

Responsible Conduct in Research and Scholarship Policy

Responsible Office:
Office of Research

POLICY STATEMENT AND PURPOSE

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

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.

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*)

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.

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.

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.

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)

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* 3rd 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
- 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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