

# CHAPTER 5: RESEARCH - ORGANIZATIONAL STRUCTURE FOR SPONSORED PROJECTS AND RESEARCH RELATED POLICIES

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This chapter covers the following:

1. Administration- an introduction to the organizations responsible for overseeing research policies and procedures at Duke University.
2. Policies - an overview of the policies with which Duke researchers must comply.

## 5.1 Administration

### 5.1.1 Research Policy and Administration

#### 5.1.1.1 Office of the Vice Provost for Research

The Office of the Vice Provost for Research (VPR) has overall responsibility for facilitating the research enterprise for Duke University's campus components (Arts & Sciences and Trinity College, Divinity School, The Fuqua School of Business, School of Law, Nicholas School of the Environment, Pratt School of Engineering, and University Centers and Institutes). The VPR works closely with the Provost Office, its staff, and the deans on research policy. The VPR supervises the offices of: Research Support (ORS), Postdoctoral Services (OPS), and Licensing and Ventures (OLV). The VPR oversees the University Committee on the Use of Human Subjects in Non-Medical Research, the Committee on Conflict of Interest, the Research Policy Committee, the Export Controls Program and also manages the Instrumentation Fund. Other areas of oversight include misconduct in research involving non-medical personnel (however, please note that the Misconduct Review Officer for non-medical personnel is the Vice Provost for Academic Affairs). In addition, the VPR participates in the management and allocation of research funds allocated by the Provost. The VPR oversees Campus-wide research planning efforts. This includes working with the OLV to encourage and support the development and marketing of Duke's intellectual property. The VPR (through the Administrative Development Group) is also responsible for the institutional research databases, including [Conflict of Interest](#) (COI) reporting system, and the [Sponsored Projects System](#) (SPS).

#### 5.1.1.2 Office of the Vice Dean for Research

The Office of the Vice Dean for Research is administratively responsible for several aspects of research operations at the School of Medicine. Areas of oversight include the Institutional Review Board (IRB) for the protection of human subjects in medical research, the Clinical Research Support Office (CRSO), conflict of interest, and misconduct in research. The office can be of assistance in questions regarding institutional resources and "dry lab" (clinical research) space, and will be increasingly involved in faculty mentoring. One component of the office seeks to match investigators and funding opportunities, and is also a good place to start when investigators have a new research idea and are looking for collaborators. The office (through the Administrative Development Group) is also responsible for the institutional research databases, including the [Faculty Research Directory](#) (FRd), the Research Executive (REX), [the Conflict of Interest](#) (COI) reporting system, and the [Sponsored Projects System](#) (SPS).

#### 5.1.1.3 Office of the Vice Dean for Basic Sciences

Within the School of Medicine, the Office of the Vice Dean for Basic Sciences serves as a liaison between the dean and the basic science faculty. The Vice Dean for Basic Sciences works with department chairs and faculty to implement the School of Medicine's strategic initiatives concerning research and education. The Vice Dean is also the administrative head of the graduate program within the school, and is jointly responsible (along with the Vice Provost for Research) for the Office of Postdoctoral Services.

#### 5.1.1.4 Research Support Services

The Research Support Services Office provides operational oversight within the Office of the Vice Dean for Research for the Human Subject Protection Program (Institutional Review Board), Animal Care and Use Program, [Clinical Research Support Office](#), conflict of interest and research misconduct. The Research Support Services Office serves as an institutional resource on the regulatory and ethical requirements for the responsible conduct of human and animal research. The Office also assists investigators in navigating the human and animal research process.

#### 5.1.1.5 Research Policy Committee

Chaired by the Vice Provost for Research, the Research Policy Committee is a standing committee of the University with representatives from the administration, Legal Counsel, and the colleges of Arts & Sciences, Business, Engineering, Environment, Law, Medicine, and Nursing. It is responsible for:

- Writing Duke University's research policies

- Reviewing institutional research policies and procedures on a regular basis and proposing modifications, as necessary
- Ensuring that the research community is educated in the standards for the conduct, reporting, and supervision of research

#### **5.1.1.6 Offices of Research Administration and Research Support**

The Office of Research Administration (ORA) and the Office of Research Support (ORS) serve as the pre-award research administration offices for Duke University, and also have responsibility for certain post-award functions, as detailed below. ORA is responsible for the institutional review and approval of externally sponsored research for Duke Medicine, while ORS has this responsibility for the Campus Schools.

Specific functions of both ORA and ORS include the following:

- Reviewing and approving proposals to assure that they comply with both sponsor and Duke guidelines; that budgets are accurate and consistent, with clear and concise justifications; and that both direct and indirect costs are appropriately recovered. All Duke proposals fall under their purview, with the following exceptions: construction and endowment proposals, which are handled by the Office of Corporate and Foundation Relations; fellowship proposals, which do not require review or approval by any University office, *if* the funds are awarded directly to an individual *and* they do not require any University involvement during the proposal or award processes.
- Negotiating and accepting grants and contracts on behalf of the University
- Issuing subcontracts
- Serving as the principal liaison between the University and its sponsors
- Approving programmatic and budgetary changes to sponsored projects (including the establishment of new fund codes)
- Facilitating closeout documentation
- Working with the Vice Provost for Research and the Research Policy Committee to develop and implement research policies and procedures

ORS, for its part, has the following additional responsibilities:

- Coordinating submissions for institutionally limited funding opportunities for both Campus Schools and Duke Medicine
- Administering the Institutional Review Board (IRB) for the Protection of Human Subjects in Non-medical Research (as noted below, Duke's medical-research IRBs are administered by a dedicated IRB Office)
- Administering the Campus Compliance Program for conflict of interest, committed effort, and subrecipient monitoring
- Administering the Export Controls Program for both the Campus Schools and Duke Medicine
- Disseminating funding information to both Campus Schools and Duke Medicine

#### **5.1.1.7 Office of Corporate Research Collaborations**

The Office of Corporate Research Collaborations (OCRC) drafts, reviews, and negotiates agreements for commercially supported research, both clinical and non-clinical, in the School of Medicine and related departments, and approves these agreements for institutional signature. These include clinical trial agreements, sponsored research agreements, data analysis agreements, network participation agreements, educational program support agreements (other than those for CME credit which are handled by the Office of Continuing Medical Education), subagreements under any of these, and an array of other similar contracts. Additionally, OCRC handles Confidentiality Agreements and agreements for transfers of research materials, data and equipment (Material Transfer Agreements, Collaborative Research Agreements, HIPAA Data Use Agreements, Data Transfer Agreements, Research Equipment Loans), and other related documents for these research endeavors for all of the University, including commercial, government, and academic sources and recipients. OCRC sees that agreements are consistent with Duke policies, applicable federal and state laws, and applicable IRS regulations relating to Duke's status as a not-for-profit organization making extensive use of facilities funded with tax-exempt bonds. OCRC advises faculty on matters arising from these agreements, particularly publication rights, intellectual property rights, confidentiality obligations, human subjects protections, and liability issues. OCRC coordinates its activities with numerous other Duke offices, including the Office of University Counsel, Office of Research Administration,

Office of Risk Management, Institutional Review Board, Clinical Research Support Office, and Office of Licensing and Ventures. OCRC advises the Office of Research Administration and the Office of Research Support on matters regarding intellectual property terms for foundation and government-sponsored research. OCRC advises the Duke University Health System (DUHS) Institutional Review Board on terms for IRB Authorization Agreements in which external entities are seeking coverage from the DUHS IRB.

#### **5.1.1.8 Office of Sponsored Programs**

The Office of Sponsored Programs (OSP) exists to perform the post-award administration of sponsored projects at Duke University, for both Campus Schools and Duke Medicine. OSP's mission is to safeguard project funds, maximize Duke's cash flow position, maintain good relations with sponsors and Duke personnel, and to be viewed by principal investigators and departmental administrators as facilitating the progress of their sponsored projects. Specific responsibilities include:

- Preparing financial and other non-scientific reports to sponsors on sponsored projects
- Monitoring projects for compliance with sponsor and Duke requirements
- Assuring reimbursement of project expenditures
- Providing support to departmental administrators
- Coordinating award documentation and approval processes with the Office of Research Support, Office of Research Administration, and other Duke service departments
- Answering questions and providing information to sponsors and Duke personnel

### **5.1.2 Compliance Offices**

#### **5.1.2.1 Compliance Office, Campus Compliance Program**

The School of Medicine Compliance Office serves as a resource to help ensure that the School's practices are consistent with federal and state laws and regulations as well as Duke policies and procedures. The Office provides general oversight and guidance for research financial compliance, clinical trials billing, human subjects research, conflict of interest, and HIPAA privacy as well as other regulatory risk areas. The Office provides advice and consultation for the research community and administration on compliance issues. The Office also proactively reviews compliance risk areas to identify areas of needed improvement and partners with operational entities and the Research Community to address any identified deficiencies. It maintains a Compliance Integrity Hot-line available 24 hours a day, which provides for anonymous reporting of compliance concerns. The Office works cooperatively with the Duke University Health System Compliance Office on the development of compliance training materials. The Chief Compliance Officer of the School of Medicine reports to the Audit Committee of the Board of Trustees through the Dean of the School of Medicine and the Chancellor for Health Affairs.

The Campus Compliance Program is administered through the Office of Research Support (ORS) and is closely associated with the ORS grants and contracts section. The compliance staff, headed by the Assistant Director for Compliance, works closely with the Campus Schools' Conflict of Interest Committee, chaired by the Vice Provost for Research, in addressing potential conflicts of interest relating to all Duke individuals with faculty status, all postdoctoral scholars and affiliates, and other individuals who have potential conflicts of interest relating to sponsored research. Additionally, compliance staff work in the areas of committed effort and subrecipient monitoring.

#### **5.1.2.2 Institutional Ethics and Compliance Program**

The Institutional Ethics and Compliance Program assures that Duke meets the requirements of federal legislation for maintaining an effective compliance program. It promotes ethical behavior for all members of the Duke community and coordinates the efforts of many managerial people who have compliance responsibilities for laws and regulations effecting Campus Schools, the Schools of Medicine and Nursing, and the Duke University Health System. These people are responsible for risk assessments regarding the laws under their purview and the development of monitoring plans consistent with those risk assessments. Operationally, the plan is managed through the Compliance Coordinating Committee, comprised of people with the most significant areas of compliance responsibility. The Steering Committee - comprised of the President, Chancellor of the Health System, Provost, Executive Vice President, General Counsel, and two Deans - oversees the program. The program reports to the Audit Committee of the Board of Trustees.

### **5.1.2.3 Institutional Review Board Offices**

Duke University has two distinct Institutional Review Board (IRB) offices. The Duke University Health System (DUHS) IRB reviews all research with human subjects that is sponsored by DUHS, involving as key personnel any employee or agent of DUHS, including students, residents or fellows, utilizing any DUHS property or facility, or utilizing any DUHS non-public information. The DUHS Institutional Review Board Office coordinates the activities of the nine convened boards assigned to review medical research projects involving human subjects, as well as the expedited reviews conducted by the IRB Chairs and Vice Chairs. The DUHS IRB also reviews non-medical research projects involving human subjects, if those projects meet any of the definitions above. All other non-medical research projects involving human subjects are reviewed by the Institutional Review Board for the Protection of Human Subjects in Non-medical Research, coordinated by the Human Protections Administration group within the Office of Research Support (see above).

### **5.1.2.4 Office of Animal Welfare Assurance**

The Office of Animal Welfare Assurance (OAWA) provides many services to assist researchers with animal care or use at Duke. Services provided by the OAWA include: protocol development, administrative pre-review of protocols, veterinary pre-preview of protocols and amendments, and laboratory preparation for Institutional Animal Care & Use Committee semiannual inspections. The OAWA also serves as the administrative support for the Institutional Animal Care and Use Committee (IACUC). OAWA also is responsible for monitoring Duke's overall compliance with regulations governing animal care and use, auditing research animal practices on campus, interacting with regulatory agencies, and responding to public concerns over animal care or use at Duke.

### **5.1.2.5 Division of Laboratory Animal Resources**

The Division of Laboratory Animal Resources (DLAR) is responsible for the daily care and welfare of all vertebrate animals on the Duke campus. DLAR is committed to programs of excellence in veterinary care and laboratory animal management practices for all species used in Duke research endeavors. DLAR provides animal procurement, housing, veterinary care, assistance with experimental design, and technical services, etc.

### **5.1.2.6 Occupational & Environmental Safety Office**

The Occupational & Environmental Safety Office (OESO) is committed to supporting the mission of Duke University (Campus Schools and Duke Medicine) to provide excellence in patient care, research, and teaching. In support of this mission, OESO ensures that the environment is in balance with all regulatory requirements, relevant community standards, and institutional resources. This balance is accomplished by identifying hazardous conditions, developing appropriate control measures, implementing controls through specialized training, and monitoring the effectiveness of the controls.

### **5.1.2.7 Research Integrity Office**

The Research Integrity Office supports the responsible conduct of research in the Schools of Medicine and Nursing. It has administrative responsibility for the conflict of interest reporting and management process, and the research misconduct process.

### **5.1.2.8 Export Controls Program**

Compliance with export control regulations for both the Campus Schools and the Schools of Medicine and Nursing is managed by the Director of Export Controls in the Office of Research Support.

The Director assists faculty, staff, and students with compliant exports from the United States. This includes the transmission or shipment of items out of the United States AND the release of technology, data, or software to a foreign national, even if it occurs in the United States. The Director will determine if goods and/or technology are controlled under the Export Administration Regulations or the International Traffic in Arms Regulations for the intended destination. The Director will also determine the applicability of any exemptions or licenses.

In addition, the Director assists faculty, staff, and students planning to travel to any of the embargoed or sanctioned countries on the Treasury Department's Office of Foreign Assets Control lists. The Director helps determine what restrictions are in place and if a license is required for the planned activity. Faculty, staff, and students may wish to consult the Director of Export Controls when giving speeches overseas or conducting research abroad in any country. The Director prepares and submits, on behalf of faculty, staff, and students, any applications for export or travel licenses.

Academic catalog courses are exempt from export controls as is information in the public domain.

#### **5.1.2.9 Office of Research Costing Compliance**

Duke University is committed to the highest standards of excellence and integrity in all research endeavors. The Office of Research Costing Compliance (RCC) helps to advance Duke's research mission and to support the culture of compliance by providing innovative and meaningful education programs, useful tools, resources and guidance, and excellent customer service to the research community including principal investigators, business managers, grant and financial administrators, and RCC Certification students. The office also monitors for compliance by testing research transaction detail in support of the Institutional Ethics and Compliance Program.

#### **5.1.2.10 Office of Internal Audits**

The objectives of the Office of Internal Audits (OIA) are to assist Duke University faculty and staff in the effective discharge of their responsibilities by furnishing them with analyses, appraisals, recommendations, counsel, and information concerning the activities it reviews, and by promoting effective control at a reasonable cost. The office has authorization for full and complete access to any of Duke University's records, either manual or electronic, as well as physical properties and personnel relevant to a review. The scope of work of OIA is to determine whether Duke's network of risk management, control, and governance processes, as designed and represented by management, is adequate and functioning in a manner to ensure:

- Risks are appropriately identified and managed
- Interaction with the various governance groups occurs as needed
- Significant financial, managerial, and operating information is accurate, reliable, and timely
- Employee's actions are in compliance with policies, standards, procedures, and applicable laws and regulations
- Resources are acquired economically, used efficiently, and adequately protected
- Programs, plans, and objectives are achieved
- Quality and continuous improvement are fostered in Duke's control process
- Significant legislative or regulatory issues impacting Duke are recognized and addressed properly

### **5.1.3 Technology Transfer**

#### **5.1.3.1 Office of Corporate & Venture Development**

The Office of Corporate & Venture Development (CVD) serves Duke University (Campus Schools and Duke Medicine) and is responsible for commercially-sponsored research, patents and licenses, new venture activity, corporate gifts, and corporate vending relationships. CVD includes:

- Vice Chancellor Corporate & Venture Development
- Office of Licensing & Ventures (see below)
- Office of Corporate Research Collaborations (see above)
- Corporate Alliances & Development
- Corporate Programs

#### **5.1.3.2 Office of Licensing & Ventures**

The Office of Licensing and Ventures (OLV) is responsible for patents, technology licenses, and startup venture development for technologies and inventions originating in all University laboratories. Duke faculty should submit patent disclosures to this office and should contact the office if individuals or groups outside of the University express interest in working with them and with Duke towards further development or commercialization of new technologies and inventions. Patent disclosure forms and answers to other FAQs are at the OLV website ([www.olv.duke.edu](http://www.olv.duke.edu)). OLV's functions include:

- Maintaining a database of University technology and capabilities
- Identifying and patenting transferable technologies
- Developing and implementing commercialization strategies
- Pursuing commercialization opportunities through option and license agreements and through venture capital opportunities.

## **5.1.4 Sponsor Relations**

### **5.1.4.1 Office of Federal Relations**

The Office of Federal Relations represents the University in Washington, D.C., on legislative and regulatory matters of interest to Duke. These issues include research and student aid funding, the reauthorization of relevant statutes (such as the Higher Education Act), visa and immigration matters, technology transfer, and intellectual property law. Additionally, the Office of Federal Relations seeks to position the University as a resource for policy makers in Washington, assists them in identifying and contacting faculty members at Duke who are interested in applying their expertise to policy development, and coordinates Duke advocacy efforts.

### **5.1.4.2 Office of Government Relations**

The Office of Government Relations serves as the point of strategy development and implementation on health-related legislative and policy issues at the federal and state government levels for Duke University Health System, including Duke University Hospital, Durham Regional Hospital, Duke Raleigh Hospital, the Private Diagnostic Clinics (PDC), Duke Medical Center basic sciences departments, the School of Medicine and School of Nursing. The office is also responsible for all state-level legislative and policy issues affecting Duke University including the Campus Schools.

### **5.1.4.3 Office of Corporate & Foundation Relations**

The Office of Corporate & Foundation Relations (CFR) works with faculty and staff throughout the University to raise funds for priority programs and institutional initiatives. Its primary charge is to support, complement, and enhance Campus Schools' efforts to secure corporate and foundation funding in the areas of student scholarships and financial aid, faculty research, and program operation funds. Services include:

- Facilitating the development of program concepts
- Identifying potential funders
- Developing strategies for working with corporations and foundations
- Reviewing and approving construction and endowment proposals to corporations and foundations submitted by Duke University Campus Schools.

### **5.1.4.4 Duke Medicine's Office of Foundation Relations**

The Office of Foundation Relations supports priority Duke Medicine initiatives by serving as the interface between Duke Medicine faculty programs and projects and the grant-making organizations and foundations that support medical research, education, and healthcare delivery. It works with the full spectrum of private foundations, from small family-based entities, to corporate philanthropic offices and to the nation's largest philanthropic organizations. As a component of Duke Medicine's Development and Alumni Affairs office, it works closely with its colleagues, the major gift officers and development directors, who serve the clinical, research, and educational missions of Duke Medicine. Services include:

- Identification of potential foundation resources
- Foundation background research
- Contact with, introduction to, and follow-up stewardship with foundations
- Proposal development and/or guidance
- Proposal review

## **5.2 Policies**

### **5.2.1 The Investigator**

#### **5.2.1.1 Principal Investigator Status**

It is University policy that only those with whom the University has or intends to have an on-going contractual relationship may serve as principal investigators or program directors for projects - research or otherwise - supported by external funding sources. See Appendix P, "Principal Investigator Status," for details on how this policy is implemented in Campus Schools and in the Schools of Medicine and Nursing.

### **5.2.1.2 Roles and Responsibilities**

While the University is ultimately responsible for any sponsored project, it is the Principal Investigator (PI) or Program Director (PD) who bears primary responsibility for directing both the research and administration of a grant, cooperative agreement, training or public service project, contract, or other sponsored project.

- The PI/PD is responsible for the completion, accuracy, and timeliness of all technical reports required by the sponsor.
- The PI/PD is responsible for ensuring that all financial aspects of the project are done in a timely manner so that financial reports can be submitted by the Office of Sponsored Programs (OSP) as required by the sponsor.
- In consultation with the department chair, the PI/PD ensures sufficient financial administrative oversight to manage the financial and other administrative functions related to the grant.
- In conjunction with the departmental financial administrator, the PI/PD ensures compliance with all applicable financial and administrative regulations and Duke University policies and procedures.
- The PI/PD is responsible for validating his or her own effort certification report in accordance with Duke's General Accounting Procedures and for validating the effort certification for any staff who work under the PI/PD's supervision.
- In conjunction with the OSP, the PI/PD approves final payment to subcontractors.

## **5.2.2 Integrity**

### **5.2.2.1 Conflict of Interest**

Duke University is committed to ensuring its faculty an open and productive environment in which to conduct teaching, patient care, and research. However, the ever-increasing complexity of our society and the various relationships between faculty members and outside institutions require attention to ensure the avoidance of real or apparent conflict of interest issues.

A *conflict of interest* can be said to exist when a member of the University community has a relationship with an outside organization such that his or her activities within the University could be biased by that relationship in a direction that would ultimately provide direct financial benefit to the individual or a close family member.

Please refer to [Appendix O](#), "Conflict of Interest Policy," for details on how Duke addresses issues of conflict of interest.

In addition to Duke policy, principal investigators must also adhere to sponsor policies governing conflict of interest. For instance, investigators applying to the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies, as well as to the National Science Foundation (NSF), are required to disclose - at the time of proposal submission - any significant financial interests that might affect or be affected by the conduct of the research in their proposals. [Further information on PHS and NSF policies](#) may also be found on the Duke Research Policies website.

### **5.2.2.2 Conflict of Commitment**

A conflict of commitment can be said to exist when a member of the University community has a relationship that requires a commitment of time or effort to non-University activities, such that an individual, either implicitly or directly, cannot meet the usual obligations to the University. In addition, the distribution of a faculty member's effort among, for example, research, teaching, committee responsibilities, and outside consulting may raise issues of conflict of commitment.

Problems of conflict of commitment do not normally arise, unless the University or the government is misled in its understanding of the amount of intellectual effort actually being devoted to the activity in question. Any faculty member planning to do research for the government under a stipulating agreement that a specified fraction of his or her effort will be devoted to the research should check with the Office of Research Support or the Office of Research Administration regarding procedures to ensure demonstrable compliance with the indicated requirements.

### **5.2.2.3 Consulting by Duke Faculty**

Faculty and senior administrative staff members may spend up to four days per month in outside activities or consulting work, averaged over an annual period of service (the academic year for faculty on a nine-month basis). Such activities are to be reported to: 1) the Provost, for those outside the Schools of Medicine and Nursing; or 2) the

Dean, School of Medicine/Vice Chancellor for Medical Center Academic Affairs. A copy of the report should be sent to the department chair. Lectures or brief consulting activities to assist another educational institution need not be reported.

#### **5.2.2.4 Guidelines for Authorship and Authorship Dispute Resolution**

Duke University has instituted authorship guidelines and dispute resolution procedures to supplement its policy on Misconduct in Research (see [Appendix P](#), Faculty Handbook). A separate but complementary policy was deemed advisable because many allegations of misconduct actually stem from and involve disputes over authorship. Because disputes over authorship rarely involve research misconduct, the Misconduct in Research policy is usually not the appropriate mechanism for resolving such disputes. Some departments and divisions at the University already provide guidelines for authorship to faculty and students, and expectations are clear on all sides. However, too frequently this does not happen, and bitterness and accusation may result. The policy on authorship, therefore, is designed to fill in the gaps and offer broad guidance across the University.

#### **5.2.2.5 Misconduct in Research**

Misconduct in research is defined as fabrication, falsification, or plagiarism. These and other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research are covered by the Duke University Policy and Procedures Governing Misconduct in Research (in [Appendix P](#)). Please note that "misconduct," for these purposes, does not include honest error or honest differences in interpretations or judgments of data.

#### **5.2.2.6 Nepotism**

The policy on nepotism is found in [Chapter 4](#) of the Faculty Handbook and is also incorporated in the conflict of interest policy. A nepotistic relationship must have appropriate approvals and must be disclosed on the annual conflict of interest form filled out by all faculty and by those granted special principal investigator status. In addition to a waiver from the University, the policy requires disclosure of the relationship to the sponsor if a family member is included on a proposal, whether as a collaborator or as an employee: "Spouses or relatives may be employed, however, as collaborators in subsidized research projects where such collaboration has been specifically approved by the sponsoring agency." (Chapter 4, page 12)

### **5.2.3 Intellectual Property**

#### **5.2.3.1 Intellectual Property Rights**

Duke's primary mission lies in the creation and dissemination of knowledge in works of the intellect, in whatever medium (tangible or otherwise) they may be embodied or expressed. Duke's policy on intellectual property rights (see [Appendix P](#)) recognizes and acknowledges that these rights (other than patent rights - see below) may arise in such works from time to time as a result of efforts by members of the Duke community. This policy addresses certain recurring issues of ownership with respect to such rights.

#### **5.2.3.2 Inventions, Patents, and Technology Transfer**

The creation of knowledge in the service of society is at the core of the Duke mission. When new inventions and patentable technology arise during the course of ongoing University research activity, researchers have a responsibility to disclose these new technologies and inventions to the [Office of Licensing and Ventures](#) for evaluation and potential licensing. Duke's policy on inventions, patents, and technology transfer (in [Appendix P](#)) has been written to assure that inventions resulting from Duke research are utilized in a manner consistent with University policies and values. The policy is written to facilitate and encourage patent protection, licensing, and the development and marketing of inventions where appropriate.

#### **5.2.3.3 National Institutes of Health (NIH) Public Access Law**

The National Institutes of Health (NIH) has released its new Public Access Policy which became effective April 7, 2008. Under a new federal law, NIH is now requiring that the author's final version of any peer-reviewed journal article resulting from NIH-funded activities must be submitted to the PubMed Central (PMC) repository, where it will be made available to the public within 12 months after the journal article is published. This new policy has several compliance issues that are addressed on the [NIH Public Access Law](#) link on the Duke Medical Center Library website.

#### **5.2.3.4 Research Records: Sharing, Retention, and Ownership**

The University, its faculty, and its trainees have a common interest and a shared responsibility to assure that research is appropriately recorded, shared, and retained. Consequently, researchers have a responsibility to retain original research results, in whatever form they may take, for a reasonable length of time to protect intellectual property rights, support scholarly collaboration and publication, and answer any questions that may arise about the conduct of the research. The University likewise has an interest in, and shared responsibility for, assuring that research is appropriately recorded, archived, and available for review under appropriate circumstances. Consequently, in May 1994, the University adopted a policy on Data Retention and Access which was revised in January 2007 and renamed *Research Records: Sharing, Retention, and Ownership*. The complete text of the revised policy is available in [Appendix P](#).

#### **5.2.4 Academic Freedom**

##### **5.2.4.1 Classified Research**

No research can be undertaken at the University that involves information, research, or results of research that are, or would be, classified by the sponsor or any third party. For example, research for the federal government under a subcontract which is classified as secret is *not* permitted. The University-Industry Guidelines (see below) ensure researchers' rights to publish research results without unduly long delays, and to engage in scholarly discussion with their colleagues.

Faculty members may arrange on an individual basis to participate in projects involving such research through other institutions. Duke University does not have any level of institutional clearance, nor can it arrange clearance on behalf of its faculty. Clearance is secured on a need-to-know basis by the organization for whom the work is to be done.

##### **5.2.4.2 University-Industry Guidelines**

Contracts received from private industry may include provisions that are contrary to University policy or that put the University at risk. Recognizing the potential conflict between the primary missions and interests of a university and those of private industry, the University has adopted a policy on industry-sponsored research. All research grants and contracts held by Duke University must conform to these University-Industry Guidelines (in [Appendix P](#)). Contracts will be negotiated by Office of Research Administration, Office of Research Support, or Office of Corporate Research Collaborations to assure that they do conform to these guidelines.

##### **5.2.4.3 Export Controls**

It is the policy of Duke University to fully abide by federal and state laws and regulations, including the Export Administration Regulations (EAR), the International Traffic in Arms Regulations (ITAR) and other bodies of export regulations. It is also imperative that the University adhere to its stated mission and policies. The export of materials (matter) to any foreign country may require a license or exemption to be exported. The release or disclosure of controlled technology or technical data to any foreign person, **whether it occurs in the United States or abroad**, is deemed to be an export, and may require either an export license, exemption documentation, or other form of legal authorization. Foreign persons include foreign individuals, corporations, government agencies, or other foreign entities. U.S. individuals are defined for export purposes as U.S. citizens, U.S. permanent residents (“green card holders”) and certain individuals in the United States under refugee or asylum status. University research may be exempt from export control laws under the “Fundamental Research Exemption” by ensuring that it meets the definition of fundamental research, which is basic and applied research that is conducted with a clear intent to publish the results, and to do so without restriction or approval, and that the research does not voluntarily exclude the participation of foreign nationals.

The Duke policies that support the Fundamental Research Exemption provided by the export control regulations are broadly applicable to all sponsored research, regardless of the source, and are articulated in the University-Industry Guidelines, as follows:

- A sponsor shall have the privilege to define broadly the topic of the research to be funded. The university principal investigator shall have final authority over the design and control of that research.
- Final determination of what may be published or not published shall remain with the University. The University will also retain the right to make a final determination with respect to publication of computer

programs. Exceptions may be granted by the Provost only after detailed review and upon the advice of the Research Policy Committee.

- A sponsor may, prior to publication, review materials resulting from research it has sponsored in those cases where possible proprietary right may be involved or where the University has been provided a sponsor's proprietary information. Such reviews should not delay publication for more than ninety (90) days, except with the approval of the Provost.
- It is also the responsibility of each individual researcher to protect freedom to communicate with colleagues and to refuse to enter into sponsored agreements that will restrict that freedom in unreasonable or unacceptable ways.

#### **5.2.4.4 Faculty and Staff Travel Abroad**

The University maintains a Duke Restricted Regions List of countries, regions, or areas that pose high risk. The [Restricted Regions List](#) is updated whenever conditions warrant by the [International Travel Oversight Committee \(ITOC\)](#), a joint faculty-administrative body that reports to the Provost. Travelers should also contact the Office of Export Controls prior to travel as there are multiple lists of countries that have been embargoed or sanctioned by the U.S. Government. This means that travel to these countries may have restrictions or require a license.

There are no restrictions on faculty and staff travel to any country or location, but faculty and staff are expected to consult the Duke Restricted Regions List and the Office of Export Controls and to explore other sources of information in arriving at their own judgment with respect to the level of risk involved. No faculty can be required to travel to a location on the Duke Restricted Regions List. Faculty and staff are requested to register their travel plans on the [Duke Travel Registry](#) web site. The Registry will be the first source of information to be consulted in case of a health emergency, natural disaster, or a crisis of civil or political unrest in a foreign location that requires assistance or evacuation.

Faculty and staff who travel internationally will be covered by Duke's international travel insurance policy. Faculty and staff planning to travel to a country sanctioned by the U.S. Government must also clear their travel plans with the Export Controls Office to ensure that any required approvals or licenses are in place prior to departure and that they are in compliance with federal regulations.

### **5.2.5 Protection**

#### **5.2.5.1 Use of Human Subjects in Research**

In order to conduct research with human subjects, investigators at Duke must do two things:

1. Become certified to conduct research with human subjects.
2. Obtain approval for research protocols.

Both the certification of investigators and the approval of protocols are required of Duke by the federal [Office of Human Research Protections](#) and the [Food & Drug Administration](#). Pertinent policies are discussed in [Appendix P](#), in the section entitled "Protecting Human Subjects in Nonmedical Research." For information regarding human subjects in medical research refer to the [Medical Center IRB](#) policies.

#### **5.2.5.2 Animal Care and Use**

All research, educational, and testing protocols performed by Duke faculty, staff, or employees, involving vertebrate animals either at Duke University or other sites, regardless of funding source, must be reviewed and approved by the [Institutional Animal Care and Use Committee \(IACUC\)](#). All animal care and use must be conducted in strict observance of federal guidelines and accreditation policies. All Duke-approved protocols must comply with the institutional policies and operating procedures for animal care and use. Policies, forms for application, expectations of care and use, and other program information is available at the animal program website: <http://vetmed.duhs.duke.edu>. Questions concerning animal care and use applications, procedures, or processes may be directed to: [IACUC@duke.edu](mailto:IACUC@duke.edu). Telephone questions may be directed to: Office of Animal Welfare Assurance at 919.688.6720.

## 5.2.6 Safety

### 5.2.6.1 Use of Recombinant DNA in Research

All research involving recombinant DNA must comply with federal regulations and guidelines and must be registered with the University (this applies to Campus Schools, Schools of Medicine and Nursing, and Health System investigators). Registration forms must be completed and submitted to the Biological Safety Division of the Occupational and Environmental Safety Office (OESO) for review and approval by the Institutional Biosafety Committee (IBC) in accordance with NIH rDNA Guidelines.

If the research involves viral vectors, there is a separate viral vector registration form that must be completed and submitted to the Biological Safety Division for IBC review and approval. If viral vector work is to be conducted in animals, a Standard Operating Procedure for safe handling of animals must also be submitted for IBC review and approval.

Experiments involving the deliberate transfer of rDNA into human subjects must also be reviewed and approved by the IBC, IRB, and the NIH Office of Biotechnology Activities. The Clinical Research Pharmacy and Infection Control must also approve the clinical procedures when a biological vector is used in a clinical trial.

A flow chart with these requirements and links to appropriate forms can be found at <http://www.safety.duke.edu/LabSafety/Docs/ResearchApprovalProcess.ppt>.

### 5.2.6.2 Use of Select Biological Agents

The purpose of Duke University's policy on the [transfer, receipt, and storage of select agents](#) is to ensure that "select agents" on Duke University campuses are handled safely, secured properly, and properly registered with the Department of Health and Human Services, Centers for Disease Control and Prevention and/or the United States Department of Agriculture, Animal Plant Health Inspection Service.

Each principal investigator (PI) is held responsible for assuring that they register all possession, transfer, and receipt of Select Agents. They are also responsible for assuring that their laboratories fully comply with all prescribed safety policies and procedures. Consequently, all PIs must work closely with the Director of the Biological Safety Division of the Occupational and Environmental Safety Office (who serves as Duke's Responsible Official, or "RO") to assure compliance with this standard.

The following are other duties of the PI:

- The PI must develop a detailed standard operating procedure (SOP) for each Select Agent used in the laboratory. The procedure should address each of the following at a minimum: 1) means of limiting access to the lab, 2) means of securing the agent and the laboratory, 3) types of personal protective equipment and ventilation controls to protect workers from exposure, 4) post-exposure procedures, 5) waste handling and disposal, 6) spill and decontamination procedures, and 7) recordkeeping methods.
- The completed SOP is submitted to the RO for review and approval.
- The PI must provide the RO with a drawing of the laboratory in which the Select Agent is used. The drawing shall include 1) fumehood and/or biosafety cabinet, 2) storage refrigerator and/or freezer, 3) air supplies and exhausts, 4) emergency eyewashes and showers, 5) handwashing sink, and 6) autoclave.
- The PI shall oversee the day-to-day adherence to the SOP.
- The PI shall provide the RO with all records of transfer or receipt (Form EA-101).
- The PI shall insure that all personnel with access to the Select Agents have completed a Security Risk Assessment with the Department of Justice prior to work in the laboratory area.

### 5.2.6.3 Use of Hazardous Materials

All work involving the use of hazardous materials must comply with federal, state, and local regulations regarding the shipment, handling, and disposal of such materials. As with recombinant DNA (see above), use of such materials may require the review and approval of the Institutional Biosafety Committee (IBC) or other institutional authority. Hazardous materials include infectious, radioactive, carcinogenic, teratogenic, mutagenic, corrosive, and flammable materials. Principal investigators (PIs) who use hazardous materials and will generate chemical and/or radioactive wastes must register as a waste generator with the Occupational and Environmental

Safety Office (OESO) to assure proper management of regulated wastes. PIs should provide a list of all chemicals used in the research to OESO to assure compliance with the Toxic Substances Control Act (TSCA) and to the notification requirements of the Emergency Preparedness and Community Right-to-Know Act.

Certain chemical materials have been designated as “Particularly Hazardous”. These include materials that are highly toxic, carcinogenic, or affect human reproduction. Investigators using any of these materials are required to prepare a written standard operating procedure that specifically identifies the methods of use as well as required protective measures. A list of these chemicals is available on the OESO website: <http://www.safety.duke.edu/LabSafetyManagement/PHSSearch.aspx>.

#### **5.2.6.4 Radiation Safety**

For radioactive materials and X-ray units specifically, use in research requires obtaining an authorization from the appropriate Institutional Radiation Safety Committee. To obtain an authorization, one must a) be a full-time member of the faculty, b) have training and experience commensurate with the types and amounts of radioactive materials you intend to use, and c) submit an application for review and approval by the appropriate Institutional Radiation Safety Committee.

#### **5.2.6.5 Laser Safety**

Lasers are a potential safety hazard in the laboratory, and Duke's Laser Safety Program is designed to address that hazard, specifically for Class 3b and Class 4 lasers, which pose the most serious risks. Under Duke policy, a faculty member responsible for such a laser is called a Principal Laser User (PLU). The PLU is directly responsible for the safe use of the lasers under his or her control, and must complete the online Laser Registration Form for each Class 3b or Class 4 laser.

#### **5.2.6.6 Reporting Accidents and Injuries**

Accidents and injuries that occur on the job must be reported to a supervisor as soon as possible. Medical attention should be sought immediately if the injury or illness is severe, and all incidents should be documented by completing the Report of Work-Related Injury or Illness. All human blood or body fluid exposures should be reported immediately to the Duke University Exposure Hotline (115 from a campus phone; 684-8115 from other phones). This information is important in helping Duke evaluate the circumstances of the incident and develop strategies for prevention of reoccurrences. All injuries, illnesses, spills, escaped animals, or other accidents involving material containing rDNA must also be reported to the Biological Safety Division of OESO. Such incidents may also need to be reported to the NIH Office of Biotechnology Activities.

#### **5.2.6.7 Safety Training Requirements**

Occupational and Environmental Safety Office (OESO) assigns training and other requirements to positions based on a risk assessment performed jointly by OESO and supervisors. Individual requirements are identified on the OESO on-line training page that can be accessed at <http://www.safety.duke.edu>. All identified requirements should be completed within the time frame specified on this page.

### **5.2.7 Stewardship**

#### **5.2.7.1 Research Costing Compliance Policy**

As a recipient of federal research awards, Duke is accountable to sponsoring agencies for financial compliance with appropriate agency regulations. Each employee of Duke University who is involved in sponsored projects administration has an obligation to ensure compliance with sponsor and University requirements for managing sponsored funds.

Duke has addressed this responsibility, in part, by instituting a strong compliance program. A key component of this program includes mandatory training of staff and faculty with grant-related financial responsibilities. In addition, Duke offers a voluntary comprehensive program of study leading to a certificate in Research Costing Compliance.

The Research Cost Compliance website provides a consolidated source of information regarding financial compliance for sponsored research. The site includes a key document summarizing the roles and responsibilities for those involved in financial compliance.

### **5.2.7.2 F&A Cost Recovery Policy on Grants and Contracts**

It is the University's policy to *require* the inclusion of full facilities and administrative (F&A) cost recovery on all proposals for external funding, except for gifts and sponsors with a stated policy of limiting or eliminating the F&A rate. In these instances the Duke policy is waived.

Direct costs of externally sponsored grants and contracts may include the salaries and wages of personnel working on these projects, the cost of equipment, travel, supplies, materials, and other such project-specific expenses. In addition to these direct costs, the University incurs a significant amount of indirect costs that are associated with projects, referred to as F&A costs. F&A costs cannot be related precisely to any individual grant or contract, since they include such items as: (1) the cost of maintenance, heating, lighting, and cleaning in buildings where sponsored research is conducted; (2) the administrative costs to the University of such components as procurement, accounting, and other units that provide services to grant and contract recipients; and (3) central support services and facilities, such as the libraries. These costs are real and the collection of F&A costs ensures the maintenance of the University infrastructure necessary for carrying out sponsored research activity.

Sponsors - particularly the federal government - recognize the need to reimburse the University for the F&A costs associated with the projects they support. To facilitate this reimbursement, the federal government negotiates the F&A cost recovery rate with the University, based on a periodic review. This process utilizes data obtained from an annual calculation of Duke's F&A costs, applied on a pro-rata basis against certain direct costs charged to its grants and contracts.

In addition to the rate associated with most on-campus research, there are several other rates set by the federal government for Duke University, related to such things as off-campus research facilities or certain special facilities at Duke, such as the research vessels. These rates are listed in the "F&A Costs" section of the Office of Research Support "Preparing the Budget" guide.

### **5.2.7.3 F&A Distribution Policy on Cross-School Grants and Contracts**

In the spirit of cooperation and collaboration among all units within the University, all awards involving investigators from multiple schools and departments will be set up with subcodes and the appropriate identifying (BFR) code for each participating department or school. This practice will ensure distribution of the facilities and administrative (F&A) costs in accordance with the direct costs associated with each participating investigator, thereby providing support for departmental space and administrative costs.

It is the responsibility of the Offices of Research Support and Research Administration, working with the principal investigator's department, to establish the appropriate subcode structure for each award.

### **5.2.7.4 Cost-Sharing Policy**

It is University policy to cost-share only when it is demonstrably in its best interest to do so. Because of this policy, the University will not generally commit resources to a project unless required to do so by the sponsor. Cost-sharing can take a variety of forms: e.g., reduced F&A cost recovery rates (see above), commitments of faculty effort, or the use of University funds for additional project support. Please note, however, that F&A costs can only be included as a cost-share on a proposal to a federal sponsor under the following circumstances:

- The agency is a member of the Federal Demonstration Partnership (refer to the online list of current members), or
- You receive prior, written approval from the agency in question.

Also, as noted above, deviations from the sponsor's official F&A rate require prior administrative review and approval.

The following criteria should be borne in mind:

- Any decision to cost-share should reflect the University's overall priorities within the functions of research and education.
- Requests for cost-sharing must be made - and the commitments must be documented - at the time of proposal submission.
- Cost-sharing is not a method of covering unexpected project expenses, or of accommodating cuts in a proposal's budget.
- Retroactive cost-sharing is generally not considered to be in the best interest of the University.

A detailed discussion of cost-sharing policies and procedures may be found in Duke's General Accounting Procedures, [GAP No. 200-140](#).

#### **5.2.7.5 Equipment Transfer Guidelines**

All guidelines for Duke departmental property officers are based on this fundamental concept: assets are owned by Duke and the government for use by particular departments of the University and its hospitals. It is the responsibility of every department to account for the assets it uses. This responsibility includes total accountability for disposal, changes, and transfers of assets, and a commitment to secure top value for all items sold or traded-in.

When an individual who has been working on a grant at Duke University moves to another institution, a question sometimes arises about the ownership of the equipment that has been purchased on the grant. In most cases, the equipment is the property of Duke or the government. However, when the principal investigator's grant-funded research activity is transferred to another institution, and the principal investigator or the granting agency submits a request for certain equipment to be transferred, it has generally been the practice to release the equipment. Such requests should be submitted first to the principal investigator's department chair and then, with the chair's approval, to the Provost.

For further information on equipment removal and equipment transfers, please refer to *Guidelines for Duke Property Officers in the Removal of Assets*, available from [Duke University Plant Accounting](#).

#### **5.2.7.6 Effort Commitment Guidelines**

Most sponsored projects require that some level of effort by key personnel is committed to the project. In most cases, this is "committed" effort that is reflected via the individual's payroll distribution. In other cases, a faculty member may have uncommitted effort specifically associated with the project. In either case, in support of applicable federal regulations, all individuals need to ensure that their annual effort certification accurately reflects the prior year's activities, both sponsored and University.

It is the University's expectation that faculty members will have non-sponsored professional activities and responsibilities as part of their faculty obligations and appointment. As a result, adequate University time must be set aside for their non-sponsored University activities, including instruction and administration. Effort commitments must be managed at time of proposal (during the identification of other support) and throughout the life of the grant to ensure that the University complies with applicable federal regulations.

In support of compliance effort reporting practices, Periodic Notice Statements are prepared for each faculty or staff member and distributed to each department or school business office. These statements serve as a notification of how the individual's effort is being distributed so that it can be modified if necessary. At the end of each fiscal year an Effort Certification Report is prepared for applicable faculty and staff members. These annual certification reports show the actual salary, supplemental pay distributions, and the percentage of annual effort for the entire fiscal year. Each employee is required to certify that the actual effort expended per the report is correct or, if incorrect, indicate the correct percentage of effort expended on the various activities. If there are significant changes of effort percentages, redistribution of salary may be required ([GAP NO. 200.170](#)).