



UNIVERSITY *of* VIRGINIA

***WHAT YOU NEED
TO KNOW
ABOUT RESEARCH
COMPLIANCE
AT UVA***

Key Offices

Office of the Vice President for Research and Public Service	434.924.3606
Office of Sponsored Programs	434.924.4270
Human Investigation Committee IRB / "HIC	434.924.2620
Behavioral Sciences IRB	434.243.2915
Animal Care and Use Committee	434.924.0405
Environmental Health & Safety	434.982.4911
Institutional Biosafety Committee (IBC)	434.982.4911
Radiation Safety	434.982.4911
University of Virginia Patent Foundation	434.924.2175

Intro

The University of Virginia has an enduring commitment to the public interest and well-being, and for two centuries, faculty outreach and research have created knowledge, developed new applications of this knowledge, and deepened our understanding of ourselves and the world. In fiscal year 2000, sponsors of grants and contracts provided the University with 27% of its revenue stream. And in fiscal year 2001, the University received over \$223 million in support of sponsored research. Our research activity drives economic development, creates jobs, stimulates start up businesses, leads to better health care for the citizens of the Commonwealth, and enhances the quality of education and training for undergraduate and graduate students.

Consistent with the mission and values of the University, our research endeavors must demonstrate adherence to state and federally mandated research guidelines. The Office of the Vice President for Research and Public Service is responsible for oversight of the University's research compliance, research enhancement, public service, federal relations and intellectual property.

Office of the Vice President for Research and Public Service
Madison Hall 314
PO Box 400301
Charlottesville, VA 22904-4301
434.924.3606

Website: <http://www.virginia.edu/researchandpublicservice/>
Email: vpresearch@virginia.edu

Compliance Committees

Institutional Review Boards

An "IRB" is a board or committee organized at a university to provide a review at the institutional level for ethical concerns in research, such as laboratory animal care and the use of human participants in research.

Human Participants in Research

The University is committed to protecting the rights and ensuring the safety of human participants in research at the University of Virginia. Whenever research involves humans, the project proposal must specify details of the research, a

discussion of the potential risks, anticipated benefits, and the measures included to both reduce risks and to protect the interests of those participants. The proposal is then submitted for review and approval. This review is done through one of two separate committees known as the Institutional Review Boards (IRB's), both of which operate under the Assurance of Compliance the University has filed with NIH as required by law.

Tutorial: To provide up-to-date information about the regulatory requirements for conducting research, the Office of the Vice President for Research and Public Service has developed a tutorial that can be used as a self-directed learning module. This tutorial reviews core concepts for the responsible conduct of research. By exploring this easy-to-use tutorial, you will be guided through the major principles for conducting research in a way that is consistent with federal and University requirements and with accepted scientific standards.

The tutorial may be used either to demonstrate core competencies (when taken as an "recorded UVA User") or as a voluntary exercise for those who simply want to refresh their knowledge (when taken as a "guest"). *Satisfactory completion of this tutorial is **required** for all key personnel included on every research protocol submitted to the University's IRB's.* Website:

<http://www.cbt.virginia.edu/HicDocs/Training/index3.cfm>

- Human Investigation Committee (HIC) 434.924.2620
 - Reviews all medically invasive research conducted on human subjects, and provides up-to-date information about the regulatory requirements for conducting research. Website:
<http://www.med.virginia.edu/medcntr/committees/human-investigation/>

- Behavioral Sciences IRB 434.243.2915
 - Reviews all non-medical behavioral human research (studies which are considered medically non-invasive). Website:
<http://www.virginia.edu/researchandpublicservice/research/researchcom/behavioral.html>

Also, refer to the Office of Research Integrity (ORI), a federal government entity located in the Office of Public Health and Science within the Office of the Secretary of US Department of Health and Human Services (DHHS). ORI promotes integrity in biomedical and behavioral research supported by the Public Health Service (PHS) at about 4,000 institutions worldwide. ORI monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through educational, preventive, and regulatory activities. Website: <http://ori.dhhs.gov/>

Animal Research 434.924.0405

The University of Virginia requires that animal research protocols be submitted for review and approval by the ACUC (Animal Care and Use Committee) before any investigator purchases/obtains and begins research involving vertebrate species. Website: <http://www.med.virginia.edu/medcntr/committees/iacuc/>

Environmental Health and Safety

Radiation Safety 434.982.4911

The Radiation Safety Office manages all aspects of the use of radioactive materials and radiation producing equipment at the University of Virginia. The Radiation Safety Office responsibilities extend to the hospital, medical school research and academic areas. Website:

<http://keats.admin.virginia.edu/rad/home.html>

Biosafety 434.982.4911

All researchers must register with the Institutional Biosafety Committee (IBC) by declaring the hazard potential of the agents manipulated in their research laboratories. In addition, those who conduct research with agents designated Biosafety Level 2, or above, must formally document the fact that their protocols and facilities do not jeopardize the health and well-being of themselves, their employees, or the general public. Website:

http://keats.admin.virginia.edu/bio/ibc_webintro.html

Conflict of Interest

Conflicts of interest can be defined as situations in which a divergence between personal and professional interests might be perceived, such that an individual's professional actions might be viewed to be influenced by considerations of

personal gain. Conflicts of interest can erode scientific objectivity. The goal of University policies in this regard are not, therefore, to eliminate all conflicts but rather to manage them. The first step and key to the conflict of interest review process is disclosure.

Under certain circumstances, the financial interests of a university faculty or staff member may limit the ability of the university to enter into certain contracts. The conflicts caused in these situations can potentially violate Virginia statutes. There are provisions under which some conflicts may be waived (and the contract may be accepted), though such waivers might require approval of the University of Virginia Board of Visitors. Faculty who find themselves in these potential conflict situations are urged to begin the disclosure process early, so that the waiver may be obtained in a timely fashion. For additional information, consult: <http://www.virginia.edu/%7Epolproc/pol/xva1.html>

Federal guidelines require the University to develop and implement an "objectivity in research policy." It is clear that federal funding agencies expect the University to develop a uniform policy for all sponsored research, not merely research funded by federal agencies. Investigators who have financial interests that might reasonably appear to be affected by the funded research grant are required to provide information on those financial interests at the time of proposal submission. The University will review the information provided by the investigator(s) to determine whether a conflict of interest exists. If there is a conflict, the University will, if possible, develop a strategy to manage the conflict of interest prior to any expenditure of the award.

See these websites for the University's current statement on conflict of interest issues, including professional ethics with regard to students, spouses also employed by the University, and contracts with other state agencies:

<http://www.virginia.edu/provost/conflict.htm> and
<http://www.virginia.edu/%7Epolproc/pol/viiiib1.html>

Please note that both PHS and NSF have set thresholds for the definition of "significant financial interest". NIH and NSF define "financial interests" as:

"anything of monetary value, including but not limited to:

- salary or other payments for services (e.g. consulting fees or honoraria)
- equity transfers (e.g. stocks, stock options or other ownership interests)
- intellectual property rights (e.g. patents, copyrights and royalties from such rights)."

Such interests become "significant" for PHS or NSF if, for any one enterprise, THE INTEREST HAS A VALUE OF \$10,000 OR MORE OR REPRESENTS MORE THAN 5% OWNERSHIP INTEREST. Note that this threshold applies to the individual or aggregated interests of the PI, spouse or domestic partner, and dependent children.

Intellectual Property

As a condition of employment the University requires all persons engaged in research to sign the Patent Policy Agreement. This agreement specifies the rights and obligations of both parties when a patentable product is produced in the course of research activities for which an employee has been compensated by or through the University or has used facilities owned, operated, or controlled by the University. The policy of the University is to consider and, where appropriate, assist in the patenting and commercial development of discoveries or inventions that are the product of University research. This policy is intended to provide incentive for creative intellectual effort, to ensure that the respective interests of the faculty member, the University, any supporting sponsor, and society are considered and protected through the development of fair contracts and procedures; to assist the researcher and the University to realize tangible benefits from inventions or discoveries; and to advance and encourage further research. The Vice President for Research administers the patent policy, with assistance from the University's Office of Sponsored Programs, subject to review by the vice president and provost.

Intellectual property is a broad term that encompasses the various intangible products of the intellect of inventors. These include patents, trademarks, copyrights, trade secrets, know-how, and other proprietary concepts, including an invention, scientific or technological development, and even computer software and genetically engineered micro-organisms.

Copyrights

University of Virginia Copyright Policy - The goal of the Copyright Policy and the associated procedures is to enable the University to recover, to the extent possible, significant University resources which may have been utilized in the

creation of a copyrightable work. To this end the copyright to works created utilizing significant University resources shall vest with the University and are not included in the group of scholarly or academic works the copyright ownership to which is ceded to the author(s) by the Copyright Policy. Amendments to these procedures may be made by the Vice President for Research and Public Service with approval by the Vice President and Provost.

Interim Administrative Procedures to Implement the University Copyright Policy:
<http://www.virginia.edu/researchandpublicservice/research/researchpol/CopyrightProcedures.html>

Financial & Administrative Policies and Procedures - Copyright Policy
<http://www.virginia.edu/%7Epolproc/pol/xve1.html>

Patents

A patent is a grant of property by the US government to the inventor, giving the owner of the patent the right to exclude others from making, using, offering for sale, or selling the invention in the US or importing it to this country.

The policy of the University of Virginia is to consider and, where appropriate, assist in the patenting and commercial development of discoveries or inventions which are the product of University research. Any person who may be engaged in University research shall be required to execute a patent agreement with the University in which the rights and obligations of both parties are defined.

The University Patent Policy can be found at this website:

<http://www.virginia.edu/~polproc/pol/xve2.html>

University of Virginia Patent Foundation 434.924.2175

The Patent Foundation is a private not-for-profit corporation that evaluates each of the many inventions generated by the University faculty and employees, protects those inventions which appear to have commercial potential, and then markets and licenses those rights to industry.

The Patent Foundation evaluates the intellectual property value and commercial research, and where warranted, seeks to patent those inventions and license them to industry. The Patent Foundation serves to promote the entry of University of Virginia-developed technologies into the commercial marketplace,

and to generate royalties which are then used to support further research. The Patent Foundation also supports and encourages local economic development by licensing to established and newly formed local companies, and serves as a University-wide resource for information about intellectual property and licensing. <http://www.uvapf.org/>

Technology Transfer

For many years it has been commonplace within the business sector of the economy to engage in transfers of information or manufactured devices, prototypes or materials, by means of a legal instrument, or through the provision of services, or through direct sales. Within the last twenty years, universities have picked up and adopted the label of technology transfer for similar activities. The phrase technology transfer in its broadest sense encompasses many activities at U.S. universities. Perhaps the best known and most widely used informal “transfer” mechanism is scholarly publication.

The term is used more narrowly to refer to the handing-off of intellectual property rights from the university to the for-profit sector for purposes of commercialization. This “passing over” or transfer is made possible through patenting of university-made inventions and assertion of copyright for university-developed software, multi-media teaching tools and educational materials. University-owned biological materials developed in university laboratories and registration of university trademarks add to the general pool of transferable intellectual property. Unlike industry, where transfer sometimes takes place as an actual sale of the information, article or service to be transferred, universities in almost all cases accomplish transfer of intellectual property through the licensing process. Bio-materials which are not captured as patents may be licensed or may be conditionally transferred under contracts known as “material transfer agreements”.

Material Transfer Agreements

Material Transfer Agreements (MTA) are used to document the transfer of biological or chemical substances from one entity to another, either to or from the University of Virginia. The MTA fixes in writing the rights and obligations

governing the distribution of biological or chemical substances owned or held by such parties to others. In exchange for granting the right to use the materials, the providing party places certain demands on the receiving party due to the proprietary nature of the material(s), the approved research plan, or the nature of the transfer itself.

Generally, an MTA imposes the following types of conditions: limits on the receiving party's use of the material(s) for specifically approved research purposes; rights to commercialize new inventions or technology; procedures to ensure the proper handling of material-related confidential information; proper acknowledgement by recipient scientist of the contribution of providing scientist in all written or oral disclosures; disclaimer of any warranty regarding the fitness or use of the material(s); limits on the potential liability for any damages or claims which may arise; restriction of access to material(s) and distribution to third parties; and incorporation of applicable laws and regulations regarding the handling and use of the material(s).

The University's Material Transfer Agreement, which is commonly used when material is being transferred to someone outside the University, may be found at this website:

http://www.virginia.edu/researchandpublicservice/research/researchpol/mta_for_m.doc

Research Integrity

The following website includes links concerning research conduct policies:

<http://www.virginia.edu/researchandpublicservice/research/researchpol/conduct.htm>

Objectivity in Research

The University of Virginia strives to support the highest standards of teaching, research, and public service. In an environment where personal integrity has been an integral part of the moral climate for nearly two centuries, a relationship of trust has been able to flourish. The importance of maintaining objectivity in all faculty endeavors, and continuing to make efforts in this direction, is paramount. To this end, the University has adopted an Objectivity in Research Policy.

Federal guidelines require the University to develop and implement an "objectivity in research policy." It is clear that federal funding agencies expect the University to develop a uniform policy for all sponsored research, not merely research funded by federal agencies. Investigators who have financial interests that might reasonably appear to be affected by the funded research grant are required to provide information on those financial interests at the time of proposal submission. The University will review the information provided by the investigator(s) to determine whether a conflict of interest exists. If there is a conflict, the University will, if possible, develop a strategy to manage the conflict of interest prior to any expenditure of the award.

Investigators submitting sponsored research proposals will be asked to identify significant financial interest that might reasonably appear to be affected by the sponsored research project. Significant financial interests include anything of monetary value including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). For additional information, see website: <http://www.med.virginia.edu/medicine/fhbook/ch3.html>

Research Misconduct

"Expressions of concern" involving issues of research misconduct should be brought to the attention of the Vice President for Research and Public Service or the Dean associated school who will determine if the complaint constitutes an "allegation" of research misconduct. This official will charge a Committee to conduct an "inquiry" to determine whether the allegation can be substantiated with sufficient evidence to warrant an "investigation." If investigation is warranted, this official will charge a Committee to examine evidence and information collected to determine whether misconduct has taken place. Necessary University sanctions or disciplinary action will be taken by the supervising Dean or appropriate senior academic official. The respondent may take action through normal grievance procedures.

Research Ethics

Research misconduct is defined as actions which cast doubt on the integrity of research and research results, such as (1) invention of data; (2) falsification of existing data; or (3) presentation as one's own of data obtained by another

without the latter's permission. The University of Virginia has two committees assigned responsibility for investigation of alleged misconduct. Investigation of suspected research misconduct in the School of Medicine will be conducted by a permanent Research Ethics Committee of the School of Medicine. The School of Medicine Research Ethics Committee serves at the request of the Dean of the School of Medicine as a permanent advisory committee. In addition to its investigatory responsibilities, it may from time to time, as it or the dean sees fit, issue statements or guidelines about research practices in the School of Medicine. Its membership includes the Assistant Provost for Research. The University Research Ethics Committee serves at the request of the Provost. Its purpose is to investigate allegations of misconduct committed during the conduct of University research by anyone other than a member of the School of Medicine.

Consulting Policy

Under certain circumstances full-time faculty may receive supplemental compensation for consulting outside the University or for assuming internal overload responsibilities outside the faculty member's normal responsibilities subject to certain limitations. Approval by the dean, Provost and Comptroller may be required. Faculty are encouraged to undertake such activities for the Division of Continuing Education but must receive prior approval in every instance. Primary responsibility for implementation of and accountability under the policy shall rest with the Provost, working through the deans of the schools. Also see "Faculty Overload Responsibilities For Supplemental Compensation" within the UVa Financial & Administrative Policies and Procedures at <http://www.virginia.edu/%7Epolproc/pol/xia1.html>

Office of University Industry Research Relations

The Office of University Industry Research Relations (OUIRR) is designed to assist faculty seek, secure and maintain research relationships with industrial sponsors and collaborators. To facilitate this process, the Office works with the Patent Foundation on intellectual property and new venture start up companies, The Office of Sponsored Programs (OSP) for industrial sponsored research funding, the UVA Foundation for use of the Research Parks as small scale start ups and full scale labs, and Virginia Gateway for linking University research with the high-technology business community. The Director of University Industry

Research Relations (Director) serves under the Vice President for Research and Public Service (VPRPS) and acts as a coordinator and point person to provide "one door" through which faculty and staff can pass for industry relations. Areas of responsibility will include:

- Contracts with industrial and other sponsors
- Research funding agreements
- Memoranda of understanding and agreement
- Partnering agreements
- Subcontracting
- Licensing and patent issues
- Conflict of interest
- Conflict of commitment
- Material Transfer Agreements

NOTES

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