

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

5.1 Organizational Structure	3
5.1.1 Policy, Administration and Compliance Offices.....	3
5.1.1.1 Animal Welfare Assurance	3
5.1.1.2 Corporate Research Collaborations.....	3
5.1.1.3 Division of Laboratory Animal Resources.....	3
5.1.1.4 Export Controls.....	3
5.1.1.5 Office of Audit, Risk and Compliance.....	4
5.1.1.6 Human Research Protections Program.....	5
5.1.1.7 Occupational & Environmental Safety	6
5.1.1.8 Ombuds.....	6
5.1.1.9 Research Administration and Research Support.....	6
5.1.1.10 Research Costing Compliance	7
5.1.1.11 Research Integrity Office (RIO).....	8
5.1.1.12 Research Policy Committee	8
5.1.1.13 Sponsored Programs	8
5.1.1.14 Vice Deans for Basic Science and Clinical Research	8
5.1.1.15 Vice Provost for Research.....	8
5.1.2 Technology Transfer	9
5.1.2.1 Office of Licensing and Ventures	9
5.1.3 Sponsor Relations	9
5.1.3.1 Federal Relations	9
5.1.3.2 Foundation Relations	10
5.1.3.3 Corporate Relations	10
5.1.3.4 Duke Medicine Foundation Relations and Corporate Giving	10
5.1.3.5 Duke Medicine Government Relations	11
5.2 Research Related Policies	11
5.2.1 The Investigator	11
5.2.1.1 Final Reporting on Sponsored Programs	11
5.2.1.2 Principal Investigator Status	11
5.2.1.3 Responsible Conduct of Research (RCR) Training	11
5.2.1.4 Roles and Responsibilities	13
5.2.2 Integrity.....	13
5.2.2.1 Authorship	13
5.2.2.2 Conflict of Commitment	14
5.2.2.3 Conflict of Interest	14
5.2.2.4 Consulting by Duke Faculty	14
5.2.2.5 Earmarks	14
5.2.2.6 Lobbying.....	15
5.2.2.7 Misconduct in Research.....	15
5.2.3 Intellectual Property.....	15
5.2.3.1 Intellectual Property Rights	15
5.2.3.2 Inventions, Patents, and Technology Transfer.....	15
5.2.3.3 National Institutes of Health (NIH) Public Access Law	15
5.2.3.4 Research Records: Sharing, Retention, and Ownership.....	15
5.2.3.5 Policy on Open Access to Research.....	16
5.2.4 Academic Freedom	16
5.2.4.1 Classified Research.....	16

5.2.4.2 Export Controls	16
5.2.4.3 Faculty and Staff Travel Abroad.....	17
5.2.4.4 University-Industry Guidelines	17
5.2.5 Protection	17
5.2.5.1 Animal Care and Use	17
5.2.5.2 Use of Human Subjects in Research	18
5.2.6 Safety	18
5.2.6.1 General.....	18
5.2.6.2 Laser Safety	18
5.2.6.3 Radiation Safety.....	18
5.2.6.4 Reporting Accidents and Injuries.....	18
5.2.6.5 Safety Training Requirements.....	18
5.2.6.6 Use of Hazardous Materials	18
5.2.6.7 Use of Recombinant DNA in Research.....	19
5.2.6.8 Use of Select Biological Agents and Toxins.....	19
5.2.6.9 Fieldwork Safety	20
5.2.7 Stewardship.....	20
5.2.7.1 Cost Sharing.....	20
5.2.7.2 Effort Commitment Guidelines.....	20
5.2.7.3 Equipment Transfer Guidelines	20
5.2.7.4 F&A Cost Recovery on Grants and Contracts	21
5.2.7.5 F&A Distribution on Cross-School Grants and Contracts	21
5.2.7.6 Research Costing Compliance	21

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.
3. “Campus Schools” referred to in this chapter include: Trinity College of Arts & Sciences, Divinity School, Fuqua School of Business, Graduate School, School of Law, Nicholas School of the Environment, Pratt School of Engineering, and Sanford School of Public Policy.
4. "Campus" refers to the above-listed schools, plus the centers and other organizational units of Duke University, other than those under the authority of the Chancellor for Health Affairs.
5. “Duke Medicine” referred to in this chapter includes the Schools of Medicine and Nursing.

5.1 Organizational Structure

5.1.1 Policy, Administration and Compliance Offices

5.1.1.1 Animal Welfare Assurance

The [Office of Animal Welfare Assurance](#) (OAWA) assists researchers with animal care or use at Duke. Services provided by the OAWA include: protocol development, administrative and veterinary pre-review of protocols and amendments, assistance with research laboratory preparation for [Institutional Animal Care and Use Committee](#) (IACUC) semiannual inspections, guidance and training for controlled substance license application and management of controlled substances when used in research animals, serving as a liaison for the IACUC in the research laboratory and for the researcher to the IACUC, and coordinating or providing for the training needs of the research community at Duke, including the Research Animal Coordinator Certification (RACC) program. The OAWA also serves as the administrative support for the IACUC. The OAWA is a primary contact with federal regulatory agencies. Under IACUC authority, OAWA is responsible for monitoring Duke's overall compliance with regulations governing animal care and use.

5.1.1.2 Corporate Research Collaborations

The Office of Corporate Research Collaborations (OCRC) reviews, drafts, negotiates and approves agreements for commercially supported research, both clinical and non-clinical, in the School of Medicine and related departments. These agreements include clinical trial agreements, sponsored research agreements, data analysis agreements, network participation agreements, consortium agreements, educational program agreements (other than those for CME credit, which are handled by the Office of Continuing Medical Education, and fellowships that are subject to ACGME or ICGME accreditation, which are handled by the DUHS Clinical Contracts Office), subagreements under any of these, and an array of other similar research contracts. Additionally, OCRC reviews, drafts, negotiates and signs agreements for transfers or exchanges of research materials, confidential information, data, technical know-how, and equipment in support of research across the University. These agreements include Material Transfer Agreements, Confidentiality Agreements, Collaborative Research Agreements, HIPAA Data Use Agreements, Data Transfer Agreements, Research Equipment Loans and other related agreements with commercial, government, non-profit and academic institutions. OCRC negotiates agreements to be consistent with Duke policies, NIH guidelines, applicable federal and state laws, and applicable IRS regulations relating to Duke's status as a not-for-profit organization. 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 Research Support, Office of Risk Management, Institutional Review Board, Duke Office of Clinical Research, Office of Licensing and Ventures, Office of Export Control and Office of Procurement.

5.1.1.3 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 at Duke in research, teaching, and testing endeavors. DLAR provides animal procurement, housing, veterinary care, assistance with experimental design, investigator training, and will conduct various technical services for researchers, etc. Further information for available services and support of research studies as well as contact information may be found on the [DLAR website](#).

5.1.1.4 Export Controls

Compliance with export control regulations for both the Campus Schools and Duke Medicine is managed by the Director of Export Controls in the [Office of Export Controls](#).

The Director assists faculty, staff, and students with ensuring that exports comply with US export control regulations. 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 assist in determining if goods and/or technology are controlled under the Export Administration Regulations or the International Traffic in Arms Regulations for the intended destination and/or recipient. The Director will also determine the applicability of exemptions or licenses for the export.

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 will evaluate the controls as they apply to Duke funded travel.

Faculty, staff, and students may wish to consult the Director of Export Controls when giving speeches or conducting research overseas, as certain types of activities may be proscribed by various government regulations.

In particular, the Duke community should consult the Director of Export Controls prior to conducting business or research with foreign governments.

Commercially available goods may be export controlled and visual exposure of controlled articles to a foreign national may be regulated. This particularly applies to goods and technology that were designed, developed, or modified for military or space application.

The Director prepares and submits, on behalf of faculty, staff, and students, any applications for export or travel licenses.

5.1.1.5 Office of Audit, Risk and Compliance

Compliance Program: The Duke University Compliance Program in the Office of Audit, Risk and Compliance administers the compliance program for the entire University. Responsibilities and aspects of the program include:

- Has oversight responsibility for compliance activities across Duke University relating to federal and state laws and Duke Policies and procedures.
- Is led by a Risk and Compliance Steering Committee (RCSC), comprised of the President (as Chair), the Chancellor of the Health System, the Provost, the Executive Vice President, the Dean of the School of Medicine, the General Counsel and a Dean appointed by the President (currently the Dean of the Engineering School). The Executive Director of Internal Audits serves as the administrative lead of the committee.
- Proactively reviews compliance risk areas to identify areas of needed improvement and partners with the operational entities and the research community to address any identified deficiencies.
- Manages the Duke University Compliance and Fraud Hotline which is an anonymous reporting mechanism to report comments, concerns or questions related to compliance issues. (1-800-849-9793) and receives all university related concerns that may come in through the Duke Medicine Integrity line (1-800-826-8109).

The Duke University Compliance Program:

- Provides the vision for institutional compliance and articulates corporate values;
- Ensures that the program meets the elements of the Federal Sentencing Guidelines related to effective compliance programs;
- Defines levels of acceptable risk;
- Visibly supports compliance efforts; and
- Evaluates and responds to instances of noted noncompliance.

The Duke University Compliance Program is responsible for compliance monitoring throughout the University, including the School of Medicine and School of Nursing. The Duke University Compliance Program is the Privacy Office for Duke University. The Compliance Program also provides general oversight and guidance for research financial compliance, clinical trials billing, human subjects' research, conflicts of interest, and HIPAA privacy as well as other regulatory risk areas. The Duke University Chief Ethics and Compliance Officer (Compliance Officer) is an ex-officio member of the Audit, Risk & Compliance Committee of the Duke University Board of Trustees.

Internal Audit: The Office of Audit Risk and Compliance is responsible for evaluating the internal controls environment for financial transactions, operational activities, compliance objectives and information technology infrastructure. Our engagements include vertical reviews of specific business units or specialized activities as well as horizontal reviews for key business processes spanning multiple stakeholder entities and University-wide activities.

The objectives of the internal audit function is to assist Duke University faculty and staff in their responsibilities by furnishing them with analyses, appraisals, recommendations, counsel, and information concerning the activities it reviews, and by promoting effective internal controls at a reasonable cost. This 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 internal audit is to determine whether Duke's risk

management, internal controls, 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
- Transactions and business operations are in compliance with policies, standards, procedures, and applicable laws and regulations
- Electronic information and data is appropriately managed and secured
- Resources are acquired economically, used efficiently, and adequately protected
- Programs, plans, and objectives are achieved
- Quality and continuous improvement are fostered in Duke's internal control and risk management processes
- Significant legislative or regulatory issues impacting Duke are recognized and addressed properly
- Business processes and internal controls that support compliance with sponsor agreements and other contractual obligations

5.1.1.6 Human Research Protections Program

Definitions:

- "HRPP," or Human Research Protections Program, is the institutional program responsible for review, approval, and oversight of research with human subjects. An HRPP includes, but is not limited to, the Institutional Review Board (IRB), Conflict-of-Interest Review Committee, and Compliance Office.
- "Duke's Main Campus HRPP" means the HRPP for Duke University and all of its academic departments, excluding the Schools of Medicine and Nursing, but including the Global Health Institute; the Schools of Arts and Sciences, Law, Divinity, Environment, Engineering, and Public Policy; Trinity College; and all academic centers and institutes.
- "Duke Medicine HRPP" means the HRPP for Duke Medicine and all components of that legal entity, including the Schools of Medicine and Nursing.
- "FDA Regulated" means fall under the governance of US Food and Drug Administration regulations and guidance.
- "Medical Intervention" means administration of: (i) a drug, device, or biologic; or (ii) a medical test, evaluation, or sample collection that would normally be conducted in a clinical setting by a trained clinician.

Basic Criteria for Determining Where Review Should Take Place:

1. Protocols will be reviewed by the Duke Medicine HRPP when the research takes place at a Duke Medicine facility, including facilities that are not on site, such as Duke Regional Hospital.
2. Protocols will be reviewed by the Duke Medicine HRPP when a researcher proposes using Protected Health Information (PHI) held by Duke Medicine.
3. Protocols will be reviewed by the Duke Medicine HRPP when the research is either: (1) FDA-regulated; or (2) involving a Medical Intervention.
4. All other protocols will be reviewed by the Duke's Main Campus IRB.

Collaborative Research:

The following collaborations between Main Campus and Duke Medicine researchers may be reviewed by the Main Campus HRPP:

1. A Duke Medicine researcher is collaborating with an investigator from a non-medical unit, for example, the Department of Psychology and Neuroscience, when the research will not take place within a Duke Medicine facility and the researchers will not use PHI held by a Duke Medicine facility.
2. A graduate student or undergraduate student from a non-medical unit, such as Trinity College or the Divinity School, asks a researcher from Duke Medicine to serve as an advisor, the research will not take place at a Duke Medicine facility, and the protocol will not use PHI held by a Duke Medicine facility.

3. A researcher affiliated with a non-medical unit wants to access directories held by Duke Medicine of people who have expressed interest in participating in research studies, provided that no PHI will be disclosed.

5.1.1.7 Occupational & Environmental Safety

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.

5.1.1.8 Ombuds

The Offices of the Ombuds address concerns about how and when to approach existing resources (Office of Institutional Equity, course directors, advisory deans, practice faculty, faculty mentors) if or when an individual feels mistreated or has a conflict with another member of the University community.

Three ombuds offices offer support to faculty, students and postdoctoral associates/fellows at Duke University:

- [The Faculty Ombuds](#)
- The Student and Postdoctoral Associate Ombuds
- The Medical Student Ombuds, Allied Health, Medical School Post Docs

The responsibilities of the Office of the Ombuds include:

- Providing neutral safe and confidential environment to talk
- Listening to concerns and complaints and discussing appropriate options
- Helping to evaluate those options
- Assisting faculty and students to resolve those options
- Mediating conflicts, convening meetings, and engaging in “shuttle diplomacy”
- Referring people to appropriate Campus or Medical School resources
- Providing information about University or Medical School resources

The ombuds does not constitute notice to the institution with regard to grievances or complaints and does not:

- Adjudicate or participate in formal University grievances
- Determine guilt of any party in a dispute
- Get involved in any formal litigation or testify in court
- Provide legal advice
- Assign sanctions on individuals
- Replace any official University office, department or process

To contact an ombuds with a concern you would like to discuss, you may simply:

- email the Faculty Ombuds at jeffrey.dawson@dm.duke.edu or call 919-613-7811 (office) or 919-257-0982 (mobile)
- email the Duke Student Ombuds at jbshear@duke.edu or call 919-673-2261 or 919-684-4039
- email the Medical Student Ombuds at ombudsman@mc.duke.edu or call 919-668-3326

5.1.1.9 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, outside of the School of Nursing (where review and approval are conducted by the SoN Research Affairs office, with the exception of NIH Type 5 applications), 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; that direct costs comply with 2 CFR Chapter II, Part 200; and that indirect costs are appropriately recovered. All Duke proposals fall

under their purview, with the following exceptions: SoN proposals (as noted above), construction and endowment proposals, which are handled by the Office of 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, subawards, and site agreements (the latter ORA only) when appropriate and applicable
- Reviewing intellectual property agreements (IPAs), nondisclosure agreements (NDAs), memoranda of understanding (MOUs), and other agreements between the University and other entities
- Serving as the authorized institutional official and principal liaison between the University and its sponsors
- Approving programmatic and budgetary changes to sponsored projects (including the establishment of new fund codes and extending existing codes)
- Reporting Financial Conflicts of Interest to sponsors associated with federal funding
- Facilitating closeout documentation
- Working with the Vice Provost for Research and the Research Policy Committee to develop and implement research policies and procedures

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

- Overseeing and managing SOM faculty's effort (i.e., G90 review)
- Reviewing MOUs associated with faculty who have VA appointments
- Providing institutional review for all industry sponsored clinical research activities, and, if appropriate, providing Institutional signature
- Reviewing Extraordinary Pay requests, and, if appropriate, providing institutional approval
- Reviewing fund codes relating a negative balance and determining whether or not the project is an "acceptable" or "unacceptable" Institutional Risk (UIR)
- Late Salary Cost Transfers (i.e., > than 180 days)
- Managing and updating Sponsored Effort System (SES) with sponsor approved effort and changes. This includes providing final approval for Other Support documentation when required by sponsors.

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

- Coordinating submissions for institutionally limited funding opportunities for both Campus Schools and Duke Medicine
- Disseminating funding information to 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, subrecipient monitoring and training programs in the responsible conduct of research. Responsibilities include:
 - administering and monitoring the online conflict of interest disclosure form for individuals whose primary affiliation is with one of Duke's Campus Schools.
 - overseeing potential conflicts of commitment, committed effort, subrecipient monitoring, past-due annual and final reports, responsible conduct of research (RCR) training, and other general compliance related matters.
 - providing training presentations and consultation on relevant topics.

5.1.1.10 Research Costing Compliance

The Office of [Research Costing Compliance](#) (RCC) supports the research compliance mission of the University in two ways. RCC serves as a compliance training resource for faculty and staff by providing multiple training venues, including mandatory training/education for principal investigators and grant managers. RCC offers several certificate programs, continuing education opportunities for business managers, CPAs, and those wishing to prepare for the national certifications. RCC also conducts comprehensive financial compliance monitoring for all sponsored activities at Duke University, and works closely with the University leadership in identifying and addressing compliance risk through policy and process development, system improvements, training, and outreach. RCC routinely monitors financial compliance risks, and reports on a regular basis to the SOM/SON and campus Management Centers, the Duke University Ethics and Compliance Office, (which in turn reports compliance activity

to the Audit Committee of the Duke University Board of Trustees), and the Research Administration Continuous Improvement (RACI) leadership team.

5.1.1.11 Research Integrity Office (RIO)

The [Research Integrity Office](#) is housed in the School of Medicine but provides services to SOM/SON faculty, staff, internal Duke Offices, and external organizations to ensure quality review, management, and reporting of conflict of interest (COI) as appropriate. In addition, RIO provides oversight of institutional conflicts of interest across Duke University, and the research misconduct process for the School of Medicine.

5.1.1.12 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, faculty, and Legal Counsel. It is responsible for:

- Writing Duke University's research policies
- Reviewing existing 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 design, conduct, reporting, and supervision of research

5.1.1.13 Sponsored Programs

The [Office of Sponsored Programs](#) (OSP) exists to perform the post-award administration of sponsored projects for all Schools of Duke University (both Campus Schools and the Schools of Medicine and Nursing). OSP's mission is to safeguard sponsored 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 invoices, financial, and other non-scientific reports to sponsors on sponsored projects
- Paying subrecipients to Duke's sponsored projects
- Monitoring projects for compliance with sponsor and Duke requirements
- Assuring reimbursement of project expenditures
- Providing advice to departmental administrators
- Coordinating award documentation and approval processes with the Office of Research Support, Office of Research Administration, Treasury Billing Services, and other related Duke departments
- Coordinating the University's effort reporting system and related processes
- Answering questions and providing information to sponsors and Duke personnel

5.1.1.14 Vice Deans for Basic Science and Clinical Research

Within the School of Medicine, the Offices of the Vice Dean for Basic Science and Vice Dean for Clinical Research serve as liaisons between the Dean and the faculty engaged in research. These offices work with department chairs and faculty to implement School of Medicine strategic initiatives concerning basic/clinical research and education, including the oversight of shared resources, and multiple regulatory/advisory committees. The Vice Dean for Basic Science also serves as the administrative lead for the graduate program within the school, overseeing the School of Medicine Research Misconduct Committee, and is jointly responsible (along with the Vice Provost for Research) for the Office of Postdoctoral Services. The Vice Dean for Basic Science also oversees the programs for conducting animal research. The Vice Dean for Clinical 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 clinical research, the Duke Office of Clinical Research (DOCR), and conflict of interest. Depending on the primary department appointment, these offices will assist with questions regarding institutional resources and space. Matching investigators with potential funding opportunities is a major priority and may be an important resource when investigators have a new research idea and are looking for collaborators.

5.1.1.15 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 (Trinity College of Arts & Sciences, Divinity School, The Fuqua School of Business, School of Law, Nicholas School of the Environment, Pratt School of Engineering, Sanford School of Public Policy, and University Centers and Institutes). The VPR works closely with the Provost's Office, its staff, and the deans on research policy. The VPR supervises the offices of Research Support (ORS), Export Controls (OEC), and Postdoctoral Services (OPS), the Office of Corporate Relations (OCR), and co-

supervises the Office of Licensing Ventures (OLV). The VPR oversees the University Committee on the Use of Human Subjects in Non-Medical Research, the Campus Committee on Conflict of Interest, the University-wide Research Policy Committee, and also manages the Instrumentation and Research 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 Research Application Development (RAD) Group) is also co-responsible, along with the Vice Dean for Research (see above), for the [Conflict of Interest](#) (COI) reporting system and the [Sponsored Projects System](#) (SPS).

5.1.2 Technology Transfer

5.1.2.1 Office of Licensing and Ventures

The [Office of Licensing and Ventures](#) (OLV) serves Duke University (Campus Schools and Duke Medicine) and is responsible for technology transfer, corporate gifts, and corporate vending relationships. The technology transfer responsibility of OLV includes patents, technology licenses, and startup venture development for technologies and inventions originating in Duke University and Health System. Duke faculty, staff, and students must submit intellectual property and invention 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. Intellectual property and invention disclosure forms and answers to other FAQs are at the [OLV website](#). OLV's functions include:

- Maintaining a database of University ideas and inventions
- Identifying and patenting transferable technologies
- Developing and implementing commercialization strategies for both patentable and non-patentable intellectual property
- Pursuing commercialization opportunities through option and license agreements and through venture capital opportunities.

5.1.3 Sponsor Relations

5.1.3.1 Federal Relations

The [Office of Federal Relations](#) (OFR) represents the interests of the University's faculty, students and staff on matters of legislation and regulations before the federal government in Washington, D.C. OFR tracks legislation regarding issues as wide-ranging as the federal budget, research and student aid funding, the reauthorization of relevant statutes (such as the Higher Education Act), visa and immigration matters, tax issues, technology transfer, intellectual property law and other areas of institutional interest. Additionally, the Office of Federal Relations coordinates Duke advocacy efforts, positions the University as a resource for policymakers in Washington and assists Duke faculty members who are interested in applying their expertise to policy development. OFR also provides many resources to faculty, staff, and policymakers on its [website](#).

In addition to Durham-based staff, OFR has two permanent staff members based in the Duke in Washington office, an academic and outreach center in Washington, DC. Located in the heart of downtown Washington, Duke in Washington supports university business in DC by:

- Providing office, meeting, and event space;
- Hosting academic programs;
- Serving as a logistical and promotional resource to faculty and staff visiting DC; and
- Connecting Duke expertise and programs to thought leaders in DC through individual meetings, briefings, and public events.

Faculty and staff traveling to DC on Duke-related business are encouraged to use the temporary office space, meeting space, and other office resources (printer, copier, wireless internet, landline, videoconferencing). More information can be found [here](#). The Office of Federal Relations also encourages faculty and staff to consider Duke in Washington as a venue to host briefings, roundtables, panel discussions, and other events to promote scholarship that would be relevant to a Washington audience.

5.1.3.2 Foundation Relations

The [Office of Foundation Relations](#) (OFR), housed within University Development, initiates and builds philanthropic relationships in support of Duke's teaching, research, and service mission. OFR's primary charge is to raise funds for priority programs and institutional initiatives. Working with administrators, faculty, and development staff, OFR's staff provides expertise, services, and tools to connect the University successfully with foundations, including corporate foundations (separate entities from their originating corporations). In addition, it manages the corporate prospect management process for the University, including all of the graduate and professional schools. Services include:

- Developing strategies for working with foundations
- Identifying potential foundation and corporate foundation funders
- Researching foundation programs and existing relationships with Duke programs
- Advising faculty on the development of program concepts and proposals
- Reviewing and approving proposals and budgets, and coordinating with Campus schools on construction and endowment proposals to foundations
- Assisting principal investigators with reporting to and stewardship of major foundations

Before contacting a foundation or corporate foundation or submitting a proposal, please contact OFR by emailing or calling Chandler Spaulding (chandler.spaulding@dev.duke.edu or 919-681-0475) for additional information and approval to proceed.

5.1.3.3 Corporate Relations

The Office of Corporate Relations initiates and coordinates relationships that support Duke's research, teaching, and service mission. Duke Corporate Relations works with Duke's faculty members, administrators, and staff to develop mutually-beneficial relationships with industry. The department works with companies to understand their goals and facilitate connections to the University's research, student talent, events, global programs, initiatives, employee development, strategic gift planning, and recruiting. The department can be reached through the general email address: corporaterelations@duke.edu.

The Office of Corporate Relations' services include:

- Researching and reporting on the historical connections between a company and Duke University
- Planning an engagement strategy with a company
- Synthesizing multiple pieces of information from constituents to create a common understanding of opportunities
- Identifying and matching the company's strategic needs and the University's strengths
- Facilitating conversations with corporate partners
- Organizing and hosting campus visits and conference calls
- Identifying opportunities for funding from corporations
- Reviewing and approving construction of proposals to corporations submitted by Duke University Campus Schools

5.1.3.4 Duke Medicine Foundation Relations and Corporate Giving

The [Office of Foundation Relations and Corporate Giving](#) supports priority Duke Medicine initiatives by serving as the interface between Duke Medicine faculty programs and projects and the grant-making organizations, including foundations and corporations, that support basic, translational, and clinical research, medical, nursing, and the PA and PT health education programs, and healthcare delivery. The office staff works with the full spectrum of philanthropic entities, from small family-based private foundations, to corporate philanthropic offices, to the nation's largest philanthropic organizations. As a component of Duke Medicine's Development and Alumni Affairs office, the Office provides the foundation and corporate fundraising expertise to the major gift officers and development directors who serve the research, service delivery, and educational missions of Duke Medicine. The Office also collaborates with colleagues across the Health System and University, including the Office of Licensing and Ventures and Duke University Office of Corporate Relations, to maximize strategic corporate partnerships. Services include:

- Identification of non-federal funding sources
- Strategic fundraising assistance
- Foundation background research
- Contact with, introduction to, and follow-up stewardship with funding sources
- Proposal development and/or guidance

- Proposal review

Before contacting a foundation or corporate foundation or submitting a proposal, Duke Medicine personnel should contact the Office by emailing or calling Anita Shirley (anita.shirley@duke.edu, 919.385.3117) for additional information and approval to proceed.

5.1.3.5 Duke Medicine Government Relations

The Duke Medicine [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, Duke Regional Hospital, Duke Raleigh Hospital, the Private Diagnostic Clinic (PDC), and Duke Medicine. The office is also responsible for all state-level legislative and policy issues affecting Duke University including the Campus Schools.

5.2 Research Related Policies

5.2.1 The Investigator

5.2.1.1 Final Reporting on Sponsored Programs

Because the University has ultimate responsibility for adherence to the terms and conditions of any accepted grant, cooperative agreement or contract, the actions of individual principal investigators greatly influence the relationship between Duke and a sponsor, even creating a situation where a sponsor could refuse to support any Duke research regardless of the project or who is named as the principal investigator.

Programmatic (financial, technical, progress, final, NIH Public Access, etc.) reports can only be prepared under the direction of a project's principal investigator. Thus, the University is dependent on the principal investigator to prepare and submit all programmatic reports on time and according to the sponsor's specifications. If a principal investigator has not submitted a report for greater than thirty days after the report due date, Duke may suspend all new sponsored research activity associated with the respective investigator or take other appropriate actions with agreement of the PI's dean/chair until the delinquent report is submitted according to the sponsor's requirements.

5.2.1.2 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 investigator or program director for projects - research or otherwise - supported by external funding sources. See [Appendix P](#), "Principal Investigator Status," for details on how this policy is implemented on Campus and in Duke Medicine.

5.2.1.3 Responsible Conduct of Research (RCR) Training

To meet the requirements of the America COMPETES Act of 2007, all Duke University Ph.D. students, postdoctoral associates and scholars, and those masters students and undergraduate students who are supported by research funds from the National Science Foundation or by training funds from the National Institutes of Health, and certain awards through the U.S. Department of Agriculture are required to participate in training programs on the responsible conduct of research (RCR). The Duke University Graduate School has mandated RCR training as a formal, academic requirement of the Ph.D. degree in every department and program of study since 2003, and training is documented on official Duke University transcripts.

Under the direction of the Vice Provost for Research, the system for identifying individuals for whom RCR training is required and verifying their compliance is administered by the Assistant Director for Compliance in the Office of Research Support.

A series of educational programs has been designed for each of these constituencies.

For Undergraduate Students: The RCR certification requirement is satisfied by completing a set of two required [online tutorials](#) on Misconduct in Research and Data Management and a third elective. Five disciplinary tracks have been established and students are asked to pick the one that best fits the discipline of the project on which they are working:

- Social and Behavioral Research (sociology, economics, political science, psychology, history, cultural anthropology)
- Physical Sciences Research (physics, chemistry, computer science, mathematics, and statistical sciences)
- Engineering Research (civil, environmental, computer, electrical, and mechanical engineering)
- Arts & Humanities Research (religion, art history, classical studies, English, literature, music, philosophy)

- Biomedical Research (biology, evolutionary anthropology, biomedical engineering, neuroscience)

For Graduate Students: The Duke University Graduate School requires that all enrolled Master's degree and Ph.D. students complete training in RCR as noted on The Graduate School website (see <http://gradschool.duke.edu/rcr>). There are distinct RCR training requirements based upon degree program and academic division:

- Ph.D. students in the Basic Medical Sciences must complete 18 total contact hours of RCR training, including the 12-hour Beaufort Retreat RCR Orientation (GS710A, see <http://medschool.duke.edu/phd-programs/rcr-orientation/beaufort-retreat>), and a 4-hour follow-up training following the completion of Year Three in their program to fulfill NIH RCR training requirements; See http://gradschool.duke.edu/academics/degree_reqs/rcr/2012%20Year%203%20RCR%20Policy%20memo.pdf
- Ph.D. students in all other departments and programs must complete 12 contact hours of RCR training, including the appropriate six (6) hour RCR Orientation (GS710) by academic division (Humanities & Social Sciences, or Natural Sciences & Engineering).
- Beyond RCR Orientation (GS710 or GS710A), Ph.D. students can fulfill the remaining RCR training requirements by attending annual RCR Forum events, preferably within the first three (3) years of their program of study (See http://gradschool.duke.edu/academics/degree_reqs/rcr/forums/index.php)
- Beginning in Fall 2013, entering Master's degree students enrolled in Duke University Graduate School must complete a four-hour (4) RCR Orientation during Orientation Week that is focused on academic integrity, research policies, and campus resources.

Each RCR Orientation program covers a wide variety of subjects, and may include the following topics:

- Academic Integrity and Misconduct (plagiarism, cheating, etc.)
- Conflict of Interest and Commitment
- Inventions, Patents, and Technology Transfer
- Human Subjects
- Animal Subjects
- Data Management
- Intellectual Property
- Authorship, Copyright, and Scholarly Communications
- Fiscal Responsibility
- Social Impact of Research
- Collaborative Research
- Mentee and Mentor Responsibilities
- Harassment Prevention and Handling Complaints

The RCR Forum Series includes more in depth information on the topics above, as well as workshops on emerging key issues such as Export Controls, FERPA or HIPAA, and others). Departmental RCR Forum events (GS712) must be pre-approved by the Graduate School but are encouraged. Contact the Graduate School with any questions at grad-rcr@duke.edu.

Postdoctoral Researchers are required to take one of two courses: The Federal requirement for RCR training can be satisfied by completion of the [RCR Orientation for Postdoctoral Researchers](#) provided by the Office of Postdoctoral Services and the Office of Research Support. The orientation includes a series of advanced lectures and case study discussions on:

- Research Misconduct
- Data Management
- Authorship
- Peer Review
- Mentor and Trainee Responsibilities
- Scientists as Responsible Members of Society

Postdoctoral researchers are then required to attend one of the [RCR Training Forum Series](#) workshops offered by the Graduate School each year for three subsequent years of their tenure at the University.

Alternatively, instead of participating in the [RCR Orientation for Postdoctoral Researchers](#), Postdoctoral Associates may participate in the [Trent Center's program on Bioethics, Humanities and History of Medicine](#) which provides an annual five-session training in the Responsible Conduct of Research (RCR). This course is open to recipients of NIH training grants and fulfills the requirement for RCR education. Each 1.75 hour session includes a half-hour lecture followed by an hour and 15 minutes of faculty-facilitated, small group case discussions. Session topics include:

- Introduction to the Responsible Conduct of Research
- Mentoring
- Research Misconduct
- Human Subjects in Research
- Publication and Authorship
- Intellectual Property
- Conflict of Interest

After completing either the [RCR Orientation for Postdoctoral Researchers](#) or the Trent Center program, postdoctoral researchers are then required to take one of the [RCR Training Forum Series](#) workshops offered by the Graduate School each year for three subsequent years of their tenure at the University.

Note: All students and postdocs doing research involving human subjects, vertebrate animals, or certain types of hazardous substances or equipment will be required to complete further ethical and safety training specific to the type of research in which they are involved.

5.2.1.4 Roles and Responsibilities

While the University is ultimately responsible for fiscally compliant management of all sponsored projects, 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 timely submission of all programmatic 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 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.
- The PI/PD is responsible for ensuring that the programmatic and financial management of subrecipients associated with his/her funded projects conduct assigned research and reporting appropriately and in a timely, accurate, and financially responsible manner.
- In conjunction with OSP, the PI/PD approves final payment to subcontractors.

5.2.2 Integrity

5.2.2.1 Authorship

The University has instituted authorship guidelines and dispute resolution procedures to supplement its policy on Misconduct in Research. Within the academic environment there is often some level of expectation regarding authorship or acknowledgement on the part of those contributing to a work. As a result, it is an appropriate practice to address questions of authorship at the earliest practical stage of a research project. Such communication can clarify roles, spur motivation, and minimize disappointments among the participants.

Disputes over authorship are best resolved at the local level by the authors themselves or in consultation with the laboratory chief, chair or head of department(s), or dean, as appropriate.

If resolution at the local level cannot be achieved, the matter can be referred to the Authorship Dispute Board in one of two ways. If the matter is taken to the Authorship Dispute Board with the unanimous agreement of all parties,

the decision of the Board will be binding on all parties. If the matter is taken to the Authorship Dispute Board without the unanimous agreement of the parties, the decision of the Authorship Dispute Board is not binding, but the Board will make a written recommendation that will be provided to all parties of the dispute and can be made public by any of the parties involved.

Please refer to [Appendix P](#), “Guidelines for Authorship and Authorship Dispute Resolution” for details on how Duke addresses issues of authorship.

5.2.2.2 Conflict of Commitment

A conflict of commitment can be said to exist when a member of the University community has an outside relationship that requires a commitment of time or effort to non-University activities, such that an individual, either implicitly or directly, cannot meet her/his 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 effort actually being devoted to the activity in question. Any faculty member planning to do research for the government under a stipulation that a specified fraction of her/his 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 Conflict of Interest

Duke University is committed to ensuring members of its faculty, scholars, and staff are provided an open and productive environment in which to teach, care for patients, and conduct research. However, the ever-increasing complexity of our society and the various relationships between faculty, scholars, and staff 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 (including her/his immediate family member(s)) has a relationship with an outside entity such that her/his activities on behalf of the University could be biased by that relationship in a direction that would ultimately provide direct financial benefit to the individual or the family member.

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

In addition to Duke's policy, principal investigators must also adhere to regulations governing conflict of interest. For instance, investigators applying to the U.S. Public Health Service agencies, which include the National Institutes of Health (NIH), and other public and private sponsors, including the National Science Foundation (NSF) and private entities such as the American Heart Association require investigators to disclose at the time of proposal submission whether any significant financial interest that could directly and significantly affect the design, conduct, or reporting of the sponsored research.

5.2.2.4 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 based on term of appointment (e.g., nine-months or eleven-months). Such activities are to be listed on an individual’s financial conflict of interest disclosure form (https://radapps.duke.edu/coi_form). All disclosed consulting relationships will be reviewed to determine if an overlap of interest exists that might be, or appear to be, a conflict of interest that would require management.

5.2.2.5 Earmarks

Duke University is committed to excellence in research and hence to competitive peer review in the federal funding of research. Research funded by earmarks threatens to undermine national excellence in research by diverting resources from the peer review process. As a result, faculty and staff are prohibited from seeking, advocating, or accepting earmarks which benefit Duke or related entities except under extraordinary circumstances and with the express permission of the President of the University. Such extraordinary circumstances would include only those in which the President, in consultation with the senior administrative leadership of the University, determined that the proposed project involved inherently unique circumstances that could not be replicated elsewhere. When the case for an exception is considered, the strong presumption must be against the taking of earmarks. See the [Memorandum on Earmarks](#) from Provost Peter Lange and Vice President for Public Affairs and Government Relations Mike Schoenfeld.

5.2.2.6 Lobbying

Duke is required by law to submit detailed quarterly reports on state and federal lobbying activity by individuals employed, or acting on behalf of, the University or Health System.

Duke recognizes and supports the individual engagement of members of the University community as private citizens in public policy and the political process; nothing in this lobbying policy applies to such private interactions. Duke also encourages and supports the engagement of our faculty and staff with policy makers at the state and national levels in their institutional roles. In order to comply with the enhanced tax, lobbying, and ethics laws and rules that govern these relationships, we must gather specific information on the activities of all individuals at the University.

On a quarterly basis, a lobbying questionnaire is sent to all senior officers, deans, school and institute directors of the University to collect the appropriate information on individual activity in their areas of responsibility.

On an annual basis, all faculty are queried about their lobbying activities as part of their Conflict of Interest reporting.

Further information regarding the policy and other helpful documents can be found [here](#) for University employees and [here](#) for Health System employees.

5.2.2.7 Misconduct in Research

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

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 arise from time to time as a result of efforts by members of the Duke community. This policy addresses 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, protection, and potential licensing and translation. Duke's policy on inventions, patents, and technology transfer (in [Appendix P](#)) has been written to assure that inventions resulting from Duke research are used in a manner consistent with University policies and values. The policy is written to facilitate and encourage patent protection, licensing, new venture creation, 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) continues to implement its Public Access Policy, which became effective April 7, 2008. Under this federal law, NIH requires that the author's final version of any peer-reviewed journal article resulting from NIH-funded activities 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. The terms of compliance with this policy, including the length, up to 12 months, of the embargo, are determined by the agreement between an author and publisher. In order to improve grantee compliance, NIH has begun to delay the processing of non-competing continuation grant awards if publications arising from those grants are not in compliance with this public access requirement.

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.

5.2.3.5 Policy on Open Access to Research

The Faculty of Duke University is committed to disseminating the fruits of its research and scholarship as widely as possible. In March 2010, the Academic Council adopted an open access policy, under which faculty authors grant to Duke University permission to reproduce and distribute their scholarly articles at no cost to readers via a repository maintained by the library. Authors may opt-out of this default policy, or may place an embargo on their works if needed. The complete text of the policy is available in Appendix P, and more information on the policy and its application can be found at <http://library.duke.edu/openaccess/>

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 5.2.4.4 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 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. The export of material or technology to a foreign country may require a license or exemption prior to export. 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. For export purposes, U.S. persons are defined as U.S. citizens, U.S. permanent residents ("green card holders"), and certain individuals in the United States under refugee or asylum status. All other individuals are considered foreign persons, as well as U.S. person employees of foreign governments (e.g., US citizens working for a foreign Embassy) or entities which are not incorporated in the U.S. University research results may be exempt from export control laws under the "Fundamental Research Exclusion" by ensuring that it meets the definition of fundamental research: 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 have any national security restrictions, such as a restriction on the participation of foreign nationals.

The "Fundamental Research Exclusion" does not apply to assistance provided to a foreign government which may be used to support a military or space program even if the activity is limited to the use of public domain information. Such assistance requires authorization from the U.S. Department of State. The "Fundamental Research Exclusion" also does not apply to encryption technology or shipments of physical goods overseas.

When strictly adhered to, Duke policies ensure the "Fundamental Research Exclusion" and are broadly applicable to all sponsored research, regardless of the source of funding. These policies 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, including the publication of computer programs, shall remain with the University. 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 intellectual property rights 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.

5.2.4.3 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 must contact the Office of Export Controls prior to travel to embargoed or sanctioned countries as indicated on the Restricted Regions List. The United States government imposes varying levels of restrictions regarding the travel to, import from, export to, or collaboration with entities from sanctions countries which may require a license.

There are no Duke-imposed 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 employee can be required to travel to a location on the Duke Restricted Regions List unless they were expressly hired to do so (i.e., agreed to travel to a specific country/region as part of their employment). 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 assistance services](#) through International SOS and CIGNA Medical Benefits Abroad.

International travel involving fieldwork must comply with the [Fieldwork Safety Policy](#). (See section 5.2.6.9 of this document for more information.)

5.2.4.4 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.

5.2.5 Protection

5.2.5.1 Animal Care and Use

The ability to care for or use animals at Duke University is a privilege granted by the IACUC when appropriate justifications for animal use, animal care, personnel qualifications, and required training provisions have been met. The program for animal care and use at Duke includes all research, educational, and testing protocols performed by Duke faculty, staff, or employees, involving vertebrate animals and select families of invertebrates either at Duke University or other collaborating or subcontracted sites where Duke is the primary funds manager for the activity (source of funds not consequential). All animal care and use must be conducted in observance of federal regulations and policies, and accreditation guidelines. Policies, forms for application, expectations of care and use, and other program information are available at the animal program website: <http://vetmed.duhs.duke.edu>. Telephone questions may be directed to: Office of Animal Welfare Assurance at 919.688.6720.

The Institutional Animal Care & Use Committee (IACUC) is mandated under federal regulation, funding agency policy, and accreditation rules to review, approve (or disapprove), and oversee all care and use of animals that occur under Duke-managed grants funds or performed by Duke staff or faculty; this includes research, testing, or teaching where animals are process participants. Approved animal activities have a life span of three years with a stipulation for annual progress updates and continuing training or skills validation. The IACUC uses a compliance monitoring process to find evidence of good performance by the research and care staff, and to identify activities which require supplemental training or skills enhancement. Members are appointed from each department or division on campus where animal use occurs to this institutional oversight body by the Dean of School of Medicine. IACUC Members include veterinarians, scientists, non-scientists, and community representatives. The IACUC uses a central email address (IACUC@DUKE.EDU) for all correspondence with the committee. Telephone questions

concerning IACUC procedures may be directed to the IACUC or the Office of Animal Welfare Assurance at 919.688.6720.

5.2.5.2 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.

5.2.6 Safety

5.2.6.1 General

Duke specific safety requirements are published in the [Duke University Safety Manual](#) and the [Duke University Laboratory Safety Manual](#).

5.2.6.2 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.

5.2.6.3 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.

5.2.6.4 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; 919-684-8115 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 at 919-684-8822. Such incidents may also need to be reported to the NIH Office of Biotechnology Activities.

5.2.6.5 Safety Training Requirements

The 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.

The general training provided by OESO does not cover project- or lab-specific hazards. Faculty are responsible for assuring that their staff and students are trained on specific hazards that they may encounter in the course of their work, along with appropriate control measures, emergency procedures, etc. Examples of specific hazards include hazardous materials (see below), physical hazards (such as exposure to electrical energy or hot surfaces), hazardous equipment, and environmental hazards (especially for studies involving field work).

5.2.6.6 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 5.2.6.6 below), 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,

toxic, reactive, corrosive, and flammable materials. A Principal investigator (PI) who uses hazardous materials and generates 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. All PIs using chemicals will need to prepare a lab-specific chemical hygiene plan. 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. A Principal Investigator who uses and generates Medical (Infectious) Waste must comply with the NC Regulations and the Duke Medical Waste Policy (see <http://www.safety.duke.edu>).

Certain chemical materials have been designated as “Particularly Hazardous Substances” (PHSs). These include materials that are reactive, highly toxic, carcinogenic, or affect human reproduction. Investigators using any of these materials are required to submit to OESO an inventory of the PHSs in their laboratories and to prepare and submit a written standard operating procedure that specifically identifies the methods of use as well as required protective measures. A list of many Particularly Hazardous Substances is available on the [OESO website](#), but note that this list is not all-inclusive.

5.2.6.7 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.

Work with viral vectors, human derived materials (including cell lines), or pathogens (Risk Group 2 or above) requires a written standard operating procedure (SOP). Recombinant DNA Registration forms and the SOP templates are found on the IBC website (<http://www.safety.duke.edu/BioSafety/ibc.htm>).

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.

5.2.6.8 Use of Select Biological Agents and Toxins

The purpose of Duke University’s policy on the http://www.safety.duke.edu/BioSafety/Docs/Bioterrorism_SelectAgent_Policy.pdf is to ensure that “select agents or toxins” 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 (CDC) and/or the United States Department of Agriculture, Animal Plant Health Inspection Service (USDA). A list of all regulated ‘Select Agents or Toxins’ can be found on the website: <http://www.selectagents.gov/>. Small quantities of some Select Toxins are exempted from the rules.

Each principal investigator (PI) is held responsible for assuring that s/he register all possession, transfer, and receipt of Select Agents and Toxins with the CDC or USDA. S/he is also responsible for assuring that his/her laboratory fully complies 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 under the Select Agent Program:
- The PI must develop a detailed standard operating procedure (SOP) for each Select Agent or Toxin used in the laboratory. The SOP must be approved by the Duke University Biological Safety Division (RO), the Duke University Institutional Biosafety Committee and accepted by the CDC or USDA during the registration process. 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 PI must provide the CDC or USDA with a drawing of the laboratory in which the Select Agent or Toxin is used as part of the registration process. 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 and that all personnel with access to the Select Agents or Toxins have received and comprehended the required training.
- All transfers or receipts of Select Agents or Toxins must be conducted through the Biological Safety Division (RO) in cooperation with the CDC or USDA. Exempt quantities of Select Toxins are ordered through the Select Agent or Toxins Ordering Site on the Safety website (<http://www.safety.duke.edu/>).
- The PI shall insure that all personnel with access to the Select Agents or Toxins have completed a Security Risk Assessment with the Department of Justice prior to work in the laboratory area, and have undergone a Pre-Access Personnel Suitability Review as required by the Select Agents or Toxins Rules.

5.2.6.9 Fieldwork Safety

Fieldwork activities such as those involving isolated or remote locations, extreme weather, hazardous terrain, harmful wildlife, or lack of ready access to emergency services can expose participants to significant risks to their health and/or safety. Faculty responsible for research, teaching, or clinical fieldwork activities must follow the [Fieldwork Safety Policy](#) and develop a [Safety Plan](#) (link goes to optional template) as required by the policy. The [Safety Guidelines for Fieldwork](#) may be consulted for guidance.

5.2.7 Stewardship

5.2.7.1 Cost Sharing

Cost sharing has a significant financial impact on the department providing the funds and on the University as a whole. It is University policy to cost share only when it is required in writing by the external sponsor. Cost sharing can take a variety of forms: e.g., reduced F&A cost recovery rates (see 5.2.7.4 below), commitments of faculty effort, or the use of University funds for additional project support. Please note, however, regardless of sponsor or circumstances, all deviations from the University's official F&A rate require prior administrative review and approval.

Exceptions to inclusion of cost sharing on a sponsored program application must be approved by either:

- SOM/SON Management Center for proposals submitted by the School of Medicine (SOM) and School of Nursing (SON),
- Office of Research Support and/or Vice Provost for Research and/or designee for proposals by University/Campus departments.

The following criteria should be borne in mind when considering cost sharing:

- 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. It is of special note that any quantifiable financial commitments included in any part of the proposal, not solely in the budget and/or justification, will be considered by the Federal Sponsor to be proposed cost sharing. Special care should be taken to not inadvertently commit to cost sharing in proposal documents.
- 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.

5.2.7.2 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 should also be noted that the PI is responsible to ensure effort is expended on sponsored projects as committed and/or within sponsor guidelines.

5.2.7.3 Equipment Transfer Guidelines

All guidelines for Duke departmental property officers are based on this fundamental concept: assets are owned by Duke or the sponsor 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, questions sometimes arise 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 sponsor. 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 Campus Schools or to the Vice Dean for Finance & Resource Planning for Duke Medicine entities.

5.2.7.4 F&A Cost Recovery 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 excluding F&A cost recovery. In these instances the Duke policy may be 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, instruction, or DOD contracts/subcontracts. See the [F&A Agreement](#) for a full list of Duke rates.

5.2.7.5 F&A Distribution 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.

5.2.7.6 Research Costing Compliance

As a responsible recipient of federal research awards, Duke University accepts full accountability to sponsoring agencies for financial compliance with appropriate federal and agency regulations. Each employee of Duke University who engages in sponsored projects administration has an obligation to ensure compliance with sponsor and University requirements for the appropriate management of sponsored funds.

Duke has addressed this responsibility, in part, by instituting a highly effective and comprehensive compliance program. A key component of this program includes mandatory training of staff and faculty with grant-related financial responsibilities, optional certificate training programs, continuing education opportunities and dedicated on-line resources.

In addition, The Office of Research Costing Compliance (RCC) conducts extensive monitoring of all applicable financial actions relating to grant and contract management. RCC identifies potential compliance risks, monitors

risk areas, and works closely with the University management centers, pre- and post-award offices to address compliance issues.

RCC is also responsible for developing and communicating financial compliance policy and practice. Through a dedicated [website](#), regular updates to the campus community and continuous engagement with University leadership, RCC provides a comprehensive approach to financial compliance management.