
Research Compliance

What is research compliance?

Research compliance refers to federal, state, and institutional policies, regulations, and laws that must be met in order to conduct research and/or to receive public and, sometimes, private funds to conduct research and sponsored project activities.

Research Compliance

What is the purpose of compliance training?

- ✧ To raise awareness of sound research practices
 - ✧ To provide a forum for discussion and create a culture of compliance
 - ✧ To ensure knowledge of applicable regulations, policies, and procedures
 - ✧ To communicate expectations, standards, and lines of authority
 - ✧ To prevent violations of laws and unsafe practices
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Research Compliance

- What are the desired outcomes for this training program?**
 - To increase knowledge about unlawful and unethical behavior
 - To encourage reporting
 - To minimize any financial loss
 - To reduce the possibility of government audits or investigations
 - To prevent loss of eligibility for the institution and/or individual researchers
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Research Compliance Training

- What is St. Mary's approach to research compliance training?
 - We have adopted a **hybrid** approach that combines formal and informal elements based upon our assessment of potential risks.
 - A hybrid approach combines required **formal** education and training, such as this session, with **informal** training through just-in-time and need-to-know individual or small group sessions and/or self-paced computer assisted learning.
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Formal and Informal Training

Formal elements:

- Human Subjects compliance
- Research Integrity compliance
- Conflict of Interest

Informal elements:

- Care of Animals Used in Research
 - Biosafety & Hazardous Materials
 - Export Controls
 - Stewardship of funds
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Compliance Requirements

□ What do federal agencies use as the framework for compliance guidance?

■ Federal Sentencing Guidelines

- Applied to emphasize the importance of an effective compliance and ethics program in settlements;
 - Fines and other sanctions are determined by two mitigating factors:
 - Effective Compliance programs
 - Self-reporting and acceptance of responsibility
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Compliance Training

- Who needs compliance training?**
 - Everyone participating in the research or sponsored project according to his/her level of responsibility.
 - Project Director or Principal Investigator
 - Co- PD/PI
 - Research Assistants
 - Staff and students
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Risk Assessment and Management

What is risk?

- Risk is any issue or event that adversely impacts the institution's ability to meet its objectives.

What is risk management?

- Managing risks is a process which --
 - identifies the risks, and
 - eliminates, limits, shifts, or accepts the risks.
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Risk Assessment and Management

What are the major risk areas?

- Financial Standards
 - Eligibility Regulations
 - Administrative Regulations & Assurances
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Risk Assessment and Management

What are St. Mary's risk areas in the conduct of research?

Financial

Time and effort reporting

Allowable costs

Record keeping

Risk Assessment and Management

- What are St. Mary's risk areas in the conduct of research?
 - Reporting requirements
 - Financial and performance
 - Ethical decision-making
 - Human subjects
 - Research Integrity
 - Conflict of Interest
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Risk Management

- Roles and responsibilities
 - Institutional responsibilities
 - Human resources
 - Physical Plant
 - Financial stewardship
 - Academic Research Activities
 - Ethical research practices
 - Knowledgeable researchers
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Responsible Conduct of Research

- What information resources are available at St. Mary's?**
 - Research Compendium
 - Compliance Matrix
 - Grants web site
 - Finance and Human Resources web sites
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Research Compliance

- How does St. Mary's monitor and enforce compliance?**
 - Internal and external audits**
 - Periodic review of research projects**
 - Grant close out and progress reporting**
 - Enforcement through adherence to policies and procedures**
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Research Policies

Research Standards

- **Research Integrity***
 - **Human Subjects in Research***
 - **Use of Animals in Research**
 - **Conflict of Interest***
 - **Intellectual Property**
 - **Biosafety & Hazardous Materials**
 - **Research with Recombinant DNA**
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Human Subjects

- St. Mary's Risk Assessment – Human Subjects
 - No dual policies or procedures
 - Follows recommended Best Practices
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Human Subjects

□ Key Principles

■ Three obligations

- Beneficence – benefits must outweigh the risks

 - Justice – must ensure fair distribution of research risks

 - Respect for persons – must recognize the personal dignity & autonomy of individuals (speaks to informed consent)
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Human Subjects

- Basics – What you need to know
 - When does the policy apply?
 - To whom does it apply?
 - What is the approval process?
 - How long does it take?
 - Who can answer questions?
 - Where can I go for more information?
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Human Subjects

- ❑ **Research** is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

 - ❑ A **Human Subject** is “a living individual about whom an investigator conducting research obtains (1) data ... or (2) identifiable private information.”
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Human Subjects

- To whom does the policy apply?

 - Anyone conducting research involving human participants.
 - Faculty
 - Staff
 - Students
 - External researchers
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Human Subjects

- Roles and responsibilities
 - IRB
 - Researcher
 - Human Protections Administrator
 - Chairs and deans
 - VPAA
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Human Subjects

□ The approval process

- Research that qualifies as exempt – see your area representative for exemption from full IRB review
 - Research requiring full IRB-HS review – see your area representative or website for forms and review timelines (1 month minimum)
 - <http://academicgrants.stmarytx.edu/pages/resources/specialresearch/human/index.html>
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Human Subjects

Resources

- Your area representative
 - Human Protections Administrator
 - Academic Grants website
 - <http://academicgrants.stmarytx.edu>
 - OHRP website
 - <http://www.hhs.gov/ohrp>
 - Compliance Compendium
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Research Integrity

□ **Federal standards**

- In 1999, the federal government charged all funding agencies with developing research integrity policies.
 - **Research Misconduct** is defined as “the fabrication, falsification of research data as well as plagiarism, theft of ideas or intellectual property, or appropriation of another’s work.”
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Research Integrity

To Whom does the Policy apply?

- Faculty Researchers
 - Student Researchers & Trainees
 - Staff Researchers
 - Research support staff
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Research Integrity

Areas Covered

- Human Subjects
 - Misconduct in Research
 - Laboratory Animals
 - Conflict of Interest
 - Data collection & management
 - Authorship and publication
 - Intellectual Property & Copyright
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Research Integrity

Roles and Responsibilities

- Principal Investigators
 - Faculty Mentors
 - Research Assistants
 - Trainees
 - Participants
 - Department Chairs and Deans
 - Vice President for Academic Affairs
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Research Integrity

Reporting Misconduct

- Policy provides procedures for reporting misconduct in research
 - Provides protection to complainant(s)
 - Ensures confidentiality of investigation
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Research Integrity

□ Resources

- Office of Research Integrity
 - <http://www.dhhs.ori.gov>
 - Academic Grants website
 - Federal Agency websites
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Conflict of Interest

- ❑ What is conflict of interest as it applies to research?

“A Conflict of Interest is defined as any situation, whether compensated or uncompensated, in which a University employee’s intellectual independence or the University’s integrity would be compromised as a result of decisions made in the process of conducting research or in those activities associated with the research.”

Conflict of Interest

Who should be concerned?

Any university employee who conducts research with or for another institution or organization.

Principal Investigators must complete a Conflict of Interest form for all funded research.

Conflict of Interest

University Code of Conduct

Although similar, does not replace the federal requirement by funding agencies to meet this compliance requirement. It applies to all university employees.

Responsible Conduct of Research

- <http://ori.dhhs.gov/documents/rcrintro.pdf>
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Conclusion

- ❑ Culture of Compliance ↓
- ❑ Best Practices and Standards ⇔
- ❑ Sound and Ethical Research
- ❑ Quality Research

