



RESEARCH COMPLIANCE GUIDE

ComplianceGuide.wustl.edu

A publication of the
Office of the Vice Chancellor for
RESEARCH

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Research Education and Information (REI)

Tel: 314.362.2709 | Web: rei.wustl.edu | Eml: rei@wusm.wustl.edu

RESEARCH COMPLIANCE GUIDE

A publication of the
Office of the Vice Chancellor for Research

ComplianceGuide.wustl.edu

Office of the Vice Chancellor for
RESEARCH
research.wustl.edu

OUR MISSION

The Office of the Vice Chancellor for Research provides innovative leadership, support, and service to the University and faculty to enhance and grow research that is conducted ethically and responsibly for the benefit of society.



MESSAGE FROM THE VICE CHANCELLOR

A robust culture of responsible conduct of research is one of Washington University's greatest assets, which is only made possible by every community member's commitment to upholding the highest ethical, legal and regulatory standards. It is with this in mind that we will continue to work with integrity as we further our mission of discovering and sharing new knowledge in service to, and for the benefit of, our community, country and world.

To provide faculty and staff with a single tool to better locate the resources and expertise to support these principles, I am pleased to present this *Research Compliance Guide*.

Jennifer K. Lodge, Vice Chancellor for Research
Washington University in St. Louis

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INSTITUTIONAL COMMITMENT

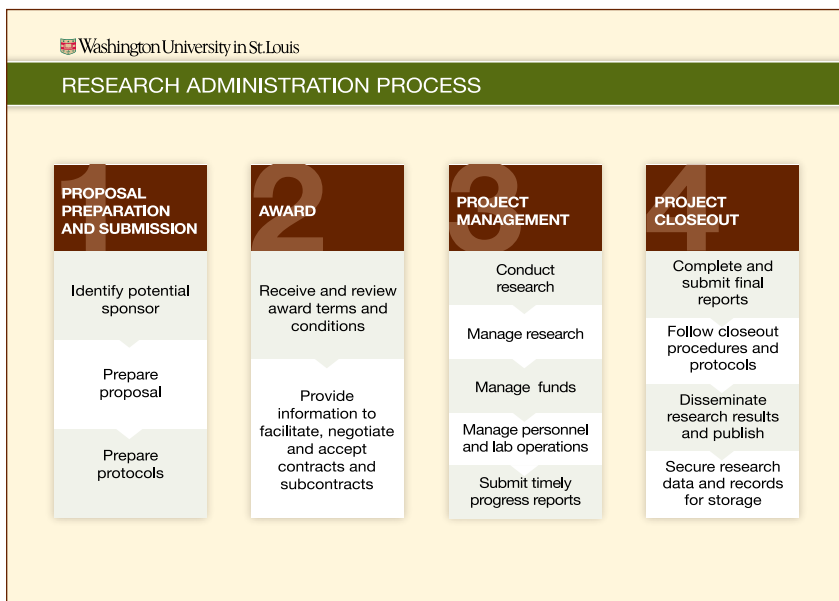
Washington University is committed to the objective, ethical, and responsible conduct of research. All members of the University community involved in research will take personal responsibility for their actions in pursuit of individual and organizational excellence. Each individual will uphold the highest standards of ethical and professional conduct in accordance with the Washington University Code of Conduct, sponsoring agency policies and regulations, and all other University policies governing research.

HOW TO USE THIS GUIDE

The research administration process (illustrated below) is a multi-stage collaborative effort between many key partners across the University. Success requires that each key partner take an active role to assure that the research is proposed, performed, and managed ethically and responsibly.

Utilize this guide to help you identify research-related compliance areas, resources, and tools that assist the Washington University research community to effectively propose, perform, and manage research projects. This guide is not meant to be a comprehensive or detailed inventory of University or office policies, guidelines, or procedures.

For the most current version of this *Guide*, please visit ComplianceGuide.wustl.edu



REPORTING VIOLATIONS AND CONCERNS

GENERAL EXPECTATIONS

Each community member is expected to report violations or concerns that come to his/her attention. Managers have a special duty to adhere to the standards set forth in the University's Code of Conduct and other policies, procedures, and guidelines; to recognize violations; and to enforce these standards. Disciplinary actions for proven violations, or for retaliation against anyone who reports possible violations, will be determined on a case-by-case basis and may include termination of employment. Individuals who violate these standards may also be subject to civil and criminal charges in some circumstances.

HOW TO REPORT A VIOLATION OR DISCUSS A CONCERN

You may report violations or concerns to your immediate supervisor or department head, if appropriate. You may also call the University Compliance Hotline at the number established for this purpose: 314.362.4998. Reports may be made anonymously to this number, if the caller so desires. This telephone line has no caller identification or number recognition.

You may also access a form that can be used to report violations or concerns on the Code of Conduct website at: <https://universitycompliance.wustl.edu/codeofconduct/Pages/OnlineReportingForm.aspx>

For matters dealing with one of the specific areas below, you may call the number indicated, or you may call the University Compliance Office at 314.362.4910.

Text from <http://codeofconduct.wustl.edu/procedures.html>

ISSUES & CONTACTS

General Concerns | University Compliance Office

Tel: 314.362.4910 | **Anonymous Compliance Hotline:** 314.362.4998

Animal Care Issues | Vice Chancellor for Research

Tel: 314.747.0515

Conflict of Interest Issues - Research | Vice Chancellor for Research

Tel: 314.747.0515

Environmental Health & Safety Issues | Asst. Vice Chancellor for Environmental Health & Safety

Tel: 314.362.6816

HIPAA (Health Insurance Portability and Accountability Act) Issues

Privacy Issues | HIPAA Privacy Office

Tel: 314.747.4975

Security Issues | Information Security Office

Tel: 314.747.2955

Human Studies Issues | Vice Chancellor for Research

Tel: 314.747.0515

Financial Issues | Vice Chancellor for Finance & CFO

Tel: 314.935.9018

Physician and Medical Professional Billing Issues | Director of Physician Billing Compliance

Tel: 314.747.7660

Research Financial Management Issues | Vice Chancellor for Research

Tel: 314.747.0515

Research Integrity Issues | Vice Chancellor for Research

Tel: 314.747.0515

COMPLIANCE AREAS

ANIMAL STUDIES

ROLES/RESPONSIBILITIES

Faculty and staff who use vertebrate animals in research or training are responsible for submitting a protocol application for approval to the Animal Studies Committee (ASC); obtaining the proper education and/or training relating to the care for and use of vertebrate animals; ensuring proper training documentation is submitted to the ASC to receive access to the animal facility from Division of Comparative Medicine (DCM); conducting research in accordance with approved protocol and University policies; cooperating with unannounced semiannual facility and/or laboratory inspections conducted by WUSTL and other regulatory entities; maintaining protocol progress reports annually; and retraining or resubmitting protocols as necessary.

EDUCATION/TRAINING

Contact the Division of Comparative Medicine (DCM) to register for training in animal welfare education. See website for details: <http://dcminfo.wustl.edu> – click on Getting Started – Training – Facility Access

POLICIES/GUIDELINES

<http://asc.wustl.edu> – click on Member Content, then Guidelines

INSTITUTIONAL OVERSIGHT

Animal Studies Committee (ASC)

Web: <http://asc.wustl.edu>

CONTACTS

For questions related to protocol submission:

Research Ethics and Compliance Office (RECO)

Campus Box 1054

Tel: 314.362.3229 | Web: <http://asc.wustl.edu>

For questions related to animal welfare education:

Division of Comparative Medicine (DCM)

Campus Box 8061

Tel: 314.362.3700 | Fax: 314.362.6480 | Web: <http://dcminfo.wustl.edu>

AUTHORSHIP & PUBLICATION STANDARDS

ROLES/RESPONSIBILITIES

Individuals that prepare scientific or other scholarly information for abstracts, publications, grant applications, or presentations are responsible for following the University Policy for Authorship on Scientific and Scholarly Publications; reviewing and adhering to specific authorship criteria set forth by publishers or granting institutions (in some cases); and reporting violations.

EDUCATION/TRAINING

For general education in University authorship standards, please access the Responsible Authorship and Publication Practices tutorial at: <http://research.wustl.edu/PoliciesGuidelines/Pages/Authorship.aspx>

Assistance in publishing support: <https://becker.wustl.edu/classes-consulting/specialized-expertise/publishing-evaluation-support>

NIH Public Access Policy education: <https://becker.wustl.edu/classes-consulting/specialized-expertise/publishing-evaluation-support/compliance>

POLICIES/GUIDELINES

Policy for Authorship on Scientific and Scholarly Publications:
<http://www.wustl.edu/policies/authorship.html>

Additional resources may be found at:

<http://research.wustl.edu/PoliciesGuidelines/Pages/Authorship.aspx>

INSTITUTIONAL OVERSIGHT

Committee on Research Integrity (CRI)

Web: <http://cri.wustl.edu>

CONTACTS

For publication support and services:

Becker Medical Library

Campus Box 8132

Tel: 314.362.7080 | Fax: 314.454.6606 | Web: <http://becker.wustl.edu>

For questions related to authorship:

CRI Program

Campus Box 1054

Tel: 314.747.5571 | Fax: 314.362.8712 | Eml: reco@wusm.wustl.edu | Web: <http://reco.wustl.edu>

Office of the Vice Chancellor for Research (OVCR)

Campus Box 8106

Tel: 314.747.0515 | Fax: 314.367.6666 | Web: <http://research.wustl.edu>

CLINICAL TRIALS

ROLES/RESPONSIBILITIES

Faculty and staff who conduct clinical trials on human subjects must register trials at ClinicalTrials.gov in accordance with sponsor and publisher policies; be aware of all aspects of human participant research protection and confidentiality requirements (see Human Research and HIPAA sections of this guide); comply with the terms of any industry-sponsored clinical trial agreements; meet all obligations of specific sponsors, such as the National Institutes of Health and the Food and Drug Administration; and comply with the institutional plan for billing compliance. Investigators are individually responsible for their compliance as well as assuring that members of their research team are conducting research ethically and responsibly.

EDUCATION/TRAINING AND HUMAN RESEARCH EDUCATION POLICY

Any faculty and staff that interact with human research participants may be required to complete human research education or training modules. For more details, please see:

<http://www.wustl.edu/policies/humansubjectseducation.html>

Staff that enroll participants into the Billing Matrix must complete training to receive access to the site. Email: ccsbillingmatrix@wusm.wustl.edu for a link to the online training module and account request information.

POLICIES/GUIDELINES

Clinical trials registration guidelines: <http://research.wustl.edu/ComplianceAreas/clinical/GuidelinesPolicies/ClinicalTrialRegistration>

Clinical research forms:

http://research.wustl.edu/ComplianceAreas/clinical/Research_forms

INSTITUTIONAL OVERSIGHT

Center for Applied Research Sciences (CARS)

Human Research Protection Office (HRPO)

Office of Physician Billing Compliance

Office of Sponsored Research Services (OSRS)

CONTACTS

For questions regarding clinical trials registration, and the Billing Matrix:

Center for Clinical Studies (Also known as CARS)

Campus Box 8009 | Tel: 314.747.4000 | Fax: 314.747.1404 | Web: <http://ccs.wustl.edu>

For questions regarding human research protocol submission and human research education:

Human Research Protection Office (HRPO)

Campus Box 8089 | Tel: 314.747.6800 | Web: <http://hrpo.wustl.edu>

For questions regarding billing compliance:

Office of Physician Billing Compliance

Campus Box 8041 | Tel: 314.747.7661 | Fax: 314.747.7666 | Web: <http://opbc.wustl.edu>

For questions regarding clinical trial agreements:

Joint Research Office for Contracts (JROC)

Campus Box 1054 | Tel: 314.747.5393 | Fax: 314.362.8712

For questions regarding clinical research grants:

Office of Sponsored Research Services (OSRS)

Campus Box 1054 | Tel: 314.747.4134 | Fax: 314.362.8712 | Web: <http://osrs.wustl.edu>

CODE OF CONDUCT

ROLES/RESPONSIBILITIES

Faculty and staff members are responsible for complying with guidelines set forth by the University Compliance Program, which includes, but is not limited to: reading, annually certifying, and adhering to the ethical and legal standards outlined in the University Code of Conduct at all times; maintaining the highest ethical standards; complying with all relevant laws and regulations; cooperating with monitoring from central offices and audits performed by the University Compliance Office; attending training as a proactive measure; attending training and conducting monitoring as required in their area of responsibility; and reporting concerns of questionable practices by any member of the University community.

EDUCATION/TRAINING

Education is administered through area-specific compliance offices such as those in this guide. For a summary of research-related programming, visit:
<http://research.wustl.edu/Pages/EducationandAwareness.aspx>

POLICIES/GUIDELINES

University Code of Conduct: <http://codeofconduct.wustl.edu> – click on “Full PDF form here”

INSTITUTIONAL OVERSIGHT

University Compliance Office (UCO)

CONTACTS

University Compliance Office (UCO)

Campus Box 8016

Tel: 314.362.4915 | Fax: 314.362.4954 | Web: <http://universitycompliance.wustl.edu>

Anonymous Hotline: 314.362.4998

Anonymous Online Reporting Form:

<https://universitycompliance.wustl.edu/codeofconduct/Pages/Onlinereportingform.aspx>

COMPLIANCE PROFILE AND EDUCATION

ROLES/RESPONSIBILITIES

Faculty and staff are responsible for completing the Compliance Profile and assigned compliance-related trainings in Learn@Work. The Compliance Profile is an interactive web-based questionnaire available to faculty and staff. It is designed to identify the various compliance and educational activities required of investigators, and is specific to their responsibilities at WUSTL. The profile also provides a direct link to the activity or additional information needed to complete the requirement.

Learn@Work, the University's cloud-based learning management system, provides a consolidated and streamlined training experience for faculty and staff to complete and track all compliance-related training activities in a single application.

EDUCATION/TRAINING

For Learn@Work training, visit: <http://LearnatWork.wustl.edu/training>

POLICIES/GUIDELINES

LearnatWork.wustl.edu

INSTITUTIONAL OVERSIGHT

Human Resources

CONTACTS

Human Resources, Learn@Work System Administrator

Tel: 314.935.5707 | Eml: LearnatWork@wustl.edu | Web: <http://LearnatWork.wustl.edu>

EFFORT REPORTING

ROLES/RESPONSIBILITIES

Faculty and staff who work on sponsored projects are responsible for reviewing and certifying accuracy of their electronic Personnel Activity Report (ePAR) to ensure that salary charges to sponsored projects are reasonable in relation to the actual work performed. The University supports the effort reporting requirements through online certification of an electronic Personnel Activity Report (ePAR). Certification is completed through the electronic Personnel Activity Reporting System (ePARS) during the fiscal year depending on faculty or staff role:

Semi-annual: School of Medicine faculty

Semi-annual: School of Engineering faculty that work on sponsored projects

Semester: Danforth faculty that work on sponsored projects

Quarter: Staff/Students that work on sponsored projects

EDUCATION/TRAINING

General Effort Reporting Education

All faculty from the School of Medicine and faculty that work on sponsored funds on the Danforth campus are required to complete effort reporting training. Staff and students that work on sponsored funds are strongly encouraged to complete effort reporting training.

The Effort Reporting Principles online training modules are accessible via Learn@Work: <http://LearnatWork.wustl.edu>

Additional educational information and resources are available on the SPA website: <http://spa.wustl.edu/effortreporting.htm>

ePARS System

ePARS is accessible via <http://one.wustl.edu>

System tutorials and training on the ePARS System are accessible via the ePARS website: <http://epars.wustl.edu>

POLICIES/GUIDELINES

<http://spa.wustl.edu/effortreporting.htm>

INSTITUTIONAL OVERSIGHT

Sponsored Projects Accounting

CONTACTS

Sponsored Projects Accounting (SPA)

Campus Box 1034

Tel: 314.935.7216 | Fax: 314.935.4309 | Web: <http://spa.wustl.edu>

ENVIRONMENTAL HEALTH & SAFETY

ROLES/RESPONSIBILITIES

Faculty and staff are responsible for attending appropriate trainings/annual retraining; ensuring that other lab personnel attend appropriate trainings/annual retraining; wearing appropriate protective equipment; cooperating with facility and/or laboratory inspections by WUSTL or regulatory agency entities; adhering to general Environmental Health & Safety (EH&S) regulatory requirements and guidelines; managing hazardous and/or radioactive materials and/or their disposal in accordance with EH&S guidelines, state and federal regulations; registering research with EH&S and/or other appropriate entities as necessary; licensing laboratory equipment and/or spaces with the State of Missouri as necessary; applying for, updating, and/or reauthorizing registrations as required.

EDUCATION/TRAINING

Requirements depend on personnel role and/or equipment need. Contact Environmental Health & Safety to determine training needs prior to working with hazardous materials and/or equipment.

POLICIES/GUIDELINES

<http://ehs.wustl.edu/committees>

<http://ehs.wustl.edu/resources/Pages/ResourcesSearch.aspx>

<https://radsafety.wustl.edu>

INSTITUTIONAL OVERSIGHT

Institutional Biological & Chemical Safety Committee

Radiation Safety Committee

Radioactive Drug Research Committee

CONTACTS

Environmental Health & Safety (EH&S)

Campus Box 1010

Tel: 314.362.6816 | Fax: 314.935.9266 | Web: <http://ehs.wustl.edu>

For each of the divisions below, call the main EH&S telephone number:

Biological & Chemical Safety - EH&S

Web: <http://ehs.wustl.edu>

Emergency Preparedness - Emergency Management

Web: <http://emergency.wustl.edu>

Environmental Compliance - EH&S

Web: <http://ehs.wustl.edu/hmm>

Occupational Safety - EH&S

Web: <http://ehs.wustl.edu>

Radiation Safety Office - EH&S

Web: <http://radsafety.wustl.edu>

24-hour emergency cell: 314.299.1322

EXPORT CONTROLS

ROLES/RESPONSIBILITIES

Export control laws govern the transfer of strategic technology and information to foreign countries and to foreign nationals within the U.S. (“deemed exports”). These regulations can affect the shipment or transfer of technologies and information overseas, foreign travel, foreign visitors, and foreign national participation in research occurring on campus. Faculty and staff are responsible for maintaining compliance with export control laws. The Export Control Manager (ECM) can assist faculty and staff to determine if, and how, export control regulations apply to their research and other activities. The ECM can also help faculty to obtain the appropriate export license(s) before controlled items or technical data are transferred across U.S. boundaries or are accessed by foreign nationals on campus.

EDUCATION/TRAINING

Information regarding export trade controls is available via:

<http://research.wustl.edu/ComplianceAreas/ExportControl>

You may contact the Export Control Manager to arrange presentations for faculty and staff.

POLICIES/GUIDELINES

The University policy on export control can be found at:

<http://research.wustl.edu/ComplianceAreas/ExportControl/Policy>

INSTITUTIONAL OVERSIGHT

Because issues related to export controls can arise in a variety of ways, whether through acceptance of sponsored research contracts, material transfers, travel, shipping, or attending conferences, institutional oversight of export trade controls works through many channels. The primary contact is listed below. In the event that a license is required to comply with export laws, faculty and staff must work with the Export Control Manager to obtain and document compliance with the applicable licensing requirements.

CONTACTS

To determine the applicability of export control regulations to a particular situation, for restricted party screening, or for other export control issues please contact:

Export Control Manager

Office of Sponsored Research Services

Campus Box 1054

Tel: 314.747.1378 | Eml: ovcreportcompliance@wustl.edu

HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

ROLES/RESPONSIBILITIES

Faculty and staff who have contact with protected health information must complete Washington University's HIPAA training prior to any contact with protected health information (PHI) or within ten days of employment.

EDUCATION/TRAINING

HIPAA training modules may be found in the Learn@Work Learning Management System:
LearnatWork.wustl.edu

POLICIES/GUIDELINES

<http://hipaa.wustl.edu>

INSTITUTIONAL OVERSIGHT

HIPAA Privacy Office
Information Security Office

CONTACTS

For questions regarding the access, use, and disclosure of PHI:

HIPAA Privacy Office

Campus Box 8098

Tel: 314.747.4975 | Fax: 314.362.1199 | Web: <http://hipaa.wustl.edu>

Toll Free: 866.747.4975

For questions regarding the physical and technical security of electronic PHI:

Information Security Office

Campus Box 8218

Tel: 314.747.2955 | Fax: 314.747.2866 | Web: <http://informationsecurity.wustl.edu>

HUMAN EMBRYONIC STEM CELL RESEARCH

ROLES/RESPONSIBILITIES

Faculty and staff using human embryonic stem cells (hESC) for research purposes must submit an application and research protocol to the Embryonic Stem Cell Research Oversight Committee (ESCRO) prior to initiation of experiments utilizing hESC (ESCRO approval may be required earlier dependent upon funding agency requirements); must also obtain IRB review; conduct research in accordance with the approved protocol and University policies; report modifications; file annual protocol renewals; adhere to material transfer agreements; and cooperate with any protocol monitoring.

EDUCATION/TRAINING

Information on human embryonic stem cell research is available via: <http://escro.wustl.edu>

Any faculty and staff involved in human embryonic stem cell research may be required to complete human research education or training, dependent upon the nature of the research. For more details, please see: <http://www.wustl.edu/policies/humansubjectseducation.html>

POLICIES/GUIDELINES

<http://research.wustl.edu/ComplianceAreas/Pages/StemCells.aspx>

INSTITUTIONAL OVERSIGHT

Embryonic Stem Cell Research Oversight Committee (ESCRO)

Web: <http://escro.wustl.edu>

CONTACTS

ESCRO Program

Campus Box 1054

Tel: 314.747.5571 | Fax: 314.362.8712 | Eml: reco@wusm.wustl.edu | Web: <http://reco.wustl.edu>

HUMAN RESEARCH

ROLES/RESPONSIBILITIES

Faculty and staff working on projects (research, teaching, or other) involving human participants and/or human embryonic stem cells must complete the appropriate online human research training module(s); submit research protocol applications for approval prior to the initiation of each project; conduct research in accordance with approved protocol and University policies; report modifications and unanticipated problems in a timely manner; cooperate with any protocol monitoring; and file annual protocol reviews. Faculty and staff that work with human embryonic stem cells must submit protocols to the Embryonic Stem Cell Research Oversight Committee (ESCRO).

EDUCATION/TRAINING

Any faculty and staff that interact with human research participants may be required to complete human research education or training modules. For more details, please see:

<http://www.wustl.edu/policies/humansubjectseducation.html>

The University offers many educational opportunities for faculty and staff involved in human research. Access the Research Education Calendar for upcoming events:

<http://research.wustl.edu/events>

POLICIES/GUIDELINES

General Human Research Policies and Guidelines: <http://hrpo.wustl.edu>

Human Research Education Policy: <http://www.wustl.edu/policies/humansubjectseducation.html>

Human Embryonic Stem Cell Guidance:

<http://research.wustl.edu/ComplianceAreas/Pages/StemCells.aspx>

INSTITUTIONAL OVERSIGHT

Human Research Protection Office (HRPO) (WUSTL IRB)

Human Research Quality Assurance and Quality Improvement Committee

Embryonic Stem Cell Research Oversight Committee (ESCRO)

CONTACTS

For human research protocol submission and human research education:

Human Research Protection Office (HRPO)

Campus Box 8089 | Tel: 314.747.6800 | Web: <http://hrpo.wustl.edu>

For human research monitoring:

Human Research Quality Assurance/Quality Improvement Program (HR QA/QI)

Campus Box 1054 | Tel: 314.747.5526 | Fax: 314.362.8712

Web: http://research.wustl.edu/Offices_Committees/hrqaqi

For human embryonic stem cell research:

Embryonic Stem Cell Research Oversight Committee (ESCRO)

Campus Box 1054 | Tel: 314.747.5571 | Fax: 314.362.8712 | Eml: reco@wusm.wustl.edu

Web: <http://reco.wustl.edu>

INTELLECTUAL PROPERTY

ROLES/RESPONSIBILITIES

Faculty and staff who have developed new technology with significant use of University resources, or are involved in the transfer of materials or other intellectual property, are responsible for submitting the necessary paperwork to the Office of Technology Management (OTM). Faculty and staff are also responsible for following University policy and guidelines that address, among other things, ownership of intellectual property and revenue sharing from the licensing of intellectual property; and are responsible for otherwise assisting the University in meeting its obligation to federal funding agencies that require commercialization of ideas for public benefit.

EDUCATION/TRAINING

OTM staff are available for formal presentations or informal discussions regarding intellectual property and technology management. OTM also runs workshops and seminars to provide researchers with seminal information relating to the invention and commercialization process. More information can be found here: <http://otm.wustl.edu/educational-opportunities>

POLICIES/GUIDELINES

Intellectual Property Policy: <http://www.wustl.edu/policies/intelprop.html>

Material Transfer Guidelines: <http://otm.wustl.edu/for-inventors/material-transfer>

Invention and Licensing Policies: <http://otm.wustl.edu/for-inventors/policies>

INSTITUTIONAL OVERSIGHT

Office of the Provost

Web: <https://provost.wustl.edu>

CONTACTS

Office of Technology Management (OTM)

Campus Box 8013

Tel: 314.747.0920 | Fax: 314.362.5872 | Web: <http://otm.wustl.edu>

PUBLIC ACCESS

ROLES/RESPONSIBILITIES

In a policy memorandum dated 22 February 2013, the White House Office of Science and Technology Policy (OSTP) directed all Federal agencies with more than \$100M in R&D expenditures to develop plans to provide public access to the “results” of federally funded research. Results are defined as “peer-reviewed research publications and digital data sets.”

EDUCATION/TRAINING

Becker Medical Library regularly offers educational presentations on how to comply with federal agency public access policies. To schedule a customized presentation for your group, you may contact any of the offices listed under Contacts.

POLICIES/GUIDELINES

Investigators are already aware of the NIH Public Access Policy which has been in force since 2008. As a result of the 2013 OSTP memorandum, other Federal agencies are implementing similar public access policies. Investigators receiving federal funds are responsible for making sure that applicable journal articles resulting from those funds are compliant with the Public Access Policy of their sponsoring agency.

INSTITUTIONAL OVERSIGHT

Assistance with public access compliance is provided by the Becker Medical Library, the University Libraries, and the Office of Sponsored Research.

CONTACTS

School of Medicine

Research and Publication Support

Tel: 314.362.7865 | Eml: sarlic@wustl.edu

Danforth Campus

University Libraries

Tel: 314.935.4819 | Eml: rlewis@wustl.edu

Office of Sponsored Research Services

Tel: 314.747.1378 | Eml: langton@wustl.edu

RESEARCH CONFLICTS OF INTEREST

ROLES/RESPONSIBILITIES

Individuals are responsible for guarding against financial conflicts of interest which might compromise the integrity and objectivity of research. In addition to all faculty, individuals having independent responsibility for the design, conduct, or reporting of research must report all personal financial interests at least annually through the Financial Disclosure System and as otherwise requested. Education is required every four years. All financial conflicts of interest must be appropriately managed to ensure the objectivity of the research according to applicable University policies.

EDUCATION/TRAINING

Information regarding research conflicts of interest is available via: <http://coi.wustl.edu>

The Program for the Ethical and Responsible Conduct of Science and Scholarship (PERCSS) Conflict of Interest online educational module is accessible via Learn@Work: <http://LearnatWork.wustl.edu>

POLICIES/GUIDELINES

University Research Conflicts of Interest Policy:
<http://research.wustl.edu/ComplianceAreas/COI/Policy>

INSTITUTIONAL OVERSIGHT

Conflicts of Interest Review Committee (CIRC)

Web: <http://coi.wustl.edu>

CONTACTS

COI Program

Campus Box 1054

Tel: 314.362.2709 | Fax: 314.362.8712 | Eml: coi@wustl.edu | Web: <http://coi.wustl.edu>

RESEARCH INTEGRITY

ROLES/RESPONSIBILITIES

Individuals are responsible for protecting the integrity of the research process by conducting research within certain ethical standards and reporting concerns of research misconduct by any member of the University community to the Research Integrity Officer (RIO), Vice Chancellor for Research (VCR), the Research Ethics and Compliance Office (RECO), or the University Compliance Hotline.

EDUCATION/TRAINING

Information regarding research integrity is available via: <http://cri.wustl.edu>

The Program for the Ethical and Responsible Conduct of Science and Scholarship (PERCSS) Research Integrity and Responsible Authorship and Publication Practices online educational modules are accessible via Learn@Work: <http://LearnatWork.wustl.edu>

For a list of other research-related educational programming, visit:
<http://research.wustl.edu/Pages/EducationandAwareness.aspx>

POLICIES/GUIDELINES

Research Integrity Policy:

<http://research.wustl.edu/PoliciesGuidelines/Pages/ResearchIntegrityPolicy.aspx>

Policy for Authorship on Scientific and Scholarly Publications:

<http://www.wustl.edu/policies/authorship.html>

INSTITUTIONAL OVERSIGHT

Committee on Research Integrity (CRI)

Web: <http://cri.wustl.edu>

CONTACTS

CRI Program

Campus Box 1054

Tel: 314.747.5571 | Fax: 314.362.8712 | Eml: reco@wusm.wustl.edu | Web: <http://reco.wustl.edu>

Research Integrity Officer (RIO)

Campus Box 1054

Tel: 314.454.8495

Vice Chancellor for Research (VCR)

Campus Box: 8106

Tel: 314.747.0515

RESPONSIBLE CONDUCT OF RESEARCH

ROLES/RESPONSIBILITIES

The University is committed to the highest ethical and professional standards of conduct in research, and relies on each community member's ethical behavior, honesty, integrity, and good judgment. Individuals are responsible for the compliant, ethical, and responsible design, conduct, reporting, and reviewing of research in accordance with federal, state, and local regulations and University and sponsoring agency policies and procedures.

EDUCATION/TRAINING

The University offers many educational opportunities for researchers interested in learning more about research integrity, ethics, and responsible conduct.

The Program for the Ethical and Responsible Conduct of Science and Scholarship (PERCSS) online educational modules are accessible via Learn@Work: <http://LearnatWork.wustl.edu>

For additional responsible conduct of research education:

<http://research.wustl.edu/events/Pages/UpcomingEvents.aspx> – search events by Subject Matter: “RCR Course Events”

POLICIES/GUIDELINES

Many University policies and procedures serve to promote responsible and ethical conduct in research. For a list of policies and guidelines related to research, see:

<http://research.wustl.edu/PoliciesGuidelines>

For guidelines and tools addressing applicable RCR requirements of the National Institutes of Health (NIH) and the National Science Foundation (NSF), see:

<http://research.wustl.edu/ComplianceAreas/rcr>

INSTITUTIONAL OVERSIGHT

Office of the Vice Chancellor for Research

Web: <http://research.wustl.edu>

CONTACTS

Research Education and Information (REI)

Campus Box 1054

Tel: 314.362.2709 | Fax: 314.362.8712 | Web: <http://rei.wustl.edu>

SPONSORED PROJECTS

ROLES/RESPONSIBILITIES

Faculty and staff are responsible for obtaining institutional signature on proposals; submitting all paperwork to the appropriate office; partnering with departmental and central administration staff for administration of sponsored project funds in accordance with sponsor regulations and guidelines, and University policy and procedures; obtaining review, negotiation, and institutional signature on all research grants, contracts and subagreements; and cooperating with and verifying award management and financial transactions on a regular basis. These responsibilities apply throughout the process of obtaining and managing sponsored funds and should be fulfilled in a time-appropriate manner in accordance with sponsor, federal, and University deadlines, until the closeout of the award.

EDUCATION/TRAINING

Education for faculty and staff on proposal development, financial and award management, and contracts and subagreements is offered regularly. Access the Research Education Calendar for upcoming courses: <http://research.wustl.edu/events>

POLICIES/GUIDELINES

For research-related policies and guidelines: <http://research.wustl.edu/PoliciesGuidelines>

For financial management policies and guidelines: <http://spa.wustl.edu/policies.htm>

CONTACTS

Proposal Submission and Non-financial Award Management

Office of Sponsored Research Services (OSRS)

Campus Box 1054 | Tel: 314.747.4134 | Fax: 314.362.8712 | Web: <http://osrs.wustl.edu>

Financial Award Management

Sponsored Projects Accounting (SPA)

Campus Box 1034 | Tel: 314.935.7089 | Fax: 314.935.4309 | Web: <http://spa.wustl.edu>

Contracts/Subagreements

For any contracts or incoming subagreements, including industry sponsored clinical trials:

Joint Research Office for Contracts (JROC)

Campus Box 1054 | Tel: 314.747.5393 | Fax: 314.362.8712 | Web: <http://osrs.wustl.edu>

For outgoing subagreements:

Office of Sponsored Research Services (OSRS)

Campus Box 1054 | Tel: 314.747.4134 | Fax: 314.362.8712 | Web: <http://osrs.wustl.edu>

RESEARCH COMPLIANCE RESOURCES & TOOLS

RESOURCE/TOOL

DETAILS & CONTACT INFORMATION

Core Research Facilities

Core Facilities provide access to specialized equipment, expertise, and support that are often not available to individual investigators or laboratories.
<http://research.wustl.edu/Cores/Pages/default.aspx>
Office of Sponsored Research Services
Tel: 314.747.1654 | Eml: determanc@wustl.edu

Compliance Profile

The Compliance Profile is an interactive web-based questionnaire available to faculty and staff. It is designed to identify the various compliance and educational activities required of investigators, and is specific to their responsibilities at WUSTL. The profile also provides a direct link to the activity or additional information needed to complete the requirement. The Profile is accessible via Learn@Work.
<http://LearnatWork.wustl.edu>
Human Resources, Learn@Work System Administrator
Eml: LearnatWork@wustl.edu

Faculty Financial Reporting

Faculty Financial Reporting (FFR) is a web-based set of reports that assist faculty members in the financial management of a grant, project, contract or other sponsored agreement for which he or she is personally responsible. FFR provides a quick "snapshot" of the fund as of the previous business day.
<http://spa.wustl.edu/ffr.htm>
Sponsored Projects Accounting
Tel: 314.935.7089 | Web: <http://spa.wustl.edu>

ONE.wustl

ONE is a lightweight portal that helps you locate university systems and services faster and easier. With robust search capabilities, ONE aggregates key services and applications across the WashU landscape into one web portal, presenting information as tasks with direct links to the desired functionality.
<http://one.wustl.edu>
Information Technology
Tel: 314.933.3333 | Eml: ithelp@wustl.edu

OVCR Website

The Office of the Vice Chancellor for Research (OVCR) website is a consolidated source of information related to research compliance, administration, and management. All information and resources included in this guide are accessible via the OVCR website.
<http://research.wustl.edu>
Research Education and Information
Tel: 314.362.2709 | Eml: ovcrinfo@wustl.edu

RESOURCE/TOOL	DETAILS & CONTACT INFORMATION
Proposal Development Resources Website	<p>The Proposal Development Resources website is an online toolkit for researchers and administrators. It provides a number of features, including the ability to locate information about the University for agency forms; find samples of successful proposals and data sharing plans; locate financial and award information and trends; and more.</p> <p>http://proposalhelp.wustl.edu</p> <p>Office of Sponsored Research Services Tel: 314.747.4134 Eml: researchgrants@wusm.wustl.edu</p> <p>Joint Research Office for Contracts Tel: 314.747.5393 Eml: wucontracts@wumail.wustl.edu</p>
Research Education Calendar	<p>The Research Education Calendar is a special feature of the OVCR Website. The Calendar is updated regularly with internal and external lectures, courses, series, and conferences related to research compliance, administration, and management.</p> <p>http://research.wustl.edu/events</p> <p>Research Education and Information Tel: 314.362.2709 Eml: ovcrinfo@wustl.edu</p>
Research News Listserv	<p>Research News is an informational tool designed by the Office of the Vice Chancellor for Research to keep faculty, research support staff, and central area offices informed about current topics and issues related to research compliance, administration, and management at the University. Research News subscribers will receive email messages on topics they have pre-selected during the subscription process. To subscribe, visit:</p> <p>http://researchnews.wustl.edu</p> <p>Research Education and Information Tel: 314.362.2709 Eml: rei@wusm.wustl.edu</p>
Research Policies and Procedures	<p>The University is committed to the development, implementation, and maintenance of policies and guidelines that promote the compliant, ethical, and responsible design, conduct, reporting, and reviewing of research in accordance with Federal, state, and local regulations and sponsoring agency policies and procedures. The OVCR website provides access to research-related policies and procedures at:</p> <p>http://research.wustl.edu/PoliciesGuidelines</p> <p>Research Education and Information Tel: 314.362.2709 Eml: rei@wusm.wustl.edu</p>
Research Roles and Responsibilities	<p>The goal of the Roles and Responsibilities document is to provide comprehensive descriptions of the duties of the key individuals and organizational units that design, conduct, report, and/or support University research activities.</p> <p>http://roles.wustl.edu</p> <p>Research Education and Information Tel: 314.362.2709 Eml: rei@wusm.wustl.edu</p>

RESEARCH COMPLIANCE RESOURCES & TOOLS, CONT.

RESOURCE/TOOL	DETAILS & CONTACT INFORMATION
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SPIN	SPIN provides intuitive and easily customizable access to the most extensive research funding opportunity database on earth. Tools are provided that are geared towards both individual and administrative users, and SPIN provides both active searching as well as automated, daily opportunity notifications. Access via RMS. http://rms.wustl.edu
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Funding Resources Coordinator

Tel: 314.747.1654 | Eml: determanc@wustl.edu

GLOSSARY OF RESEARCH COMPLIANCE TERMS

GLOSSARY OF RESEARCH COMPLIANCE TERMS

TERM	DEFINITION
AAHRPP	Association for the Accreditation of Human Research Protection Programs. WUSTL has full AAHRPP accreditation.
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care. WUSTL has full AAALAC accreditation.
ASC	Animal Studies Committee
Audit	Formal examination of the transactions, controls, and system of an organization or individual. An audit may also include examination of compliance with applicable terms, laws, and regulations. Audit types include internal audits, external audits, and funding agency audits.
Authorized Signature	The signature of an institutional official who is designed to give assurances, make commitments, and execute such documents on behalf of Washington University. Signature of an authorized official certifies that commitments made on grant proposals or contract agreements will be honored and ensures that all sponsored agreements conform to Federal regulations, agency guidelines, and Washington University policy.
CARS	Center for Applied Research Sciences
Clinical Trial	An agreement to test drugs, devices, or other controlled substances for FDA approval or for-profit corporations. A clinical study involves the use of humans; a pre-clinical study may involve animal subjects.
CFR	Code of Federal Regulations
CIRC	Conflicts of Interest Review Committee
COI	Conflict of Interest
Compliant	The state of being in accordance with the relevant Federal or regional authorities and their requirements.
CRI	Committee on Research Integrity
DCM	Division of Comparative Medicine
Effort	The amount of work that an individual is compensated by WUSTL, regardless of the number of hours worked.
Effort Certification	Per Federal requirements, all effort applied to Federally-sponsored contracts or grants are verified after the fact to see that effort reasonably reflects the planned distribution of pay.

TERM	DEFINITION
Effort Reporting	Process by which an individual confirms that the salaries charged to sponsored projects are reasonable in relation to the work performed.
EH&S	Environmental Health and Safety
ESCRO	Embryonic Stem Cell Research Oversight Committee
Ethics	Thinking systematically about morals and conduct; making judgments about right and wrong; guidelines for action that draw on what is right or wrong; beyond talk and thinking to performance and action.
Federal False Claims Act	Allows private citizens to file a lawsuit in the name of the US Government charging fraud by government contractors and others who receive or use government funds and share in any money recovered. This is referred to as qui tam.
GAO	US General Accountability Office
Grant	In general terms, awards given to the university for a specific purpose to support instruction, research or public service. A grant is also a specific type of award (as opposed to contract or cooperative agreement). In this context, a grant is a pledge of support where the sponsor has little involvement in conducting the project.
Grant Administrator	University employees that help manage the sponsored project
Grant/Contract Officer	Sponsor's employee that is officially responsible for the project's business management.
Grantee	The recipient of a grant. When the university accepts a grant award on behalf of an individual the university becomes the grantee.
HIPAA	Health Insurance Portability and Accountability Act of 1996
HRPO	Human Research Protection Office
HR QA/QI	Human Research Quality Assurance/Quality Improvement Program
Human Subject	Living individual from which an investigator conducting research obtains data through intervention or interaction with the individual
IACUC	Institutional Animal Care and Use Committee. Animal Studies Committee is the equivalent WUSTL entity.
IBC	Institutional Biological and Chemical Safety Committee. The WUSTL IBC is administered by Environmental Health & Safety.

GLOSSARY OF RESEARCH COMPLIANCE TERMS, CONT.

TERM	DEFINITION
Identifiable Information	Information from which the identity of the subject is or may be readily ascertained or associated.
Informed Consent	The voluntary agreement obtained from a subject (or the subject's legally authorized representative) to participate in research or related activity, before participating in that activity. The consent must permit the individual (or legally authorized representative) to exercise free power of choice without undue inducement or any element of deceit, fraud, force, duress, or other form of coercion or constraint.
Intellectual Property	A broad term that encompasses the various intangible products of the intellect of inventors. These include patents, trademarks, copyrights, trade secrets, know-how, and other proprietary concepts, including an invention, scientific or technological development, and even computer software and genetically engineered microorganisms.
Internal Control	Broadly defined as a process, established by an entity's board of directors, management, and other personnel, designed to provide reasonable assurance regarding achievement of objectives in the following categories: effectiveness and efficiency of operations, reliability of financial reporting, compliance with applicable laws and regulations.
Invention	A patentable invention is any new and useful process, machine, article of manufacture, or composition of matter, or new and useful improvement thereof (35 United States Code 101).
Inventor	Employee who produces a development that must be disclosed to the Office of Patents & Technology Marketing in accordance with the Regents' Patents and Technology Transfer Policy.
IP	Intellectual property
IRB	Institutional Review Board
JROC	Joint Research Office for Contracts
Key Personnel	Term used by Washington University to describe individuals who are responsible for the "design, conduct or reporting of research." The Principal Investigator, and any other individual identified by the PI on a sponsored research project, is included in this category.
License	Legal permission from a patent owner to practice an invention. The license term is negotiated with the licensee.
Material Transfer Agreement	Legal contracts stating conditions under which a proprietary research material is being transferred from one institution or company to another.

TERM	DEFINITION
MTA	Material Transfer Agreement
Office of Research Integrity	Federal office that promotes integrity in biomedical and behavioral research, supported by the Public Health Service (PHS).
OGC	Office of General Counsel
OMB	Office of Management and Budget
OMB Circular A-21	Principles for determining costs applicable to grants, contracts, and other agreements with educational institutions. This document establishes uniform regulations that the University must follow in regards to determining costs applicable to grants, contracts, and agreements with other institutions. Each Federal agency applies these laws in its own regulations that are listed in the Code of Federal Regulations (CFR) and explained in its policy handbook (if it has one). The OMB Circular is the backbone of agency regulations; the agency cannot impose regulations that are inconsistent with the Circular or impose additional requirements.
ORI	Office of Research Integrity
OSRS	Office of Sponsored Research Services
OTM	Office of Technology Management
OVCR	Office of the Vice Chancellor for Research
Patent	A grant of property by the United States government to the inventor giving the owner of the patent the right to exclude others from making, using, offering for sale, or selling the invention in the US or importing it to this country. A US patent is granted for 20 years.
PI	Principal Investigator
Principal Investigator	The individual primarily responsible for a research grant, animal research protocol, cooperative agreement, training project, contract, or other sponsored agreement. The Principal Investigator is accountable for the design, direction, oversight, conduct, successful completion, and reporting of the sponsored project, and for managing any collaborative relationships.
Proprietary Research	Research sponsored by non-governmental entity or individual that involves restrictions on the distribution or publication of the research findings or results following completion, for a specified period or for indefinite duration.
Protocol	The methodology used in conducting a research project.

GLOSSARY OF RESEARCH COMPLIANCE TERMS, CONT.

TERM	DEFINITION
RCR	Responsible Conduct of Research
RECO	Research Ethics and Compliance Office
REI	Research Education and Information
Responsible Conduct of Research	The commitment to and application of shared values, such as honesty, accuracy, efficiency, and objectivity, in professional research settings.
RIO	Research Integrity Officer
Site Visit	An agency-initiated review of a project conducted at the applicant's institution.
SPA	Sponsored Projects Accounting
Sponsored Project	A project supported by an external funding source under a mutually binding agreement that restricts the use of funds to the approved project and stipulates other conditions with which the university must comply.
UCO	University Compliance Office
VCR	Vice Chancellor for Research

COMPLIANCE OFFICES QUICK DIRECTORY

COMPLIANCE OFFICES QUICK DIRECTORY

Animal Studies Committee

Tel: 314.362.3229 | Campus Box 1054 | Eml: asc@iacuc.wustl.edu

Becker Medical Library

Tel: 314.362.7080 | Campus Box 8132 | Web: <http://becker.wustl.edu>

Center for Applied Research Sciences

Tel: 314.747.4000 | Campus Box 8009 | Eml: ccs@wusm.wustl.edu

Committee on Research Integrity

Tel: 314.747.5571 | Campus Box 1054 | Eml: reco@wusm.wustl.edu

Conflicts of Interest Review Committee

Tel: 314.362.2709 | Campus Box 1054 | Eml: coi@wustl.edu

Contracts and Subagreements – *See Joint Research Office for Contracts***Division of Comparative Medicine**

Tel: 314.362.3700 | Campus Box 8061 | Eml: aebelb@dcm.wustl.edu

Environmental Health and Safety

Tel: 314.362.6816 | Campus Box 1010 | Eml: ehs@wustl.edu

Grants & Contracts – *See Office of Sponsored Research Services***HIPAA Privacy Office**

Tel: 314.747.4975 | Campus Box 8098 | Eml: hipaa@wusm.wustl.edu

Toll Free: 866.747.4975

HIPAA Information Security Office

Tel: 314.747.2955 | Campus Box 8218 | Eml: infosec@wusm.wustl.edu

Human Research Protection Office

Tel: 314.747.6800 | Campus Box 8089 | Web: <http://hrpo.wustl.edu>

Human Research Quality Assurance/Quality Improvement Program

Tel: 314.747.5526 | Campus Box 1054 | Eml: morrisam@wustl.edu

Institutional Biological and Chemical Safety Committee

Tel: 314.362.6816 | Campus Box 8229 | Eml: ehsibc@wustl.edu

Joint Research Office for Contracts

Tel: 314.747.5393 | Campus Box 1054 | Web: <http://osrs.wustl.edu>

Office of Physician Billing Compliance

Tel: 314.747.7661 | Campus Box 8041 | Web: <http://opbc.wustl.edu>

Office of Sponsored Research Services

Tel: 314.747.4134 | Campus Box 1054 | Web: <http://osrs.wustl.edu>

Office of Technology Management

Tel: 314.747.0920 | Campus Box 8013 | Eml: otm@dom.wustl.edu

Office of the Vice Chancellor for Research

Tel: 314.747.0515 | Campus Box 8106 | Eml: ovcrinfo@wustl.edu

Radiation Safety Committee

Tel: 314.362.3476 | Campus Box 8053 | Eml: radsafety@wustl.edu

Radioactive Drug Research Committee

Tel: 314.362.2809 | Campus Box 8223 | Eml: siegelb@mir.wustl.edu

Research Administration Services

Tel: 314.747.6253 | Campus Box 1054 | Eml: tsvirkom@wusm.wustl.edu

Research Education and Information

Tel: 314.362.2709 | Campus Box 1054 | Eml: rei@wusm.wustl.edu

Research Ethics and Compliance Office

Tel: 314.362.2709 | Campus Box 1054 | Eml: reco@wusm.wustl.edu

Sponsored Projects Accounting

Tel: 314.935.7089 | Campus Box 1034 | Eml: jjindhart@wustl.edu

University Compliance Office

Tel: 314.362.4910 | Campus Box 8016 | Eml: universitycompliance@wustl.edu

NOTES

Washington University is committed to the highest ethical and professional standards of conduct as an integral part of its mission, the promotion of learning. To achieve this goal, the University relies on each community member's ethical behavior, honesty, integrity, and good judgment. Each community member should demonstrate respect for the rights of others. Each community member is accountable for his/her actions.

- Excerpt from the Washington University Code of Conduct

Office of the Vice Chancellor for

RESEARCH

research.wustl.edu



Washington University in St. Louis

Animal Studies
Authorship and Publication Standards
Clinical Trials
Code of Conduct
Compliance Profile and Education
Effort Reporting
Environmental Health and Safety
Export Controls
Health Information Portability and Accountability Act (HIPAA)
Human Embryonic Stem Cell Research
Human Research
Intellectual Property
Public Access
Research Conflicts of Interest
Research Integrity
Responsible Conduct of Research
Sponsored Projects

Office of the Vice Chancellor for
RESEARCH

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