

RESEARCH COMPLIANCE WEBSITE

GOALS

- Improve website navigation
- Increase clarity of information
- Encourage research integrity
- Promote research collaboration

INSPIRATION

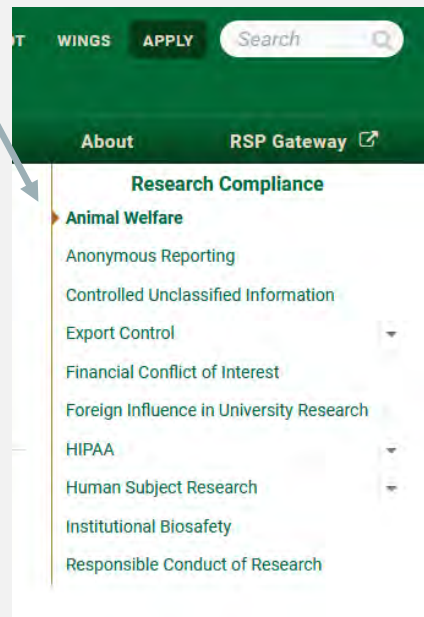
WRIGHT STATE UNIVERSITY

LOCATION CUES



Research Compliance

- Animal Welfare
- Anonymous Reporting**
- Controlled Unclassified Information
- Export Control
- Financial Conflict of Interest
- Foreign Influence in University Research
- HIPAA
- Overview**
- References
- Incident Reporting
- Contact Information
- Human Subject Research
- Institutional Biosafety
- Responsible Conduct of Research



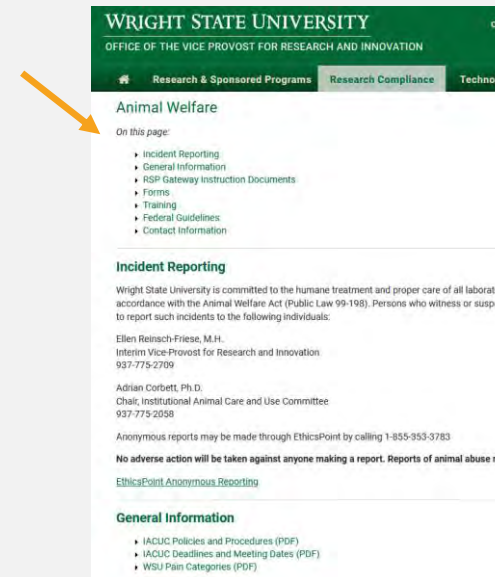
WRIGHT STATE UNIVERSITY
WINGS APPLY Search

About RSP Gateway

Research Compliance

- ▶ Animal Welfare**
- Anonymous Reporting
- Controlled Unclassified Information
- Export Control
- Financial Conflict of Interest
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STRUCTURAL LINKS



WRIGHT STATE UNIVERSITY
OFFICE OF THE VICE PROVOST FOR RESEARCH AND INNOVATION

Research & Sponsored Programs Research Compliance Technology

Animal Welfare

On this page:

- ▶ Incident Reporting
- ▶ General Information
- ▶ RSP Gateway Instruction Documents
- ▶ Forms
- ▶ Training
- ▶ Federal Guidelines
- ▶ Contact Information

Incident Reporting

Wright State University is committed to the humane treatment and proper care of all laboratory animals in accordance with the Animal Welfare Act (Public Law 99-198). Persons who witness or suspect an incident are required to report such incidents to the following individuals:

Ellen Reinach-Friese, M.H.
Interim Vice-Provost for Research and Innovation
937-775-2709

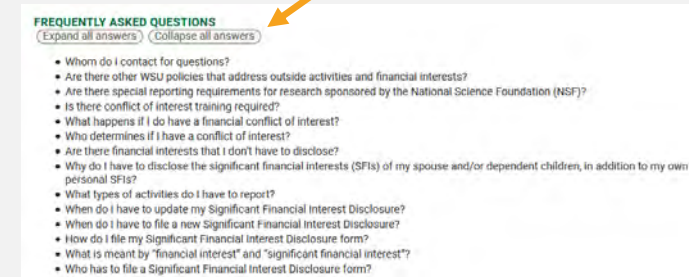
Adrian Corbett, Ph.D.
Chair, Institutional Animal Care and Use Committee
937-775-2058

Anonymous reports may be made through EthicsPoint by calling 1-855-353-3783

No adverse action will be taken against anyone making a report. Reports of animal abuse may be made through EthicsPoint Anonymous Reporting.

General Information

- ▶ IACUC Policies and Procedures (PDF)
- ▶ IACUC Deadlines and Meeting Dates (PDF)
- ▶ WSU Pain Categories (PDF)



FREQUENTLY ASKED QUESTIONS

[Expand all answers](#) [Collapse all answers](#)

- Whom do I contact for questions?
- Are there other WSU policies that address outside activities and financial interests?
- Are there special reporting requirements for research sponsored by the National Science Foundation (NSF)?
- Is there conflict of interest training required?
- What happens if I do have a financial conflict of interest?
- Who determines if I have a conflict of interest?
- Are there financial interests that I don't have to disclose?
- Why do I have to disclose the significant financial interests (SFIs) of my spouse and/or dependent children, in addition to my own personal SFIs?
- What types of activities do I have to report?
- When do I have to update my Significant Financial Interest Disclosure?
- When do I have to file a new Significant Financial Interest Disclosure?
- How do I file my Significant Financial Interest Disclosure form?
- What is meant by "financial interest" and "significant financial interest"?
- Who has to file a Significant Financial Interest Disclosure form?

COLUMBIA UNIVERSITY

DEFINITIONS AND CHARTS

Research Misconduct

Columbia University is committed to ensuring the integrity of research conducted under its auspices and has put in place policies and procedures that define misconduct, outline the process for investigating allegations, and explain the consequences of committing misconduct.

The University's Standing Committee on the Conduct of Research implements the Institutional Policy on Misconduct in Research ("Policy"). The Office of Research Compliance and Training helps administer the Policy and is a resource for anyone with concerns or questions about possible research misconduct. Naomi Schrag, the Vice President for Research Compliance, Training and Policy, is Columbia's Research Integrity Officer.

The University defines research misconduct, in accordance with federal policy, as any fabrication, falsification or plagiarism in proposing, performing or reviewing research or in the reporting of research results. Research misconduct does not include honest error or differences of opinion, authorship disputes that do not involve plagiarism, and violations of other University policies (e.g., sexual harassment policy).

Type of Research Misconduct	Definition
Fabrication	The making up of data or results and the recording or reporting thereof
Falsification	The manipulation of research materials, equipment or processes, or the change or omission of data or results such that the research is not accurately represented in the research record
Plagiarism	The appropriation of another person's ideas, processes, results or words without giving appropriate credit. It is important to recognize that plagiarism may occur not only in published work, but also in presentations of your research, and in grant proposals

Expand all Collapse all

University Procedures

Contact
Naomi J. Schrag, JD
Vice President for Research Compliance,
Training, and Policy
Office of Research Compliance and Training
212-854-8123
ns2333@columbia.edu

For scheduling, please contact Anderson Smith

Home
Office of Research Compliance and Training

University Compliance Hotline ☎
Phone: 866-627-3768

What You Need to Know about Research Misconduct
Columbia University - Office of Research Compliance and Training

Research Misconduct Safeguards and Procedures**

Resources

STRUCTURAL LINKS

Economic Sanctions and Restricted Parties

Certain entities and individuals are subject to sanctions or other restrictions under U.S. law. These restrictions apply to both domestic and foreign entities and individuals and may restrict your ability to engage in a project, collaboration or other transaction with that entity or individual. Columbia's online screening tool, Visual Compliance, allows you to quickly determine whether an entity or individual is listed on a Restricted Party List. If you are considering entering into a transaction with an entity or individual listed on a Restricted Party List, immediately contact Columbia's Research Export Control Officer.

For information regarding opening a Visual Compliance account, please contact Columbia's Research Export Control Officer.

Economic Sanctions and Restricted Parties Topics

- Jump To:
- OFAC Sanctions Programs
 - Other U.S. Restricted Party Lists
 - Restricted Party Screening Using Visual Compliance
 - U.S. Agency Prohibition on Certain Chinese Telecommunications and Video Surveillance Services or Equipment
 - Where to Go for Help

Home
Office of Research Compliance and Training

Contact
Michelle Avallone, JD
Director of Export Controls
Office of Research Compliance and Training
212-851-9822
mia25@columbia.edu

Janique Cheesman, MS
Regulatory Compliance Specialist
Office of Research Compliance and Training
212-853-1686
jtc2168@columbia.edu

- Related Links
- Anti-Boycott
 - Anti-Corruption
 - Export Controls
 - International Research
 - Unmanned Aerial Vehicle (Drones)

UNIVERSITY OF MICHIGAN

LOCATION CUES

Office of Research | UMOR Units | Research & Sponsored Projects | Research Ethics & Compliance | eResearch | Finance-Sponsored Programs

RESEARCH ETHICS & COMPLIANCE

COMPLIANCE HOTLINE

ANIMAL CARE & USE | **HUMAN SUBJECTS** | HUMAN PLURIPOTENT STEM CELLS | RESEARCH SAFETY | RESEARCH INTEGRITY | CONFLICT OF INTEREST | CONTROLLED SUBSTANCES | EXPORT CONTROLS | RESEARCH INFORMATION SECURITY

Home | Human Research Protection Program (HRPP)

Human Research Protection Program (HRPP)

06/22/20: Human research studies paused during the COVID-19 pandemic can **apply for reactivation** to the Human Research Activation Committees charged by the Office of the Vice President for Research.

The **Human Research Protection Program (HRPP)** is an institutional-wide program coordinated by the University of Michigan Office of Research (UMOR) and composed of the executive officers, research review committees, and other entities that are responsible for protecting the rights and welfare of participants in research conducted or reviewed by the U-M.

HRPP Components

OVERSIGHT UNITS

- Institutional Review Boards (IRBs)
- Office of Research Compliance Review (ORCR)

RESEARCH REVIEW UNITS

- Institutional Biosafety Committee (IBC)
- Conflict of Interest Review Committee (COI-UMOR, MEDCOI)
- Human Pluripotent Stem Cell Oversight Committee (HPSCRO)
- Radiation Policy Committee (RPC), part of U-M Environmental Health & Safety (EHS)
- Investigational Drug Service (IDS), part of the U-M Hospital and Health Centers
- Protocol Review Committee (PRC), part of the U-M Rogel Cancer Center
- Michigan Clinical Research Unit (MCRU), part of U-M MICH
- Michigan Medicine Clinical Engineering (formerly BEU)
- Tissue Procurement Core (TPC)

See the Operations Manual - Part 2: Organization of the HRPP for full details.

Researcher Roles & Responsibilities

As a U-M Investigator or research staff working on a human subjects study, you are expected to following the federal, state, and university policies regarding the protection of human subjects. The **HRPP Operations Manual** outlines the U-M policy in detail. At a high-level, investigators and research staff are responsible for:

YOU ARE HERE:

PROJECT LIFECYCLE

Find Funding | Draft Protocol | Submit Protocol | IRB Review | IRB Approval | IRB Monitoring | IRB Reporting | IRB Renewal | IRB Closure

RELATED INFORMATION

U-M FEDERAL WIDE ASSURANCE
FWA 00004969
Expiration date changes frequently. Look up the current date on the OHRP web site (enter U-M FWA #).

HRPP RELATED PROCESSES

- Single IRB-of-Record (HRPP)
- Authorization Agreements (HRPP)
- Certificates of Confidentiality (HRPP)
- Investigational New Drugs and Devices (IRB/IED)
- IRB Enrollment Definition (UMOR)
- Sensitive Data Guide (ITS Safecomputing)
- IRB application (eResearch)

EXPLANATORY GRAPHICS

U-M Implementation: Informed Consent Changes

11/13/18: The U-M IRBs have posted Informed Consent templates updated for the 2018 Common Rule on their websites. See [References and Resources](#) for links.

Under the revised 2018 Common Rule, the **requirements for informed consent** will change, with the addition of:

- Key information to be presented at the beginning of the consent form
- New consent elements
- Changes to waiver criteria and documentation (plus other process changes)
- A "broad consent" option for unspecified future use of identifiable data/biospecimens

The intent of these changes is to facilitate the subjects' understanding of the proposed research and also ensure that they understand how their data and biospecimens may be used.

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Revised Common Rule: Federal Register Volume 82, Number 22 (Thursday, January 19, 2017)

Key Information

The preamble to the Final Rule (revised) lists five (5) factors that suggested "key information" that would likely assist a potential subject in understanding the nature of the project and in determining participation.

1 A statement that the project is research and participation is voluntary	2 A summary of the research, including: • Purpose • Duration • List of procedures	3 Reasonable, foreseeable risks or discomforts	4 Reasonable, expected benefits	5 Alternative procedures or course of treatment, if any
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Modified from www.fda.gov

How a study team applies the "key information" requirement, and to what level of detail, will depend on the complexity of the research project. Many social/behavioral research projects already employ a brief informed consent document, so including a "key information" section may be redundant. The Final Rule preamble includes some considerations regarding the application of this requirement, but further federal guidance is expected at a later date.

If you have questions about how to apply the new "key information" requirement for a particular project, contact your U-M IRB for advice.

New Consent Elements

Where your project will involve...	Include in the informed consent...
The collection of identifiable private information or identifiable biospecimens	A statement indicating whether: <ul style="list-style-type: none"> identifiers may be removed, and de-identified information or biospecimens may or may not be used or shared for future research
Use of biospecimens	A statement indicating whether: <ul style="list-style-type: none"> biospecimens may be used for commercial profit, and



RELATED INFORMATION

U-M INFORMED CONSENT TEMPLATE WEBSITES

- IRB-HSBS: Informed Consent Guidelines (updated template now available)
- IRB/IED: Informed Consent Templates
- IRB Flint: Sample Templates (updated Adult Informed Consent template now available)

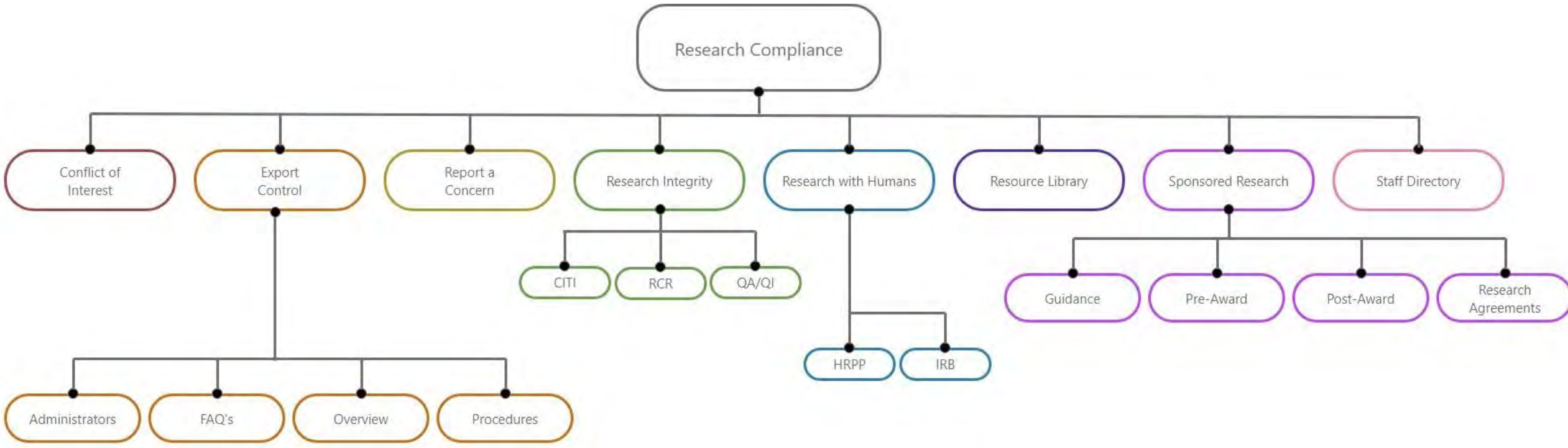
KEY TAKEAWAYS

- Follow '3 Click Rule'
- Show current location
- Integrate consistent design elements
- Include structural links within pages
- Provide definitions and explanatory graphics

BUT FIRST, RESTRUCTURING

CURRENT SITEMAP

Landing Page	A Guide to Research and Sponsored Projects Compliance at CUNY	
	Guidance for Terms and Conditions of Internal Grant Programs	
	Responsible Conduct of Research (RCR)	Responsible Conduct of Research & Research Misconduct Resources
Human Research Protection Program (HRPP)	Private: Changes to the Common Rule - Federal Policy for the Protection of Human Subjects HRPP Policies and Procedures	Recruitment of Students as Research Subjects
	Transition to IRB Manager	
	HRPP References & Resources	
	HRPP Coordinators List	
Conflict of Interest		
Export Control	Overview	
	Export Control FAQ's	
	Export Control Procedures	Work Instructions by Functional Area
	Export Control Administrators	
Sponsored Research and Projects	Sponsored Research Compliance Guidance	Principal Investigator (PI) or Project Director (PD) The Grants Office CUNY Office of Research Research Foundation of CUNY Pre-award Management and Oversight Post-award Management and Oversight Openness in Research
	Research and Sponsored Projects Agreements	Point Person for Research Agreements
	Training and Education	Plagiarism in Research: Common Pitfalls and Unforeseen Consequences CITI Training Resource Library
	QA/QI	
	Reporting your Comments or Concerns	
	Staff Directory	
	College Conflict Officers	
	Research Integrity Officers	



PROPOSED SITEMAP

ADD SECTIONS?

- Animal Welfare
- Controlled Substances
- Controlled Unclassified Information (Data Management)
- Institutional Biosafety
- Stem Cell Research

THANK YOU!