCU employee, so on occasion they may be different. A common example is that the recipient of a research fellowship is explicitly not an employee, so that person's major professor manages the award's account.

**University Member:** All VCU full- and part-time faculty, classified employees, administrative staff, paid student assistants, students, volunteers, fellows and trainees, visiting faculty and researchers, and those employees and visitors covered by sponsored program Agreements or other contractual arrangements are considered University Members for purposes of this Policy, and are subject to its terms.

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## PRINCIPLES

Virginia Commonwealth University is committed to fostering an environment of uncompromising integrity and ethical conduct. As such, all University Members are expected to adhere to the highest ethical standards of professional conduct and integrity. Our core values and principles include: respect, honesty, excellence, responsibility and accountability, stewardship, and compliance.

These core values provide an overarching framework that applies to the conduct of research and scholarly activities carried out by University Members. The responsible conduct of research at VCU is built on this foundation and specifically encompasses five areas: subject protection, research integrity, environmental and safety issues, fiscal accountability, and education.

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## POLICY

All University Members engaged in research or supervising research activities are obligated to uphold the highest standards in the responsible conduct of research by:

1. Ensuring research subject protection through:
  - a. Prior and ongoing institutional review and approval of all research involving animal or human subjects, and
  - b. The ethical conduct of research involving subjects, in compliance with federal and state laws and University policies and procedures.
2. Ensuring research integrity through:
  - a. Sound procedures for data collection, management, storage, sharing and ownership,
  - b. Proper authorship and publication practices,
  - c. Responsible mentoring of early stage researchers and of all research trainees, and
  - d. Clear guidelines in collaborative research, including the protection of intellectual property.
3. Ensuring environmental health and safety through:
  - a. Ensuring awareness and adequate training and
  - b. Compliance with federal and state laws and University policies and procedures.
4. Ensuring fiscal accountability through:
  - a. Effecting the proper and responsible use of research funds and

- b. Complying with federal, state, and University requirements for recognizing, declaring, and managing conflicts of interest.
- 5. Participating in educational opportunities that teach and foster the responsible conduct of research and promoting such education among all research trainees.

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## **Guidelines for Responsible Conduct in Research:**

### ***Overview***

The principles upon which Responsible Conduct of Research are based emanate from three sources.

- First, there are federal and state laws that govern responsible conduct such as those which relate to the protection of research subjects or the use of hazardous materials.
- Second, there are regulations or policies, typically published by funding agencies, which apply to such areas as data sharing and objectivity in research. Arguably, these have the force of law.
- Third, there are guidance documents, policies, and position papers that are produced and promoted by professional societies, organizations, and publishers of scholarly journals which can be used to inform researchers of established or emerging best practices.

Specific examples of entities in this latter category include the National Academy of Sciences, the American Association for the Advancement of Science, the Association of American Medical Colleges, the International Committee of Medical Journal Editors, The Council of Science Editors, and a number of discipline-specific scientific societies like the American Chemical Society, The American Psychological Association, and the Society for Neurosciences.

The VCU Responsible Conduct in Research and Scholarship Policy draws from all three of these sources. All University Members engaged in or supervising research are expected to understand and are required to comply with federal, state, and local laws pertaining to research. Compliance with relevant University policies, procedures, and guidelines is also required, as is compliance with policies from any source that is formally connected to research conduct. Finally, best practices from a variety of sources have helped provide a basis of prevailing accepted conduct. Against this backdrop, the Policy is implemented to provide University Members with important principles to guide their research conduct.

### **Research Subjects Protection**

The Institutional Review Board (IRB) at VCU is charged with reviewing all research protocols involving human research subjects to ensure compliance with federal, state,

and local regulations. The VCU IRB must review and approve all activities that meet applicable definitions pertaining to the terms ‘human subjects’ and ‘research,’ before research may begin. Specialized training is required for University Members conducting research involving human subjects.

Federal regulations for human subjects research are based in three overarching ethical principles, also known as the Belmont Principles. These are:

1. *Respect for Persons* – respecting the autonomy of individuals to make their own decisions and protecting individuals with diminished autonomy.
2. *Beneficence* – protecting research participants from risk of harm while optimizing possible benefits of the research.
3. *Justice* – fairly distributing the benefits and burdens of research.

The VCU IRB subscribes to these basic ethical principles of the Belmont Report in the review of all research activities, including informed consent, risk/benefit analysis and the selection of subjects for research.

The Institutional Animal Care and Use Committee (IACUC) at VCU is charged with reviewing all research protocols involving the use of animals to ensure compliance with federal and other relevant laws. Such protocols must be reviewed and approved by the IACUC before the research may begin.

Public and scientific concern continues to shape the laws that regulate the humane care and use of *animals* in research, testing, and instruction. These laws have changed and updated over the years as public attitudes and awareness have matured. VCU employs the following ethical mandates, known as “The Three Rs” of animal research:

1. *Reduction* - required proof that the number of animals is reduced to the smallest number possible (respecting the value of each life);
2. *Replacement* - required proof that a non-animal model is not available and/or that the species identified is justified (replacing animal use where feasible); and,
3. *Refinement* - required proof that all procedures ensure the highest quality of compassionate care and comfort (applying standards developed to ensure quality of life through the minimization of risk and discomfort, adequacy of housing, and advanced veterinary medicine).

Before engaging in research involving human or animal subjects, VCU investigators, staff, and trainees must successfully complete relevant online training, and must comply with requirements for ongoing refresher training to maintain their certification. The Education web pages for both the IRB and IACUC provide current educational requirements:

- For human subjects: <http://www.research.vcu.edu/irb/citi.htm>
- For animal subjects: <https://www.vcu.edu/research/iacuc/education.htm>



## **Research Integrity**

**Data Collection and Management:** At the outset of any research project all participants are expected to discuss and agree upon data management and access and retention procedures including procedures for having participants join or leave the project. Privacy of collected data and rights to intellectual property must be protected. Student rights to data are expected to be clearly specified.

All documentation necessary to reconstruct investigations is expected to be available and data is to be recorded in a timely and consistent manner.

Sharing of published data with other researchers upon request is expected of authors. Authors should comply with requests for published data. Such requests should be honored in a timely fashion, at reasonable cost to the researcher making the request, and for noncommercial purposes. Requests connected to commercial purposes (e.g., from a corporate entity) can be honored under the auspices of a Material Transfer Agreement in order to protect the intellectual property rights of the Principal Investigator and the institution. Additional university guidance and policy on data sharing is available in the VCU Policy on Data Ownership, Retention and Access.

Research record keeping varies depending on the discipline, but VCU holds the following principles as essential to the responsible acquisition and maintenance of research data.

- The Principal Investigator is responsible for defining the record keeping requirements of his or her group. This includes the type of data book to be used, requirements and details of record keeping, both in data books and electronically if appropriate. These requirements should be in keeping with best practices of the researcher's discipline.
- Each member of the research team (e.g., faculty, trainee, or technician) should maintain a data book compliant with these standards and the data book must be freely available to the Principal Investigator for purposes of review, analysis, and use of data to prepare reports of any type.
- The decision to publish data is the responsibility of the Principal Investigator.
- Data books, other research data, and all supporting materials derived from the research belong to Virginia Commonwealth University as prescribed in the VCU Policy on Data Ownership, Retention and Access. The Principal Investigator serves as the steward for the University in the process. Should the Principal Investigator leave the institution, transfer of data may be arranged in keeping with the VCU Policy on Data Ownership, Retention and Access.

Principal Investigators, departments or schools within VCU are encouraged to develop guidance documents on proper maintenance of research notebooks. Specific guidance

for research recordkeeping may be found on the web page of the VCU Tech Transfer Office ([http://www.research.vcu.edu/ott/inventors\\_creators.htm](http://www.research.vcu.edu/ott/inventors_creators.htm))

**Authorship and Publication Practices:** The publication of results is an essential component of the research process. It disseminates new knowledge, an expectation that is inherent to sponsored research. It creates a basis of assigning credit to the authors, thus providing support for seeking professional advancement or completing training requirements. It establishes scientific priority with implications for credit for discovery or for intellectual property protection. Finally, publication allows others to assess, correct, or build on the authors' results and this is crucial to scientific progress.

Authorship requirements frequently are defined by publishers, scientific societies, and organizations with a vested interest in scientific publication. In the biomedical and life sciences, the most comprehensive description of publication requirements has been promulgated by the International Committee of Medical Journal Editors (ICMJE). The credibility of these requirements is strengthened by their frequent updating and by the fact that several hundred journals either use them in whole or in part. Many publication practices embraced by the ICMJE guidelines may be found in the instructions to authors of diverse scholarly journals and in the guidelines published by professional societies ranging from the American Sociological Association, to the Society for Neurosciences, to the American Society for Civil Engineering. In keeping with the guidance offered by all of the above and related sources, Virginia Commonwealth University offers the following consensus guidance for authorship.

1. Authorship is a privilege that is based upon fulfillment of three separate conditions:
  - a. making a significant contribution to the conceptualization, design, execution, or analysis and interpretation of the research;
  - b. contributing to the writing of the paper or to critically revising it for intellectual content; and,
  - c. approving the submitted version of the manuscript.
2. All authors must be able to take public responsibility for their contribution to the work.
3. Deliberate omission of a qualified author (ghost authorship) or inclusion of a person as an author who does not qualify for authorship (guest authorship) is inappropriate.
4. In the absence of 1-3 above, activities that constitute insufficient grounds for authorship include: acquisition and provision of funding, provision of space or equipment, involvement in patient care or providing patient samples, routine technical work, copy editing, and general supervision of the research group.
5. Where permissible, use of the contributorship model is recommended wherein the contributions of each of the paper's co-authors are briefly listed in a footnote or in the acknowledgements section of the paper.

6. Similarly, use of the guarantor model is encouraged wherein at least one author takes full responsibility for the content of the paper.
7. Authors are urged to publish their original research results in the peer-reviewed literature.
8. Duplicate publication is inappropriate as is the publication of unduly fragmented research reports.
9. Full disclosure of financial conflicts of interest must be made to editors, and as appropriate, included in the published paper.
10. Clinical trials must be registered at <http://clinicaltrials.gov/> prior to enrolling any patients in the research. Failure to comply with this will jeopardize being able to publish results of the work in a large number of scientific journals.
11. Authors who publish the results of research supported by grants from the National Institutes of Health (NIH) are required to make such publications available on the National Library of Medicine's PubMed Central in keeping with NIH policy (<http://www.pubmedcentral.nih.gov/>).

VCU encourages its researchers to engage in scientific peer review. Peer review is essential to the conduct of science. Peer review includes the critique of submitted manuscripts for publication as well as the critique of grant proposals being considered for funding. In both cases individuals may participate in this process as part of a formal structure (editorial board or proposal review panel) or as an ad-hoc referee. In either case the responsibilities of peer reviews are the same. Reviewers must be expertly qualified in the subject matter of the manuscript or proposal. In so doing, individuals must avoid any real or perceived conflict of interest that might result from financial considerations or collaboration or a close relationship with the authors or proposal investigator. Disclosure of conflicts is the responsibility of the peer reviewer who must recuse him or herself from the review. The peer review process must be focused on the available submitted information and/or on material in the public domain. Information that is not publicly available should not be used to influence the peer review process. Finally, material under peer review is privileged information. It may not be shared, copied, distributed, or retained by the peer reviewer without appropriate permission from those managing the peer review process.

**Mentoring:** The mentor-protégé relationship is essential to the training and professional socialization of scholars and researchers. This relationship is complex and involves more than just supervision of the novice by an experienced investigator. Rather it is a process characterized by personalized teaching, training, and interactive evaluation. Over time, successful mentoring yields a protégé who becomes increasingly skilled and independent in the conduct of research. In the academic setting, protégés may be trainees like graduate students or postdoctoral scholars, or they may be faculty investigators who are beginning or restarting their research careers.

At VCU, the responsibilities and duties of both mentors and protégés are addressed in three separate resources:

- The School of Medicine's Faculty Mentoring Guide (<http://www.med.vcu.edu/facultyaffairs/facdec/facultymentoring.html>)
- The Graduate School's Handbook which contains a chapter on graduate student mentoring (<http://www.graduate.vcu.edu/programs/mentor.html>)
- The "Responsibilities of Postdoctoral Scholars and Mentors" section of the VCU's Postdoctoral Policies (<http://www.research.vcu.edu/vpr/postdoc/policies.htm#scholar>)

Trainees and faculty should use these resources as guidelines. These resources review the foundational basis of the mentor-protégé relationship broadly covering the primary responsibilities of orientation, education, and evaluation. Both the Graduate School Handbook and the Postdoctoral Policy enumerate expectations in terms of the responsibilities of trainees, and also the responsibilities of mentors. In summary, these resources articulate the core values and standards that undergird mentoring in research and scholarly training at VCU.

There are a number of resources created by various organizations and societies that may also prove useful to mentors and protégés. These may be used on an individual, department, or school basis to augment the VCU guidance materials cited above. Most notable in this regard are two Compacts available from the Association of American Medical Colleges.

- Compact Between Biomedical Graduate Students and their Research Advisors (<http://www.aamc.org/research/gradcompact/start.htm>)
- Compact Between Postdoctoral Appointees and their Mentors (<http://www.aamc.org/research/postdoccompact/start.htm>)

Both of these compacts offer a broad set of guidelines for promoting appropriate mentoring relationships at both the graduate and postdoctoral trainee level. Although, they were developed specifically for use by mentors and trainees in the medical and biomedical sciences, they offer guidance that is broadly applicable across many disciplines in the sciences and engineering.

**Collaborations:** Collaboration has long been an important driving force in research. The growth of interdisciplinary approaches and powerful specialized technologies has dramatically elevated the need and importance of collaborative research. Collaborations often allow researchers to ask and answer novel questions about complex problems which are not possible to address by other means. However, the increase of interdisciplinary collaborative research has created some challenges. Recognizing, understanding, and dealing with such challenges and related issues will help ensure responsible, effective, and productive research collaborations. Guidance for University Members considering or engaged in research collaboration includes the following.

1. Collaborations must involve strong resolve and commitment on the part of all participating researchers. They should be carefully considered and not entered into lightly.
2. Defining the means and ground rules for communication is essential. Effective communication among participating researchers must prevail throughout the collaborative relationship.
3. Roles and responsibilities of collaborators should be defined and their expected contributions anticipated at the beginning of the relationship. Investigators should acknowledge that research progress may require modification of such plans and this should be addressed in a timely manner.
4. Collaborators should develop a timeline for the work, which includes the terms of when the collaboration will end.
5. Ground rules dealing with the operation of the collaboration should be openly discussed and agreed upon at the outset. These include: authorship and publication issues, intellectual property ownership and protection, data sharing, and regulatory compliance.

### **Environmental Health and Safety**

The VCU Office of Environmental Health and Safety (OEHS) is charged with development and compliance oversight of workplace standards for environmental health and safety. OEHS also provides relevant educational programs and materials.

OEHS specifically assists Researchers and manages those aspects of university research which are essential for continued compliance with requirements from governmental regulators, grantors, and credentialing agencies. The Chemical and Biological Safety Section (CBSS) and Biological Safety Office provide mandatory laboratory safety training, resources, additional services, and review and approval procedures for researchers at the University.

Additional research areas overseen by the CBSS and Biological Safety Office range from Worker's Right to Know requirements and personal protective equipment assessments, to environmental permitting standards and hazardous waste disposal procedures. In the area of laboratory safety, requirements exist for a Laboratory Safety Program, an Annual Laboratory Safety Evaluation, Laboratory Signage, Emergency Notification Procedures, Biological Safety Cabinet Inspections, the shipment of dangerous goods, and needle recapping. A complete overview of the Office's activities is found at: <http://www.vcu.edu/oehs/>.

University Members are required to be in compliance with all necessary health and safety requirements connected to their research programs. Further they must complete OEHS-offered training in areas relevant to their research. Principal Investigators are responsible for ensuring that all members of their groups (trainees, staff, visiting scientists, etc.) are made aware of research-related health and safety requirements and that compliance is met. Principal Investigators are responsible for

ensuring that their research group members complete necessary training in health and safety-related topics.

### **Fiscal Accountability**

**Fiscal Responsibilities:** Members of the University community must not accept money for research or gifts on behalf of the University or as part of their University activities except as prescribed by University policy. All funds provided for research are expected to be spent in ways consistent with the funding documents and in compliance with the guidelines on allowable costs. The University has the obligation to provide up-to-date records of financial transactions. Individuals in charge of budgets have an obligation to monitor records of expenditures for compliance with University policies and procedures and to allow these records to be viewed by appropriate parties. Departmental files are the property of the University. All Principal Investigators and Fiscal Administrators must successfully complete the online training module, *Sponsored Projects Training*, available on the University BlackBoard web site.

**Conflicts of Interest:** Conflicts of interest exist in many forms and are inherent to the nature of the research enterprise. A conflict of interests comprises a situation in which there is discord between a primary duty and secondary interests. While interests can be either financial or non-financial, they can lead to bias in the conduct and/or interpretation of research, and they can have an impact on the safety of human or animal research subjects. Often financial conflicts of interests will simply create the appearance of compromising an investigator's professional judgment in conducting or reporting research. Such appearance may give rise to the perception that a conflict exists and this must be addressed. Investigators and participants in the research enterprise must be able to recognize real or perceived conflicts and report them as required by Virginia Commonwealth University. , Conflicts of interest must be managed in keeping with recommendations of the Conflict of Interest Committee.

It is the policy of the University that researchers at VCU are expected to avoid conflicts of interests that appear to directly and significantly (1) compromise objectivity in carrying out University research responsibilities; (2) affect the University's interests; or (3) otherwise compromise the performance of University responsibilities, unless such conflicts are managed, reduced or eliminated in accordance with this Policy. University Members engaged in research are required to be aware of, understand, and comply with the *VCU Researcher Conflict of Interest Policy*. Principal Investigators are responsible for ensuring that all members of their research team are made aware of these requirements.

### ***Educational Opportunities at VCU Dealing with the Responsible Conduct of Research***

VCU offers multiple educational opportunities that serve to promote the responsible conduct of research (RCR) among its University Members. Formal courses are:

- **MICR510:** Scientific Integrity (1 credit; fall semester).
- **CCTR690:** Research Seminars in Clinical and Translational Sciences: Responsible Conduct of Research. (1 credit; any semester depending on need).

Both of these courses cover the core topics areas in RCR including authorship and publication practices, mentoring, recordkeeping and data management, subjects protection, collaborative research, and conflict of interests. Both courses involve face-to-face, student-driven case discussions in all of these topic areas and students must complete a writing assignment. MICR510 is a classroom based course. CCTR690 is comprised of on-line instruction and classroom-based case discussions. Both of these courses are open to all University Members involved in research.

In addition to formal courses, VCU offers regular RCR educational workshops that are comprised of half-day didactic and case study sessions coupled to on-line training exercises. These workshops cover all of the above-cited RCR topic areas. This workshop training is required of all postdoctoral fellows and postdoctoral scholars at VCU.

Instruction in the responsible conduct of research is required of certain University Members. Included in this category are pre- and postdoctoral trainees support by NIH training grants (T32 and R25 awards), or those supported by NIH Fellowship Awards (F31 or F32 awards) and any University Members supported by certain types of NIH career (K awards) grants. The National Science Foundation (NSF) mandates that undergraduate students, graduate students, and postdoctoral researchers participating in NSF-funded research receive appropriate training and oversight in the responsible and ethical conduct of research. Some departments and interdisciplinary programs at VCU also have an RCR educational requirement for their graduate trainees.

It is the responsibility of VCU Principal Investigators and K-award mentors to be aware of educational requirements for trainees and awardees and to ensure that such requirements are successfully met in a timely fashion. Regardless of formal requirements, VCU principal investigators and academic leaders should promote the responsible conduct of research by urging general participation in educational offerings and other appropriate instructional modalities.

VCU maintains a web page of resources that deal with a variety of issues related to the responsible conduct of research. University Members should use those resources on a regular basis. The site may be accessed at: <http://www.courses.vcu.edu/rcr/>.

In addition to RCR programs, there are a variety of topical educational opportunities in areas related to research integrity, including: research ethics, subjects protection, occupational health and safety, and fiscal responsibility. Such seminars and workshops are listed on the [Office of Research Events Calendar](#).

## **Disclosure**



This policy was inspired by and sometimes draws specific content from a variety of writings including, texts, extant policies, and guidance documents. Some content printed here includes paraphrased material or small verbatim passages taken from those works. Resources used are listed as follows:

- Macrina, F.L. 2005. *Scientific Integrity- Text and Cases in Responsible Conduct of Research* 3<sup>rd</sup> edition. ASM Press, Washington, DC
- *Dynamic Issues in Scientific Integrity: Collaborative Research* (1995) American Academy of Microbiology. Washington, DC  
[http://academy.asm.org/index.php?option=com\\_content&task=view&id=153&Itemid=66](http://academy.asm.org/index.php?option=com_content&task=view&id=153&Itemid=66)
- NIH Standards of conduct policy  
<http://www.training.nih.gov/handbook/research.html>
- NIH Objectivity in research policy. 2003.  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-026.html>
- *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*. 2008. International Committee of Medical Journal Editors. <http://www.icmje.org/>



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## POLICY STATEMENT AND PURPOSE

This document establishes a policy for Virginia Commonwealth University (the University) with respect to Intellectual Property developed by members of the University community.

The University shall retain all rights, title, and interest in any and all Intellectual Property generated, created, or developed in facilities operated or controlled by the University, supported by funds administered by the University, and/or performed in the course of regular duties by University Members, unless exempted by other provisions of this policy.

The Vice President for Research shall have the right to exercise broad discretion necessary for the encouragement, development, and protection of inventions, patents, and other Intellectual Property. The Vice President for Research shall consult with the Intellectual Property Ownership Committee, the Office of Technology Transfer and the Intellectual Property Foundation in matters requiring the exercise of broad discretion.

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## WHO SHOULD READ THIS POLICY

This Policy shall apply to all University Members, and all University Members should read this policy.

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## RELATED DOCUMENTS

[Policy on Research Data Ownership, Retention and Access](#)

Policy on Corporate Sponsored Research

Office of Research Conflict of Interests Policy

Conflict of Interest Policy for the Commonwealth of Virginia

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## CONTACTS

VCU Office of Research officially interprets this policy and shall revise or eliminate any or all parts as necessary to meet the changing needs of Virginia Commonwealth University. Please direct policy questions to [VCU Office of Research](#). Revisions to this policy are subject to University Board of Visitors approval.

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## DEFINITIONS

|                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Assigned Duty                     | Assigned duty is narrower than “scope of employment” and is a task or undertaking resulting from a specific request or direction. The general obligation for faculty to engage in research, scholarship, and teaching is not an assigned duty nor does it result in works “made for hire”. A specific request or direction to prepare a particular article, laboratory manual, computer program, etc., is an assigned duty. If an employee’s written job description specifies duties which result in the creation of Intellectual Property, the Intellectual Property is considered “work-for-hire”. |
| Author                            | One or more University Member(s) who create a Copyrighted Work.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Assignment                        | The document executed by inventors which confers legal transfer of title and interest from one party to another, for example from Inventor(s) to Virginia Commonwealth University.                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Board of Directors (the Board)    | The Board which supervises the affairs of the Virginia Commonwealth University Intellectual Property Foundation, and advises the Vice President for Research and the President.                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Contributor(s) (VCU Contributors) | The university members listed on the invention disclosure for the purpose of revenue distribution. The inventors on a patent application may differ from the list of the contributors and will be determined according to the U.S. patent law.                                                                                                                                                                                                                                                                                                                                                        |
| Copyrighted Work                  | An original work of authorship (i.e., writing, work of art, work of music, computer program, etc.) for which property rights are protected under copyright legislation.                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Creator                           | One or more inventor(s) in the context of inventions protectable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

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|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                 | by patent or the author(s) in the context of Copyrighted Work.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Intellectual Property Foundation<br>(the Foundation or VCU-IPF) | The Intellectual Property Foundation of Virginia Commonwealth University (VCU-IPF), a nonprofit organization contracted by the University to commercialize Intellectual Property created at, and solely for the benefit of, Virginia Commonwealth University.                                                                                                                                                                                                                                                                                                                                                                                |
| Intellectual Property                                           | Anything developed by anyone covered by this policy that falls under, but is not limited to, one or more of the following categories:<br>a) an Invention<br>b) an issued patent<br>c) a Copyrighted Work<br>d) a legal right inherent in a patent, copyright, trademark<br>e) know-how or trade secrets, or<br>f) tangible research property; including, but are not limited to, compositions, biologicals, materials, illustrations and drawings, prototypes, devices, and equipment.                                                                                                                                                       |
| Intellectual Property Ownership Committee (IPOC)                | The IPOC is a standing committee established by the Vice President of Research consisting of 6 faculty members recommended to the Provost by the Faculty Senate, 1 staff member appointed by the Staff Senate, and 1 student recommended by the Dean of the School of Graduate Studies, 1 administrator appointed by the Vice President, Office of Research, in addition to the Director of the Office of Technology Transfer who shall serve in ex officio, non-voting capacity. IPOC shall assist the Vice President of Research and the Office of Technology Transfer in dispute resolution regarding ownership of Intellectual Property. |
| Invention                                                       | An invention may take the form of a new machine, article of manufacture, composition of matter, process, or useful improvement to any of these. Inventions also include novel combinations of prior art. In order for an invention to be patentable, it must be novel, non-obvious and useful.                                                                                                                                                                                                                                                                                                                                               |
| Invention Disclosure                                            | The document by which one party reports a creation of Intellectual Property to another, for example, University Members report an invention to Virginia Commonwealth University or to a sponsor.                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Inventor                                                        | One or more University Member(s) who create an Invention.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Material Transfer Agreement (MTA)                               | A contract to provide or receive material, which will restrict the material's use, and therefore, liability associated with its use,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

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|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                        | and may contain language concerning rights to inventions made while using the material.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Office of Technology Transfer                                          | The university office responsible for: 1) educating University Members about Intellectual Property, 2) encouraging University Members to timely disclose and protect Intellectual Property, 3) processing Invention Disclosures and determining ownership, 4) overseeing assignment of Intellectual Property to the University, and, 5) processing MTAs and NDAs.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Nondisclosure Agreement (NDA)                                          | A contract that states the terms and conditions for sharing of confidential information between the University and an outside organization.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Royalties                                                              | Anything of value received by the University, including cash payments as well as the market value of any property or services received, in consideration for a transfer of rights and/or title to Intellectual Property in which the University claims an interest. Funds received by the University to support research that results in the development of Intellectual Property is not royalty income.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Significant Use of University Resources (applies to Copyrighted Works) | What constitutes significant use of University resources is a question that must be answered on the basis of the facts and circumstances of each case. A University-wide formula to define <b>significant use</b> is inappropriate because of the different needs among various disciplines. Customary and normal usage of University facilities; such as telecommunications systems (telephone and internet access), web and file servers, course management software (e.g. Blackboard), library resources, secretarial help, office equipment, or other support services, do not constitute a significant use. When questions arise, creators may seek a written opinion from the department chair or program head, before or after a project, and if there is a disagreement, may appeal to the Vice President for Research or his/her designee ( <i>please see the dispute procedure below</i> ). |
| University Member                                                      | All VCU full-and part-time faculty, classified employees, administrative staff, paid student assistants, students, volunteers, fellows and trainees, visiting faculty and researchers, and those employees and visitors covered by sponsored program agreements or other contractual arrangements are considered University Members for purposes of this Policy, and are subject to its terms.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| VCU Tech Transfer                                                      | VCU Tech Transfer consists of two entities: Office of Technology Transfer, a part of the VCU Office of Research and VCU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

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|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                             | Intellectual Property Foundation (VCU-IPF).                                                                                                                                                                                                                                                                                    |
| Vice President for Research | For purposes of this policy, Vice President for Research shall mean the Vice President for Research, or his/her designee, such as the Director of the Office of Technology Transfer. If a designee is appointed by the Vice President for Research, the appointment and the revocation of said appointment must be in writing. |

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## PROCEDURES

### Ownership of Intellectual Property

The University claims an interest in Intellectual Property when it asserts a right in that property under its Intellectual Properties Policy. The University may choose not to claim an interest in some forms of Intellectual Property, even though legally it may be able to assert ownership.

This Policy should apply without limitations to all persons (paid or unpaid) using the University resources and/or facilities or working under the supervision of the University personnel, including visiting and adjunct faculty and researchers, undergraduate and graduate students.

The University recognizes the traditional distinction between Intellectual Property subject to copyright and that subject to patent protection. In higher education, the right of faculty and others to create and produce Copyrighted Works and to receive royalties generated from their use has long been recognized. This policy reaffirms that distinction.

#### *Inventions*

The ownership of novel results of research developed by University Members, using University resources and/or facilities (including but not limited to: use of equipment, laboratory space, university time of University Members, funds administered by the University including funds from sponsored research or gifts, etc.) vests in the University.

#### *Copyrighted Works*

##### 1. Copyrighted Works owned by University Members

University Members shall retain all rights relating to publication, preparation of derivative works, distribution, and classroom use of works which they have prepared **on their own initiative**, including both papers published in scholarly journals or books, theses, and dissertations, provided the University does not

possess rights of ownership as described below. In the publication of scholarly work, University Members, where possible, should consider retaining copyright for non-commercial use. Ownership of course-related materials remains the same whether the material is presented in traditional classroom or in electronic form.

## 2. Copyrighted Works owned by the University

Even though the ownership of the copyright interest in a work vests in the author of that work, the Copyright Act of 1976 provides that when a Copyrighted Work is produced by one person who has been employed by another for that purpose, the employer is considered the owner of the property. For purposes of this policy, the University shall own the entire right, title, and interest in all materials subject to copyright when required by law or contract or when the University Member:

- a) creates the material as an assigned duty; and/or
- b) makes Significant Use of University Resources in their creation.

In the event that a faculty member terminates employment with the University with less than 3 months notice, the University shall have a royalty-free, non-exclusive, course-specific, educational-use-only license to use course materials created and owned by the faculty member for a period not to exceed 6 months. Use beyond 6 months shall be subject to the approval of the Creator.

When Intellectual Property is created under an internal or external grant, contract, or other agreement approved by the University, the terms of which stipulate ownership of Intellectual Property, the terms of the agreement will prevail over conflicting terms of this Policy. If the University possesses rights of ownership, it will be the duty of the University Member to acknowledge University ownership and to execute the documents required to demonstrate University ownership. When there is a dispute between the University and Creator(s), or between Creators, over ownership of Intellectual Property, the dispute shall be resolved as per the Dispute Resolution section of this policy. Rights of ownership assigned to the University will be managed by the Foundation which shall be responsible for commercialization of University Intellectual Property.

### **Administration**

The University vests administrative authority over all matters of Intellectual Property in the Vice President for Research who may issue administrative procedures as are necessary or desirable for the implementation of this Policy. The Vice President for Research shall be responsible for ensuring that information relative to the existence and terms of the Policy be regularly disseminated or made available to University Members.

The Vice President for Research shall have final authority to act for the University in all matters involving Intellectual Property, including the making of contracts and the waiving, assigning, or transferring of University rights, consistent with law and University policy.

The Vice President for Research shall appoint a Director of the Office of Technology Transfer. The Director shall be responsible for:

- implementing this Policy,
- educating University Members about Intellectual Property and the technology transfer process; and,
- all matters involving Invention Disclosures, MTAs, NDAs, and waiving, assigning, or transferring University Intellectual Property rights.

The Director of the Office of Technology Transfer will also serve ex-officio as President of the VCU-Intellectual Property Foundation and will serve ex-officio in a non-voting capacity on the IPOC. The President of the Foundation will be responsible for all matters involving protection, marketing, and licensing of University owned Intellectual Property. A Foundation Board of Directors shall be responsible for monitoring all aspects of the business of the Foundation, including commercialization of University-owned Intellectual Property.

### **Procedures for Submitting Invention Disclosures**

In order to protect the rights of the creators and the University, **prior to public disclosure**, University Members are required to report all Intellectual Property in which the University may claim an interest (including explicitly all inventions and Copyrighted Works which are owned by the University in accordance with *Ownership of Intellectual Property* section above) to the Office of Technology Transfer using the appropriate Invention Disclosure form that may be downloaded from the VCU Tech Transfer web site. Failure to disclose Intellectual Property in a timely manner may result in loss of value of the Intellectual Property. University Members should address all questions regarding issues of Intellectual Property and public disclosure to the Director of VCU Tech Transfer.

Disclosure of any Intellectual Property to VCU Tech Transfer shall not be considered to be a public disclosure. University Members understand that information relating to Intellectual Property and commercialization may be confidential and that such information should not be publicly disclosed without first consulting with VCU Tech Transfer. The Invention Disclosure will:

- identify all Contributors,
- include sufficient information and supporting data describing the Intellectual Property,
- identify the source(s) of funding that supported the discovery; and,
- contain any other relevant information necessary for evaluation of the Intellectual Property.

When more than one individual has participated in the creation of the Intellectual Property, the invention disclosure should specify the percentage of relative contribution that each individual claims to have in its development. If the Contributors do not mutually agree on the relative percentage for each, the percentage contribution shall be considered equal for all Contributors.

If so requested, VCU Tech Transfer must notify the Contributor(s) in writing within 90 days of receipt of the completed invention disclosure whether or not the University claims an interest in the Intellectual Property. The deadline for this decision may be extended by mutual agreement between the Contributor(s) and VCU Tech Transfer.

If the University does not claim such an interest, the University will no longer have any responsibilities, ownership rights, or obligations pertaining to that Intellectual Property except the obligation of confidentiality of proprietary information.

If the University claims an interest and has elected to protect and commercialize Intellectual Property may later decide that it no longer wishes to pursue further development of the Intellectual Property, VCU Tech Transfer will notify the Contributors(s) and will execute the necessary documents assigning all rights to the appropriate party, usually the Creator(s). However, third parties may have certain rights in Intellectual Property developed under sponsored research or other contractual obligations that the University cannot waive. For Intellectual Property that is returned to the Creators, the University may claim a percentage of any future revenues from the commercialization of the Intellectual Property.

### **Protection and Commercialization**

To provide maximum benefit to the University, the public, and the Creators of Intellectual Property, the University will evaluate each Intellectual Property for potential commercial value, and where it is deemed appropriate, seek to protect and commercialize that Intellectual Property.

The University's Vice President for Research is charged with overseeing the protection and commercialization of Intellectual Property coming under the provisions of this Policy.

VCU Tech Transfer will determine promptly if a disclosed Intellectual Property is owned by the University or its Creator(s) and will determine after evaluation if a disclosed Intellectual Property should be protected, and if so, will initiate the appropriate action to secure protection in a timely manner. Reasonable commercial judgment will be used in determining the appropriateness and the methods of protection and commercialization.

To protect the rights of the Creators and the University, all details in the Intellectual Property disclosure will be maintained in confidence. Disclosures to outside parties will be through appropriate confidentiality (nondisclosure) agreements.

Public disclosure of details of invention disclosures prior to filing for patent protection may result in the immediate loss of legal protection and commercial value. Filing for patent protection may only occur after VCU Tech Transfer has evaluated an invention disclosure and has formally requested such protection. It is therefore important that Creators consult with VCU Tech Transfer prior to revealing novel and, therefore, perhaps patentable discoveries in scholarly publications, abstracts for presentation at conferences, seminars, thesis publications or posting on web pages.



To protect the rights of the author and the University, any Copyrighted Work should contain an appropriate copyright notice. VCU Tech Transfer will assist Creators in selecting the appropriate copyright notice.

When it is in the best interests of the University, the Vice President for Research, after consultation with the Office of Technology Transfer and the Foundation, may enter into agreements that relate to the assignment of rights and the division of royalties that differ from other provisions of this document.

### **Distribution of Income**

Revenues generated from the commercialization of the Intellectual Property will be distributed to the Contributors as indicated and agreed by them. In absence of an agreement between the Contributors, revenues will be distributed equally between all listed Contributors).

With the exception of other contractual arrangements, the University shall pay semi annually to the Contributor(s), or their heirs, successors, or assignees, fifty percent (50%) of the net royalties received by the University, subject to the following considerations:

- a) When the University through the Foundation assumes the cost of development and/or protection and commercialization of an Intellectual Property, sixty seven percent (67%) of the initial gross royalties received by the Foundation shall be applied to the reimbursement of direct costs and expenses incurred by the Foundation with respect to the Intellectual Property. The remaining thirty three percent (33%) will be treated as net royalties and distributed forty percent (40%) to the Contributor(s), forty percent (40%) to the Foundation, ten percent (10%) to the department(s) and ten percent (10%) to the school(s). After the direct costs and expenses incurred by the Foundation have been reimbursed, all subsequent income from that Intellectual Property shall be treated as net royalties, and divided forty percent (40%) to the Contributors(s), forty percent (40%) to the Foundation, ten percent (10%) to the department(s) and ten percent (10%) to the school(s).
- b) When the Foundation enters into an institutional agreement with an outside firm for the development of an Intellectual Property, the distribution of net royalties from this arrangement shall be divided forty percent (40%) to the Contributor(s), forty percent (40%) to the Foundation, ten percent (10%) to the department(s) and ten percent (10%) to the school(s), unless specified otherwise in the agreement.
- c) When the Creator(s) initiate and develop arrangements with a third party for Intellectual Property development, the distribution of royalties may be negotiated among the three principals, subject to existing law and policy.

Any net revenue received by the Foundation from the commercialization of University Intellectual Property as specified above shall be used for the exclusive benefit of Virginia Commonwealth University to:

- a) promote, encourage, and aid scientific investigation within the University, and
- b) protect, defend, market, and license and otherwise promote commercialization of University Intellectual Property.

### **Dispute Resolution**

If a dispute about the application of the Policy arises between a Creator and the University that cannot be resolved by the Officer of Technology Transfer, the dispute shall be presented to the Vice President for Research for informal mediation. If the mediation is not satisfactory to all parties to the dispute, any unsatisfied party may request a hearing before either the Intellectual Property Ownership Committee ("IPOC") if the issue relates to an ownership dispute, or before the Intellectual Property Foundation's Board of Directors ("the Board") if the issue relates to licensing or marketing of the Intellectual Property. The decisions made by the IPOC or the Board shall be final unless either party appeals in writing to the President of the University within 10 calendar days of receipt of the decision. Upon request for an appeal, the President shall review the record and render a decision. The President's decision shall be final and there shall be no further appeal within the University.

### **Amendment and Periodic Review of this Document**

In compliance with the over arching Policy on Policies, this policy shall be reviewed, and amended if appropriate, at least every five years, with the IPOC acting as the focal point for the review. Broad University input should be solicited as part of this review.

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## **POLICY STATEMENT AND PURPOSE**

The purpose of this Researcher Conflict of Interests Policy (hereinafter, the “Policy”) is to define the process for identifying, reporting, evaluating, and managing investigators’ financial relationships that have or may have an impact on the objectivity and integrity of research conducted at Virginia Commonwealth University

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## **WHO SHOULD READ THIS POLICY**

All University Members involved in the design, conduct, review, reporting, or supervision of research should read this Policy.

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## **RELATED DOCUMENTS**

[Objectivity in Research](#) – Public Health Service (PHS) Rules

[Conflict of Interest](#) – National Science Foundation (NSF) Rules

[21 CFR 54](#) – FDA regulation for Financial Disclosure by Clinical Investigators

[Virginia State and Local Government Conflict of Interests Act](#)

Institutional Conflict of Interests in Human Subjects Research (URL Pending)

[Conflict of Interests Policy](#) within the VCU Financial Policies

[Outside Professional Activity and Employment, Research, and Continuing Education Policies and Procedures for Misconduct in Research and Scholarly Activities](#)

VCU Institutional Review Board (IRB) [Written Policy and Procedure #VIII-10](#) *Evaluating Investigator Conflicts of Interest*

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## **CONTACTS**

[VCU Office of Research](#) officially interprets this policy and will prepare revisions, as needed, to meet the changing needs of Virginia Commonwealth University. All revisions shall be subject to University Board of Visitors approval following review by university leadership (Vice Presidents, Council of Deans, University Council, and Faculty Senate).

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## DEFINITIONS

**Conflicts of Interest** exist when financial or other personal interests or considerations of the researcher, or members of his or her immediate family, may directly and significantly affect, or have the appearance of directly and significantly affecting, a researcher's professional judgment in exercising any University duty or responsibility, including the design, conduct or reporting of research. Researcher financial Conflicts of Interests occur when the researcher, or any member of that person's immediate family (spouse, or domestic partner, and any other person residing in the same household as the researcher, who is a dependent of the researcher or of whom the researcher is a dependent, possesses a prohibited financial interest in a research activity that involves his or her University responsibilities. For some activities, such as [human subjects research](#), any financial interest will be deemed to give rise to a Conflict of Interests whereas in other situations, only a Significant Financial Interest (as that term is defined in this Policy) will give rise to a prohibited Conflict of Interests.

**Conflict of Interests Committee** (*for research*) is a standing committee of the University, composed of faculty and administrative personnel, as needed, and convened under the authority of the Vice President for Research by his or her designee. The Committee is charged to evaluating investigator reports of financial conflicts of interest and determines an appropriate resolution, including the development/recommendation of a management strategy, as appropriate. Committee

members are responsible for adhering to applicable rules of privacy and confidentiality when commencing conflict of interests assessments.

**Financial Interest** (for the purposes of this policy) includes anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, or payments for serving on a corporate Board of Directors or Scientific Advisory Board); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). It does not include salary, royalties, or other remuneration originating from VCU or the VCU Health Systems, income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities, or income from service on advisory committees or review panels for public or nonprofit entities.

**Financial Interest Related to the Research**, under [FDA regulations](#), means a financial interest in the sponsor, product, or service being tested, or competitor of the sponsor or product or service being tested.

**Investigator or Researcher** describes any individual who is responsible for the design, conduct, or reporting of a research project. The roles of individuals with such research responsibilities may be, but are not limited to, key personnel, co- or sub-investigator, medical investigator, student, trainee, or research coordinator.

**Significant Financial Interest** (or *Personal Interest, as termed in the Virginia Code*) includes Financial Interest, as defined above, at an income level exceeding \$10,000 per year and/or equity interests of 3% or more, individually or in aggregate, accruing to the researcher or any member of the researcher's immediate family.<sup>1</sup> In the case of NIH sponsorship, this term does not include investigator ownership interests in the institution, if (1) the institution is an applicant under the Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer Program (STTR), and (2) the funding is for Phase I support. To the extent to which state law deviates from, and imposes more strict criteria than federal law and/or regulations, VCU, as a public instrumentality of the Commonwealth of Virginia, necessarily must defer to state law.

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## INTRODUCTION

Conflicts of Interests exist in many forms and frequently are inherent to the nature of the research enterprise. A Conflict of Interest can arise in situations in which there exists discord between a primary duty and a secondary interest. While such interests can be either financial or non-financial, they, nevertheless, can yield conscious or subconscious bias in the conduct and/or interpretation of research, and, potentially can adversely impact the safety of human or animal research subjects. Often financial Conflicts of Interest will simply present an appearance of compromising an investigator's professional judgment in conducting or reporting the results of research.

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<sup>1</sup> A Significant/Personal Interest also may exist by virtue of ownership of real estate or personal property, the value of which exceeds \$10,000, or personal liability (e.g., debt) assumed on behalf of a business if the liability exceeds 3% of the net assets of the business.

Accordingly and whether real or only perceived, all identified conflicts of interests must be addressed. Investigators and participants in the research enterprise must be able to recognize real or perceived conflicts and report them as required by this Policy. Where appropriate, Conflicts of Interests must be managed in keeping with recommendations of the Institutional Conflict of Interests Committee.

Faculty and non-faculty employees generally are encouraged to engage in outside professional activities and relationships so long as such relationships and activities are consonant with the objectives of the University and are mutually beneficial to participants as well as to society, at large. While Conflicts of Interests also may involve institutional relationships with for-profit or non-profit entities that may need to be addressed, this Policy focuses on Conflicts of Interests involving individual Investigators and members of the research team.

This policy is largely governed by the [Virginia State and Local Government Conflict of Interests Act](#), which may be found in the Code of Virginia, beginning with Section 2.2-3100. Faculty and non-faculty employees should be aware of the provisions of State law as well as VCU's Policy on [Outside Professional Activity and Employment, Research, and Continuing Education](#) and the University's [Conflict of Interests Policy](#), included within the University's Financial Policies.

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## **POLICY**

### **Researcher Conflicts of Interests**

Conflicts of Interest may exist in situations in which financial or other personal considerations may directly and significantly affect, or have the appearance of directly and significantly affecting, a Researcher's professional judgment in exercising any University duty or responsibility, including the design, conduct or reporting of research. A Researcher at VCU may be considered to have a Conflict of Interest when he or she, or a member of that person's immediate family, as previously defined, possesses a personal or Financial Interest in an activity that involves his or her University responsibilities.

University policy expects Researchers at VCU to avoid Conflicts of Interests that may, or may appear to, (1) compromise objectivity in carrying out University research responsibilities; (2) adversely affect the University's interests; or (3) otherwise compromise the performance of University responsibilities, unless such conflicts are managed, reduced or eliminated in accordance with this Policy. Research activities and responsibilities are meant to be all-inclusive under this policy and include research design and proposal writing, applying for research funding, performing research, reviewing research proposals and protocols, reporting Intellectual Property (IP) resulting from research activities, entrepreneurship and new venture creation as they relate to the results of research, and reports of research results in any form.

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## PROCEDURE

### Reporting by the Researcher

The Principal Investigator, or Researcher, and all other involved investigators must submit a completed [Conflict of Interests Reporting Form](#) and a [Supplement Form](#), as appropriate, with (1) each new, continuation, or revised grant or contract application submitted to the Office of Sponsored Programs, (2) each new protocol involving animal or human subjects, and (3) whenever there is a change in status from the previous report. The Financial Interests of each Investigator, as well as those of the immediate family, are subject to financial Conflict of Interests reporting.

In the event an Investigator is the applicant who submits a marketing application for FDA approval, the applicant is responsible for submitting the appropriate certification and reporting statements to the FDA, in addition to those submitted to VCU. Information about such statements appears in [Part 54 of the FDA federal regulations](#).

Conflict of Interests reporting, assessment, and management is addressed in federal regulations pertaining to federal funding agencies, such as NIH or NSF, and for research seeking FDA approval. VCU policies for reporting and dealing with financial Conflicts of Interest reflect the stricter requirements of the Commonwealth of Virginia in areas where federal regulations differ.

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### Review by the Conflict of Interests Committee

If a real or apparent Conflict of Interest is reported on the part of an Investigator or a member of his/her immediate family, it will be referred to the Conflict of Interests Committee (COIC), which will evaluate the report. Once referred to the COIC, an Investigator may not proceed in research, nor may he/she assign students, post-doctoral fellows or other trainees to the research, without prior approval of the COIC if:

- The Investigator has any Financial Interest and the research involves human subjects or is being conducted for the purpose of regulatory approval (by the FDA, for example); or
- The Investigator has a Significant Financial Interest even though the research neither involves human subjects nor is being conducted for the purpose of regulatory approval.

Additional approval is required if the sponsor of the research is a business in which a University employee has a Significant Financial Interest.

Members of the COIC who have financial or non-financial interests in a particular proposal or IRB or IACUC protocol shall recuse themselves from review of said protocol.

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## **Managing Conflicts of Interest**

If a Conflict of Interest exists that would reasonably appear to compromise the objectivity of the research, the COIC requires that a strategy for managing, reducing, or eliminating the conflict must be adopted prior to expenditure by VCU of any part of any sponsored research award or contract and/or before the research begins. The Investigator reporting a Conflict of Interest on the Reporting and/or Supplement Forms may propose a management strategy for ensuring research objectivity that will be considered by the COIC. Possible strategies for management of Conflicts of Interest include, but are not limited to:

- public disclosure of the financial interest;
- written affirmation of the VCU COI and/or IP Policy;
- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification of an Investigator(s) from participation in all or a portion of the research;
- divestiture of the Financial Interest;
- severance of relationships that create Conflicts of Interest; or
- VCU declining the award.

For management plans that require monitoring of the research, individuals reporting financial or non-financial Conflicts of Interest in the project shall not be assigned as independent reviewers.

In circumstances wherein a VCU researcher has a Significant Financial Interest, or personal interest (termed as such in state law), in a contract between VCU and research and development or commercialization of intellectual property, or a business, the COIC will require additional consultation in dealing with the conflict of interests, as provided in Virginia Code.

The COIC has the authority to modify and approve, or disapprove, the Investigator's proposed management strategy, if submitted. A final management strategy developed by the COIC must be accepted in writing by the Investigator.

The signed management strategy notice must be shared with the appropriate academic Dean. It must also be submitted to:

1. the *Office of Sponsored Programs* prior to expenditure by VCU of any part of the affected award. The management strategy will become part of the sponsored program record maintained by VCU.



2. the *Office of Research Subjects Protection*, as applicable, for review by the IRB or IACUC. The COIC-approved management strategy may not be altered by the IRB or IACUC but it may be augmented to ensure the optimal protection of research subjects. For example, the IRB may require disclosure in the informed consent form or the IACUC may require additional safeguards to protect the well-being of laboratory animals. The research protocol cannot be approved until the IRB or IACUC have reviewed the COIC management plan. The COIC management strategy, together with any additional requirements by the IRB or IACUC, will become part of the approved protocol record maintained by VCU.

The Investigator must provide the COIC and appropriate academic Dean with an annual update on the fulfillment of the management strategy. Monitoring compliance with the agreed strategy shall be the responsibility of the Dean.

An appeal of a COIC determination can be made directly to the COIC Chairperson who may call for reconsideration by the COIC if additional supporting information has become available since the initial review. The conflicted individual may be required to attend the reconsideration session. The decision of the COIC re-review may be further appealed to the Vice President for Research (VPR) by an Investigator. The Investigator must notify the VPR of any intended appeal within 5 days of receiving notice of the management plan. The VPR will form an *ad hoc* Appeal Panel comprised of three senior faculty, and other consultants as needed, who will have 30 work days to review the relevant materials. The Appeal Panel's recommendation is made to the VPR who will render a decision within 10 work days. The decision of the VPR will be final and there shall be no further appeal within the University.

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## **Reporting Significant Conflicts of Interest by VCU**

Significant Financial Conflicts of Interest must be reported to PHS (Public Health Service) sponsors, as required by the relevant federal agencies, by the Office of Sponsored Programs. A reported conflict must be certified as having an appropriate management plan. In the event a Significant Financial Conflict of Interest is identified subsequent to the initial report under the award, the conflict also must be reported to sponsors, as appropriate. All information regarding reported Significant Financial Conflicts of Interest must be made available upon request by the PHS-funding agency, along with how those conflicting interests have been managed, reduced, or eliminated.

Records of reports and management plans of significant financial Conflicts of Interest are to be maintained as follows: 1) in the case of grants or cooperative agreements, for a period of at least five years after submission of the final expenditures report, unless otherwise directed, or 2) in the case of research contracts, for at least five years after final payment, unless otherwise directed.

## **Policy Implementation and Policy Breaches**

The Vice President for Research, or his/her designee, is responsible for the implementation of this Policy, including the process and mechanism for Conflict of Interests reporting and management, and the appointment of members to the COIC. The Vice President for Research, or his/her designee, will oversee all identified breaches of Conflict of Interests reporting, review, and approval process, including:

- failure to comply with the process (e.g., failure of Investigators to report Conflicts of Interest, failing to respond to COIC, IRB, or IACUC inquiries, or responding with incomplete or knowingly inaccurate information);
- failure to remedy conflicts; and
- failure to comply with a prescribed monitoring plan.

Violation of the Conflict of Interests policy is subject to action, as appropriate, under University policies and procedures, including the University's [Outside Professional Activity and Employment, Research, and Continuing Education](#) policy or under VCU's [Policies and Procedures for Misconduct in Research and Scholarly Activities](#).

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## POLICY STATEMENT AND PURPOSE

This policy asserts and protects the rights of Virginia Commonwealth University (the University), and its Member researchers, in regard to ownership and retention of research data and related records.

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## WHO SHOULD READ THIS POLICY

All University Members involved in the conduct of research should read this policy.

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## RELATED DOCUMENTS

- [Virginia Public Records Act, §§42.1-76 et.seq. of the Code of Virginia](#)
- [Commonwealth of Virginia Records Retention and Disposition Schedule No. 111](#)
- [VCU Records Management Procedure](#)
- Intellectual Property Policy (*link pending policy approval*)
- Responsible Conduct in Research Policy (*link pending policy approval*)

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## CONTACTS

[VCU Office of Research](#) officially interprets this policy and will prepare revisions, as needed, to meet the changing needs of Virginia Commonwealth University. All revisions shall be subject to University Board of Visitors approval following review by university leadership (Vice Presidents, Council of Deans, University Council, and Faculty Senate).

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## DEFINITIONS

**Investigator** means any University Member engaged in the conduct of research as either an employee or student of the University or any person using facilities owned or operated by, or resources administered by, the University.

**Principal Investigator** has primary stewardship of Research Data on behalf of the University. In this capacity the Principal Investigator (PI) is responsible for data collection, recording, storage, access, and retention in keeping with this policy and best practices in the PI's discipline.

**Report** means any summary, statement or description of Research activities published in the open literature or provided to the public, the University, a sponsor, or other researchers by a University Member.

**Research** means a systematic investigation designed to develop or contribute to knowledge and may include the stages of development, testing, and evaluation.

**Research Development Advisory Council (ReDAC):** Inaugurated in 2006, its members are Associate/Assistant Deans for Research or individuals who hold comparable responsibilities for research development within their respective College/School. Council members represent the research interests of each of the Schools and Colleges at the University, and serve as a conduit of information from the Office of Research back to their constituencies. The Council meets regularly with the Vice President for Research and the Associate Vice President for Research Development to address topics of specific interest to the University research enterprise, and to identify resources and supports necessary for increasing the strength and competitiveness of VCU as a research university.

**Research Data** means recorded information, regardless of form or the media in which it may be recorded, which constitute the original observations and methods of a study and the analyses of these original data that are necessary for reconstruction and evaluation of the Report(s) of a study made by one or more Investigators. Research Data also includes all such recorded information gathered in anticipation of a Report. Research Data differ among disciplines. The term may include but is not limited to technical information, computer software, laboratory and other notebooks, printouts, worksheets, other media, survey, memoranda, evaluations, notes, databases, clinical case history records, study protocols, statistics, findings, conclusions, samples, physical collections, other supporting materials created or gathered in the course of the Research, Tangible Research Property, unique Research resources such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA as well as genetic sequences and mapping information, crystallographic coordinates, plants, animals and spectroscopic data, and other compilations formed by selecting and assembling preexisting materials in a unique way.

The term does not include information incidental to research administration such as financial, administrative, cost or pricing, or management information.

**Tangible Research Property** means products of research that include, but are not limited to, compositions, biologics, materials, illustrations and drawings, prototypes, devices, and equipment.

**University Member** means any full- or part-time faculty member, classified employee, administrative staff member, paid student assistant, student, volunteer, fellow or trainee, visiting faculty member or researcher. One is not a University Member when acting in a purely private role that in no way or manner implicates the University, unless the activity results in a Report in which the individual is identified as having a University affiliation.

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## **POLICY**

### **Acquisition and Use of Research Data**

Investigators shall record original observations in accordance with the standards of their respective disciplines and the University Responsible Conduct of Research Policy. The Investigator who gathers or creates Research Data may use the information as he/she deems appropriate and may authorize others to make appropriate use thereof, subject to University and personal contractual commitments and University policies. The use of Research Data gathered or created within a group of Investigators is subject to the reasonable control of the Principal Investigator.

### **Custody of Research Data**

All Research Data shall be preserved in the custody of, or as arranged by, the Principal Investigator on behalf of the University.

The Principal Investigator is charged with the integrity, preservation and security of Research Data, appropriate marking and reporting of all University intellectual property that may be included in, or derived from, the Research Data. In the case of incapacity of the Principal Investigator, that individual's supervisor will take custody of that individual's Research Data until other appropriate arrangements are made for alternative custody.

Investigators on Research teams have obligations to discuss responsibilities of data acquisition, use, management, access and retention with other members of a Research team. This especially includes the further access and use of de-identified human subjects data that is acquired via student research projects.

Preservation and security of Research Data is typically an allowable direct cost of conducting research and can be a budgeted item in many sponsored program agreements.

In cases involving misconduct in research and scholarly activities, the threat of imminent loss of data custody, maintenance of intellectual property records, or for other justifiable causes, the University, acting through the Vice President for Research or designee, may take immediate custody of Research Data.

### **Retention of Research Data**

The Principal Investigator of each Research program must ensure that Research Data documenting the methods and accuracy of data collection and interpretation is retained. Research Data disclosed or referenced in publications, including the primary experimental results, must be retained for a minimum of five (5) years (or as otherwise defined by state regulations or agreement) to allow analysis and replication by others. Research Data resulting from sponsored programs are to be retained for a minimum of five (5) years after submission of the final Report on the Research project, unless a longer retention period is specified by the sponsor. Research data collected for product application to the Food & Drug Administration (FDA) may be subject to additional data retention requirements as specified by the sponsor and/or the FDA.

If an investigation, legal action or official inquiry concerning a Research activity is ongoing; all Research Data related to the project must be retained and made accessible until all issues are resolved.

In addition to the 5 year retention requirement above, if a student or trainee is involved, Research Data must be retained at least until the degree is awarded to the student, the training period is complete, or it is clear that the student has abandoned the work. Research Data should be kept for as long as may be required to protect any patents or other intellectual properties resulting from this work.

This policy does not create an obligation to retain Research Data ensuing from an abandoned or unfunded project, unless it results in a Report in which the investigator is identified as a University Member, constitutes a record of University intellectual property, or involves the use of animal or human subjects.

## Access to Research Data

The University has the right to access Research Data for all Research that is either performed at the University, supported by University administered funds, or conducted using University facilities, provided such access shall be for reasonable cause, at reasonable times and after reasonable notice, except in the event of a bona fide emergency. The University's right of access shall continue regardless of the location of the Principal Investigator or of the Research Data.

Information or data that would violate the confidentiality of sources or subjects involved in the Research shall not be disclosed except in accordance with law or regulation. The University and appropriate external officials shall have access to Research Data concerning matters of compliance with human or animal research subject laws, regulations and policies. Subject to provisions of law, individual human research participants may be allowed to access Research Data that pertains to themselves, but not to access Research Data pertaining to others.

Extramural sponsors providing support to the University or appropriate governmental officials also may have the right to review the Research Data resulting from that extramural support.

University Members who are an integral part of a Research project have the right and responsibility to review all Research Data that they gathered or created, or which support publications for which they are named authors, even after departure from the University, to the extent that such Research Data continues to exist and can be identified.

Sharing of Research Data (that has been published) is held by the University to be a tenet of the scientific community. Standards of data sharing have been published by national scientific organizations and by federal funding agencies:

- [Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences](#) (*The National Academies Press*)
- [NIH Data Sharing Policy](#) (*National Institutes of Health*)
- [NSF General Grant Conditions](#) (*National Science Foundation*)

Scientific and scholarly publications increasingly include statements that promote data sharing in their instructions to authors. This language may indicate that such sharing be a condition of publication (Piwowar, H. and W. Chapman. 2008<sup>2</sup>). University Members are expected to share their published data upon request. Sharing of data should occur in a timely manner and involve only necessary costs. Data are to be shared in reasonable but limited quantities with members of the research community for non-commercial purposes. In the case of requests that have commercial implication or those that involve Tangible Research Property which may represent potential or protected intellectual property such materials may be shared under the terms of a University-approved Materials Transfer Agreement. Shared data

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<sup>2</sup> [A Review of Journal Policies for Sharing Research Data](http://elpub.scix.net/cgi-bin/works/Show?001_elpub2008). Proceedings ELPUB 2008 Conference on Electronic Publishing. [http://elpub.scix.net/cgi-bin/works/Show?001\\_elpub2008](http://elpub.scix.net/cgi-bin/works/Show?001_elpub2008).

resulting from human subjects research shall be de-identified, with the linkage code residing in the custody of the University Principal Investigator.

### **Transfer of Research Data**

When an Investigator separates from the University, a written Agreement on Disposition of Research Data shall be negotiated between the Investigator and the Investigator's department chair or dean. In most cases, this agreement shall allow the Investigator's Research Data (other than personally identifiable clinical Research records) to be transferred with the Investigator. These agreements will serve to ensure appropriate access to the transferred Research Data in fulfillment of the University's obligations to funding sources and other supporting entities, and for research compliance purposes. Under the terms of the agreement, the Investigator shall have the obligation to hold these Research Data in trust for the University. See [Appendix I](#) for a template *Written Agreement on Disposition of Research Data*.

In some cases (e.g., Research Data supporting a patent application, Research Data generated and/or used by other University Investigators, some Tangible Research Property, or as required by the terms of extramural funding agreements), it may be necessary for original Research Data to be retained at the University. In such cases, this agreement shall allow the Investigator to access and, where practical, to copy Research Data. In cases of multi-institutional studies, the institution of the primary study director shall be responsible for arranging appropriate access to, use of, and retention of Research Data.

When required by law, regulation or contract, or to fulfill other obligations, the University may transfer title or custody of Research Data and records at its discretion. In such cases, the University, insofar as possible, will ensure access by Principal Investigators, Investigators and other appropriate individuals to that Research Data.

### **Ownership of Research Data and University Disposition**

Consistent with federal policy and prevailing higher education practice, Research Data belong to the University. In the event that Investigator data retention and maintenance practices are found to be contrary to this Policy, the University may make disposition of these Research Data and related property rights in a manner that is consistent with law and policy, including, but not limited to, the VCU Intellectual Property Policy and the VCU Policy and Procedure for Misconduct in Research and Scholarly Activities.

### **Research Data Policy Oversight and Dispute Resolution**

The Vice President for Research has responsibility for oversight of, and resolution of, disputes resulting from this policy. If an Investigator desires to contest the decision of the Vice President for Research, the Investigator may file a written appeal to be reviewed by a committee of researchers, appointed by VCU Research Development Advisory Council.



## **APPENDIX I: TEMPLATE**

### **Written Agreement on Disposition of Research Data**

Research Data pertaining to this agreement: Original research data from [Investigator's name; name of study(ies); and funding source(s)].

In order to remain in accordance with the University's policies on the transfer of research data, [Investigator] and [name of Chairperson; Department name] agree that the following original items will be transferred with the Investigator, [name], to [name of institution].

- [List all completed instruments, signed consent forms, other sources of data, etc.]

All copies of the data will remain in the [indicate location within Department or School] at Virginia Commonwealth University. [Name of faculty] will have access to the copies in the event such copies are needed in the future. The original data and copies have been de-identified, as applicable, in accordance with University data policy.

Signed copies of this agreement will be provide to [Dept.], to the Investigator, and to the Chair.

\_\_\_\_\_  
Signature of Chairperson                      Date

\_\_\_\_\_  
Signature of Investigator                      Date

*Enclosure: Transfer of Research Data excerpt from Data Ownership, Retention, and Access Policy*