



Corporate Research Agreements

Policy Type: Administrative

Responsible Office: Office of Research and Innovation

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Policy Statement and Purpose

In support of all potential research-related endeavors, Virginia Commonwealth University (VCU) is committed to reviewing a research agreement with a Corporate Entity for compatibility with VCU's principles and compliance with applicable laws. Toward that end, this policy outlines the explicit requirements and principles for conducting Corporate Research at VCU. This policy also provides the requisite procedures for seeking university review, negotiation, and execution of Corporate Research agreements, including clinical trial agreements, material transfer agreements, non-disclosure agreements, research agreements, and service agreements. In support of VCU's mission, Corporate Research projects and the review of these agreements must preserve the public's trust, support the spirit of shared governance, and contribute to VCU's commitment to transparency.

Principles

First and foremost, Corporate Research relationships must conform to VCU policies in support of investigators' academic freedom and mitigate conflicts of interest that could affect or create a perception of affecting the research itself. Both the individual engaging in Corporate Research and the agreement setting forth the research relationship must respect the following principles:

1. Compatibility with VCU's Mission - Corporate Research must be consistent with VCU's comprehensive mission and 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 University, faculty, students, and/or community. Involvement of students and/or trainees engaged in Corporate Research is appropriate when in support of the instructional learner-centered mission of the University.
2. Investigator Autonomy - VCU supports faculty who wish to undertake Corporate Research, provided the research is consistent with the mission of VCU and the research agreement conforms to the policies and procedures of the University. No investigator shall be required to participate in

Corporate Research. Principal Investigators are free to accept or reject a proposal for Corporate Research.

3. Responsible Conduct of Research - Established principles and procedures related to ethics and scientific integrity of research apply to all research activities, including Corporate Research
4. Conflict of Interest Considerations - VCU affirms that all research conducted at the university must be consistent with state and federal law related to conflicts of interest and all sponsored projects must comply with university policies (including *Conflicts of Interest in Research* and *Institutional Conflicts of Interest in Research*) that define the process for identifying, evaluating, managing, and reporting financial relationships that have or may appear to have an impact on the objectivity and integrity of the research conducted. VCU requires strict adherence to these established policies in the proposing, performing, reviewing, and reporting of research.
5. Conflict of Commitment Considerations - A Conflict of Commitment could arise when a researcher engages in external activities that interfere with his/her primary obligation and commitment to the University. Researchers, under the supervision of their chairs and deans, should consider potential conflicts of commitment and manage external interests in order to avoid compromising their ability to carry out their primary obligations the University.

Explicit Requirements

A. **All** Corporate Research agreements must comply with the following requirements:

1. Administration and Signature Authority – Agreements for Corporate Research are negotiated and administered by the Office of Sponsored Programs in the Office of Research and Innovation. The designated signatory is determined by the Vice President for Research and Innovation, in accordance with the *Authority to Execute Contracts and Other Documents*.
2. Binding Arbitration – Pursuant to Virginia law, VCU employees do not have the authority to enter into binding arbitration or to agree in contract to foreclose any remedies that would otherwise be available by law. Any agreement must provide that any disputes arising under the Agreement are resolved amicably or that the University's available remedies are preserved.
3. Indemnification – Pursuant to Virginia law, VCU may not enter into an agreement to indemnify any person or entity against damages arising from a sponsored project conducted by VCU.
4. Intellectual Property (IP) and Research Data Ownership – Intellectual property created solely by VCU members during the conduct of Corporate Research and the financial proceeds resulting from commercialization of such VCU-created intellectual property must be addressed consistent with

VCU's *Intellectual Property Policy*. Research Data is governed by *Research Data Ownership, Retention, Access, and Security*.

5. Non-Disclosure and Confidentiality

- a. *General*: Proprietary or confidential information (which may include Corporate Entity-generated information as well as information or data generated by the investigator) may be disclosed prior to or during the conduct of the study and should be appropriately marked or otherwise identified by the discloser as confidential at the time of disclosure. Such information may be received and maintained under a promise of confidentiality for a period, not to exceed five (5) years from the expiration/termination of the agreement, or alternately, seven (7) years from the date of disclosure. This time period must be agreed upon by both the Corporate Entity and the principal investigator.
 - b. *Confidentiality Disclosure Agreements*: A Corporate Entity may require the University to enter into confidentiality disclosure agreements for the express purpose of disclosing proprietary or confidential information to the proposed principal investigator to determine their interest in participating in a study. Information disclosed for this purpose may be received under a promise of confidentiality for a period not to exceed ten (10) years from the date of agreement execution. Subsequent Corporate Research agreements shall be negotiated using the preferred confidentiality terms not to exceed (5) years from the expiration/termination of the agreement or seven (7) years from the date of disclosure of confidential information as stipulated above.
 - c. *Restrictions*: As a public University, VCU must disclose public records in accordance with the Virginia Freedom of Information Act. All Corporate Research agreements must be consistent with this legal requirement.
 - d. VCU will not accept trade secrets.
6. Publication Rights – 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. University members must be free to share, publish, or publicly present their research results. Corporate Research agreements with VCU must explicitly provide for the open communication of research results and not be subject to the Corporate Entity's permission for publication. VCU recognizes a Corporate Entity's obligation to protect its confidential and proprietary information. In addition,
- a. Service agreements permit the publication of general scientific results. VCU may permit a Corporate Entity to review research materials that include a Corporate Entity's proprietary information prior to publication, given the following parameters:

- Reviews by Corporate Entities generally should not delay submission for publication for more than thirty (30) days.
 - A Corporate Entity may be granted an additional period of review for the purpose of securing patent protection. This additional period should not exceed 60 days.
 - Multi-site Clinical Research Agreements may include publication delays not to exceed 18 months to permit data coordination among the multiple sites.
8. Retention of Documents – Documents created or received under this policy are subject to the *Virginia Public Records Act* §§ [42.1-77](#) and [42.1-86.1](#) of the *Code of Virginia*. Documents should be retained for a minimum of five (5) years as set out in the [Records Management State Agency General Schedules](#) of the Library of Virginia; however, otherwise stipulated contractual or federal obligation beyond 5 years would prevail as the requirement.

B. **Corporate-Initiated** research agreements must comply with the following **additional requirements**:

1. Full Cost Recovery – All corporate-initiated research must recover the full costs (all costs associated with research activities sponsored), including the direct and facilities and administrative costs.
2. Research-Related Injury Coverage in Clinical Research – In accordance with [21 CFR §50.25 \(6-7\)](#), VCU agreements with corporate sponsors of corporate-initiated clinical research involving *greater than minimal risk* must include clear and appropriate provisions for ensuring adequate compensation for medical care in the case of research-related injury.

Corporate Agreements for clinical research studies where the Corporate Entity holds the Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) and controls the study protocol should stipulate that the Corporate Entity will fund medical care costs for research-related injury. Incidences of research-related injury must be determined to be probably or definitely related to the research study, wherein the condition would not have existed outside of participation in the research. Such determinations must be made by VCU, together with the Corporate Entity.

VCU may execute contracts where research-related injury is defined with study-specific exclusions, such as injury or illness which is:

- Primarily due to a participant's underlying medical condition or progression of disease;
- Associated with the known risks of routine patient care portions of the study;
- Attributable to the negligence or willful misconduct on the part of the University.

Noncompliance with this policy may result in disciplinary action up to and including termination. VCU supports an environment free from retaliation. Retaliation against any employee who brings forth a good faith concern, asks a clarifying question, or participates in an investigation is prohibited.

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Who Should Know This Policy

All University members involved in or contemplating a Corporate Research agreement should read and understand this policy.

Definitions

Agreement

A generic name for a grant, contract, or other written arrangement which is enforceable by law and must be executed in accordance with the VCU policy entitled *Authority to Execute Contracts and Other Documents*.

Clinical Trial

A type of a clinical research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (Source: [National Institutes of Health](#)).

Conflict of Commitment

Activities outside of the workplace, either paid or unpaid, that affect or appear to affect an individual's primary obligation to the university or performance of university responsibilities.

Corporate Entity or Corporate Research

A for-profit organization providing full or partial support for a research activity. Additional conditions include:

- Corporate Initiated – where the Corporate Entity initiates the research activity.

- Corporate Sponsored – where the Corporate Entity fully covers all costs associated with the research activity. In a clinical trial, this would include all research-related clinical care costs.
- Corporate Support – where the Corporate Entity supports a portion of the project in the form of materials, financial support, or other resources.

Facilities and Administrative (F&A) Cost Rate

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 F&A costs include general administration (accounting, payroll, purchasing, etc.), sponsored project administration, plant operation and maintenance, library expenses, general 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." The F&A cost rate is expressed as a percentage of a base amount, typically Modified Total Direct Costs "MTDC" or Total Direct Costs "TDC".

Intellectual Property

As defined by the *Intellectual Property Policy* including, but 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, know-how, or trade secrets; or
- e) tangible research property, including, but not limited to, compositions, biologicals, materials, illustrations and drawings, prototypes, devices, and equipment.

Principal Investigator (PI)

The individual with final responsibility for the conduct of research or other activity described in a proposal or an award and/or the individual with fiduciary responsibility for an award's management.

Research Data

Recorded information, regardless of form or the media on 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.

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, and resource asset to, the Office of the Vice President for Research and Innovation (OVPRI) for their constituencies. The Council meets regularly with the Vice President for Research and Innovation 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.

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.

Contacts

The VCU Office of Research and Innovation officially interprets this policy. The VCU Office of Research and Innovation is responsible for obtaining approval for any revisions as required by the policy *Creating and Maintaining Policies and Procedures* through the appropriate governance structures. Please direct policy questions to the VCU Office of Research and Innovation.

Policy Specifics and Procedures

The VCU Office of Sponsored Programs will review, negotiate, and execute Corporate Research agreements to ensure compliance with this policy. In support of an expeditious agreement process, corporate entities are encouraged to consider VCU requirements in advance of offering a research

agreement. Individuals are encouraged to share this document in advance with any and all corporate entities.

The Vice President for Research and Innovation may consider limited requests for exceptions to policy requirements on a case-by-case basis. In doing so, the Vice President for Research and Innovation will inform the Research Development and Advisory Council (ReDAC) of his or her intention to allow an exception in a pending agreement. A ReDAC review of any planned exception will be initiated if such a request is made by a majority of its members. In certain cases, the Vice President for Research and Innovation may request that ReDAC provide a review. Following their review, the ReDAC will provide an official recommendation to the Vice President for Research and Innovation. The ReDAC has the right and responsibility to recruit and engage faculty experts in their review of any agreements. The Vice President for Research and Innovation will report to the Faculty Senate on a regular basis concerning review activities and decisions that fall outside the norms of this policy. The Vice President for Research and Innovation will make the final decision on acceptance or rejection of corporate research agreements, in consultation with ReDAC.

Exception Process – Requests for exceptions are initiated by the Office of Sponsored Programs in consultation with the Principal Investigator.

Concerns - If any University member believes that any proposed Corporate 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 ReDAC Member of the respective school. The ReDAC Member may request to have that potential project reviewed by the Vice President for Research and Innovation and/or the ReDAC. Alternatively, University members may utilize the [VCU Helpline](#) and/or contact the [Ombudsperson](#).

Forms

There are no forms identified for this policy.

Related Documents

1. VCU Policy: [Authority to Execute Contracts and Other Documents](#)
2. VCU Policy: [Intellectual Property Policy](#)
3. VCU Policy: [Research Data Ownership, Retention, Access, and Security](#)
4. VCU Policy: [Conflicts of Interest in Research](#)
5. VCU Policy: [Institutional Conflicts of Interest in Research](#)
6. VCU Policy: [Responsible Conduct in Research and Scholarship](#)
7. VCU Policy: [Principal Investigator Eligibility](#)
8. [Records Management State Agency General Schedules](#) of the Library of Virginia

9. Virginia Public Records Act §§ [42.1-77](#) and [42.1-86.1](#) of the Code of Virginia
10. VCU [Research Development Advisory Council Member List](#)

Revision History

This policy supersedes the following archived policies:

04/05/2012	<i>Policy on Corporate-Sponsored Research Agreements</i>
11/11/2010	<i>Policy on Corporate-Sponsored Research Agreements</i>
05/15/2009	<i>Policy on Corporate-Sponsored Research Agreements</i>

FAQ

There are no FAQ associated with this policy and procedures.