

# 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.

Approved Board of Visitors 5-15-09