



*Research and  
Sponsored Programs*

# Compliance Plan



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## Acronyms

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CIRC	Conflict of Interest Review Committee
CSC	Campus Safety Committee
FRC	Faculty Research Committee
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IRB	Institutional Review Board
RCO	Research Compliance Officer
RCC	Research Compliance Committee
RDR	Radioactive Drug Research
RSC	Radiation Safety Advisory Committee
RSO	Radiation Safety Office

# 1.0 Introduction

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## 1.1 PURPOSE

The Research and Sponsored Programs Compliance Plan (Research Plan) provides guidance to the James Madison University community regarding the responsible conduct of research. The Research Plan is intended to be a resource and guide for James Madison University community personnel involved in research and sponsored program activities at or through James Madison University.

## 1.2 MISSION STATEMENT

The mission of the Research Plan is to provide guidance to the James Madison University research community and support to the University research oversight committees, boards and offices. The Research Plan integrates the guidance of all University research oversight committees, boards, and offices to ensure that the University's research activities meet the ethical standards of a public comprehensive university. These standards include honesty, justice, integrity, respect, and a sense of responsibility to others. James Madison University believes that laws exist for the benefit and well-being of individual persons and to this end, all individuals involved in University-related research activities are expected to comply with applicable laws related to research activity and the ethical standards of a public comprehensive university.

## 2.0 Research Code of Conduct

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### 2.1 COMPLIANCE WITH FEDERAL AND STATE LAWS, REGULATIONS, AND UNIVERSITY POLICIES

Faculty, staff and administrators shall comply with all applicable laws, regulations, and contracts related to the conduct of research and sponsored program activities conducted at and/or approved by James Madison University.

Those involved in research and sponsored programs activities at or through James Madison University shall conduct their activities with the highest ethical standards and in accordance with the standards of the community and their respective professions.

The following sections highlight some of the research activities that are governed by specific laws or regulations and may require approval of one or more University committees/boards and/or additional training before research activity can be initiated.

### 2.2 RESEARCH ACTIVITIES

#### 2.2.1 Protection of Human Subjects, Animal Welfare, and Biohazardous Agents

Projects that involve the use of human subjects, animals, recombinant DNA molecules, infectious agents, or other biohazardous agents must comply with federal and University requirements. A research protocol at James Madison University involving any of these items must be submitted to and approved by the appropriate University research oversight committee, board, or office before the project can begin.

Any research protocol involving human subjects, including exempt projects, must be reviewed by James Madison University's Institutional Review Board (IRB) before initiating the research project. IRB review and approval ensures compliance with federal regulations. Principal Investigators or Program/Project Directors and their staff are expected to comply with all federal laws and regulations, as well as IRB requirements and procedures, during all phases of research involving human subjects. *See Policy 1104 the Institutional Review Board on the Use of Human Subjects in Research*  
<http://www.jmu.edu/JMUpolicy/1104.shtml>

Any research protocol involving vertebrate animals must be submitted to Institutional Animal Care and Use Committee (IACUC) for review and approval. Principal Investigators or Program/Project Directors and their staff are expected to comply with

all federal laws and regulations, as well as IACUC requirements and procedures, during all phases of research involving vertebrate animals. *See Policy No. 2202, Institutional Animal Care and Use*, <http://www.jmu.edu/JMUpolicy/2202.shtml>

Any research protocol involving the use of recombinant DNA, infectious agents, and/or other biohazardous agents must be reviewed and approved by the Institutional Biosafety Committee (IBC). *See Policy No. 2207 Institutional BioSafety*, <http://www.jmu.edu/JMUpolicy/2204.shtml>

### **2.2.2 Environmental Health and Safety in Research Activities**

All Research Personnel shall ensure a safe and healthy environment by complying with the Occupational Safety and Health Administration (OSHA) guidelines and all applicable federal, state, and local guidelines related to laboratory standards and disposal of hazardous waste. All Research Personnel conducting research involving potentially hazardous and/or regulated materials must have knowledge of and be responsible for those materials. These personnel must receive required training in accordance with the Hazard Communication Standard (29 CFR 1910.1200), Laboratory Safety Standard (29 CFR 1910.1450), and, if working with human blood, with the Bloodborne Pathogens Standard (29 CFR 1910.1030). Additionally, those conducting research involving human blood, tissue, and/or body fluids that may contain blood must have proper documentation of immunization for Hepatitis B or a written statement of their decision to decline immunization. Those using any chemicals in research must maintain an annually updated inventory of those chemicals and Material Safety Data Sheets (MSDS) for all chemicals on hand within the facility with ease of accessibility in case of emergency. When a laboratory is to be vacated, the lead researcher in the laboratory shall ensure proper redistribution or disposal of excess chemicals and or chemical waste. *See Policy No. 3109 Blood Borne Pathogens* <http://www.jmu.edu/JMUpolicy/3109.shtml>

### **2.2.3 Radiation Safety in Research Activities**

The Principal Investigator or Program/Project Director is responsible for all activities involving radioactive materials, radiation generating equipment, and/or lasers in the laboratory. This person must apply for and receive a permit from the Radiation Safety Committee (RSC) to use radioactive materials before such work may commence. It is this person's responsibility to understand the state and federal regulations and conditions of his/her permit, and to ensure that all staff in the laboratory comply with those regulations and conditions.

The Radiation Safety Office (RSO) is available to assist with issues related to use of radioactive materials, radiation generating equipment, or lasers and is charged with overseeing laboratory compliance in this area by inspecting laboratories and reviewing

records. All Research Personnel are expected to cooperate with the RSO. *See Policy No. 3108* <http://www.jmu.edu/JMUpolicy/3108.shtml>

## **2.3 RESEARCH INTEGRITY**

### **2.3.1 Authorship**

Standards for authorship vary among disciplines, journals, and other outlets for communicating research. In the absence of specific standards as required by a publisher or editorial board, the following guidelines should be followed.

Authorship should be limited to those who have made a direct significant intellectual contribution to the concept, design, execution, or interpretation of the work. Every individual who has made such a contribution should be offered the opportunity to be listed as an author. Honorary, guest, or fictitious authorship is not acceptable. Other contributions by individuals, including acquisition of funding; provision or recruitment of technical services, materials, or subjects; management of a study; or collection of data should be acknowledged. Such contributions, even if essential to the work, are not in themselves sufficient for authorship.

A primary author who is responsible for the work as a whole, from inception to publication, should be identified. The primary author should verify that all authors meet basic standards for authorship and all contributions are acknowledged.

All authors of a work should participate in drafting or revising the manuscript, should provide final approval of the finished work before its publication, and should be provided with a copy of the finished work as submitted for publication.

Numerous practices exist for determining order of authorship. Each Principal Investigator or Program/Project Director should develop a prospective guideline for authorship in their area. All authors should be aware of and agree with the practice used.

### **2.3.2 Disclosure of Financial Support**

The sources of financial support for the project should be disclosed prior to submitting a funding application in accordance with the guidelines of the funding agency or sponsor. See Policy No. 2208 Conflict of Interest for Sponsored Programs <http://www.jmu.edu/JMUpolicy/2203.shtml>

### **2.3.3 Peer Review**

Through peer review, members of the scientific community advise each other regarding research proposals, publishing research results, and career advancement. Peer review is

an essential component of the research process and serves its intended function only if members of the scientific community are prepared to provide thorough, fair, and objective evaluations based on requisite expertise. Privileged information or ideas obtained through peer review must be kept confidential and must not be used for competitive gain.

Those engaged in peer review should disclose conflicts of interest resulting from direct competitive, collaborative, or other relationships with any of the authors and should avoid cases in which such conflicts preclude providing an objective evaluation.

### **2.3.4 Data Management**

All research data from sponsored or nonsponsored studies must be recorded and maintained in a reasonable, responsible, and honest manner by the Principal Investigator or Program/Project Director. Data from sponsored studies must be recorded and maintained according to guidelines specified by the sponsor. See *Institutional Data Stewardship Model* at <http://www.jmu.edu/JMUpolicy/12052.shtm>

### **2.3.5 Research Misconduct**

Research Personnel are expected to conduct their activities in accordance with the requirements of applicable funding agencies, federal and state laws and regulations, and this Research Plan. James Madison University will not tolerate misconduct in any research or sponsored program activities conducted and/or approved through the University. See Policy No. 2205, *Misconduct in Research and other Scholarly Work* at <http://www.jmu.edu/JMUpolicy/2205.shtml>

## **2.4 FISCAL STEWARDSHIP**

### **2.4.1 Research and Sponsored Program Funds**

The Principal Investigator or Program/Project Director is responsible for all aspects of the research project or sponsored program, including the proper stewardship of research or sponsored program funds.

All funds must be spent in a manner consistent with the funding documents and notice of award (e.g., grants, contracts, research protocol) and in compliance with University policies. Those in charge of research or other sponsored program budgets have an obligation to monitor records of expenditures for compliance with University policies and procedures and to allow inspection of those records by appropriate parties or government agencies. See Policy No. 2201, *Sponsored Programs Pre-Post Award Procedures* <http://www.jmu.edu/JMUpolicy/2201.shtml> and *Financial Procedures Manual* at <http://www.jmu.edu/finprocedures/>

## 2.4.2 Conflict of Interest

Research Personnel are expected to conduct their research and sponsored program activities in such a manner as to avoid any conflict of interest or the appearance of a conflict of interest. All Research Personnel are required to comply with all federal regulations related to financial conflicts of interest in the conduct of grant, contract, or cooperative agreement activities. In addition, Research Personnel are required to comply with the following James Madison University policies as applicable:

- *Conflict of Interest Disclosure for Sponsored Programs*,  
Policy No.2203: <http://www.jmu.edu/JMUpolicy/2203.shtml>
- *Conflict of Interest Policy for All Employees*,  
Policy No. 1106: <http://www.jmu.edu/JMUpolicy/1106.shtml>

The complete text of the policies and procedures at *James Madison University* is available at <http://www.jmu.edu/JMUpolicy/>

## 2.5 OTHER RELATED UNIVERSITY COMPLIANCE PROGRAMS, POLICIES, AND PROCEDURES

### 2.5.1 Intellectual Property

Research Personnel are expected to comply with the University's policy regarding the conditions for ownership, legal protection, licensing, and development of any intellectual property conceived of or first reduced to practice by any University-associated personnel. For further information see Policy No.1107 *Intellectual Property*, at <http://www.jmu.edu/JMUpolicy/1107.shtml>

## 3.0 Scope and Definitions

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### 3.1 SCOPE

This Research Plan applies to all James Madison University faculty, administrators, staff, students, and other persons involved in the design, administration, financing, conduct, or reporting of research or sponsored program activities at or through James Madison University, regardless of the source of funding or the location where the activity is conducted.

### 3.2 DEFINITIONS

1. **Research** is a systematic investigation designed to develop or contribute to generalizable knowledge, including social sciences and behavioral research. The term encompasses basic and applied research and product development. It includes studies that are funded by the University and studies that are funded by external sponsors.
2. **Sponsored programs** are programs funded by external sponsors. Such programs include research, instruction and training, public service, evaluative testing, and other scholarly and creative activities conducted under the direction of University faculty and staff.
3. **Research and sponsored programs** is a term used to describe the full scope of activities that are subject to one or more of the compliance standards described in this Plan. It includes those research projects that are not sponsored by external funding and those sponsored programs that are not research-related.
4. **Research misconduct**, is *fabrication, falsification, or plagiarism* in proposing, performing, or reviewing research, or in reporting research results. See *Misconduct in Research and Other Scholarly Work*, at: <http://www.jmu.edu/JMUpolicy/2205.shtml>
5. **Research data** are the data originally recorded by or for Research Personnel and commonly accepted in the scientific community as necessary to validate research findings.
6. **Principal Investigator** or **Program/Project Director** is the person who assumes primary responsibility for the research and/or sponsored program activity or who is the signatory person for the research and/or sponsored program activity.

7. **Research Personnel** include Principal Investigators, Program/Project Directors, co-investigators, co-directors, research associates, postdoctoral fellows, technicians, graduate students, undergraduate students, professional students, or any other persons involved in the design, conduct or reporting of research and/or sponsored program activities.
8. **Funding documents** involve the following three basic models:
  - *Grant* is a legally binding document that specifies the terms and conditions of an award of funds to a recipient individual or organization and involves projects that are generally considered as being “for the public good.”
  - *Cooperative Agreement* is a legally binding document that specifies the terms and conditions of agreement between or among two or more parties that agree to work jointly on a project.
  - *Contract* is a legally binding document that specifies a sponsor’s terms and conditions for awarding funds to procure services and/or goods for the direct benefit of the sponsor as specifically defined in the request for proposal inviting bids or quotes.
9. **Financial Conflict of Interest** is defined as a significant financial interest that could significantly affect the design, conduct, or reporting of an externally funded research project. See Policy No. 2203 *Conflict of Interest Disclosure for Sponsored Programs*: <http://www.jmu.edu/JMUpolicy/2203.shtml>

## 4.0 Compliance Structure

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### 4.1 UNIVERSITY PRESIDENT

The Research Plan was established at the request of the President to the Provost for Academic Affairs to ensure appropriate oversight of research and sponsored program activities conducted at or through James Madison University. The Provost for Academic Affairs has delegated oversight to the Vice Provost of Research and Public Service who serves as the Institutional Official for the University. The Research Compliance Officer (RCO) and the Research Compliance Committee (RCC) report to the Vice Provost for Research and Public Service who reports to the Provost for Academic Affairs.

### 4.2 FACULTY RESEARCH COMMITTEE

The Faculty Research Committee provides leadership and direction for the University's research mission and serves as an interface with the RCC to address recommendations from the Research Compliance Committee related to implementation and operation of the Research Plan.

### 4.3 RESEARCH COMPLIANCE COMMITTEE

The Research Compliance Committee (RCC) assists the RCO in implementing, and overseeing the Research Plan. The RCC is composed of the RCO; the chair or his/her designee who is an active researcher from each of the following areas: (1) Institutional Review Board, (2) Institutional Animal Care and Use Committee, (3) Institutional Biosafety Committee, (4) Radiation Safety Committee, (5) Campus Safety Committee, (6) Director of Sponsored Programs Administration and Accounting, (7) Policy and Legal Affairs Advisor (nonvoting), and (8) Vice Provost for Research and Public Service. At the college deans' discretion, he/she may attend the RCC meetings or appoint an individual in his/her stead to attend the RCC meetings as an ex officio member. The RCC meets at least twice annually and/or once in the fall and spring semester unless otherwise determined by the RCO.

### 4.4 RESEARCH COMPLIANCE OFFICER

The RCO is responsible for the implementation, oversight and monitoring of the Research Plan. The RCO assists each University research oversight committee, board, and office responsible for specific elements of research compliance (i.e., IRB, IACUC, IBC, RSC, Sponsored Programs Administration and Accounting) to ensure compliance with the regulatory requirements related to research activity conducted at and/or approved through James Madison University.

#### **4.4.1.1 Responsibilities**

The RCO, with input and assistance from the RCC and Policy and Legal Affairs Advisor, shall:

- Chair the RCC;
- Ensure that a periodic risk assessment of research and sponsored program activities is conducted;
- Periodically review and update the Research Plan to ensure it addresses relevant risk areas and is consistent with applicable laws and regulations, as well as institutional research compliance activities;
- Serve as a resource for each University research oversight committee, board, or office in their development, implementation and coordination of policies, training and monitoring programs;
- Develop and implement policies, training programs and monitoring activity related to the Research Plan;
- Assist in internal and external audits of research compliance activities;
- Review and respond to internal or external reports of alleged research non-compliance;
- Coordinate investigation of matters related to non-compliance through the applicable research oversight committee, board, or office;
- Coordinate with Policy and Legal Affairs Advisor the self-reporting of any identified violations of federal requirements; and
- Maintain the vitality of the research compliance program through on-site visits, bulletins, and notification of risk areas.

The RCO reports directly to the Vice Provost for Research and Public Service. The Vice Provost for Research and Public Service serves as the interface between the RCC and the Faculty Research Committee.

### **4.5 RESEARCH COMPLIANCE**

The Director of the Office of Research Compliance and/or Research Compliance Officer assists in coordinating and implementing research compliance education programs for the Research Plan and serves as a resource for the research oversight committees, boards, and offices.

### **4.6 RESEARCH COMPLIANCE EVALUATOR/MONITOR**

The Director of the Office Research Compliance and/or RCO directly evaluates and monitors the protection of human subjects, use of animals in research and BioSafety

research projects. In addition, the director will Evaluate/Monitor research compliance and serves as a resource for the research oversight committees, boards, and offices.

## **4.7 UNIVERSITY RESEARCH OVERSIGHT COMMITTEES, BOARDS, AND OFFICES**

### **4.7.1 Institutional Review Board ( Chair, 540.568.2834 or 540.568.2318)**

The Institutional Review Board (IRB), appointed by the University President, reviews for approval and monitors for progress all research protocols in which human subjects or human biological samples are involved.

Website: <http://www.jmu.edu/sponsprog/irb.html>

Policy No.: <http://www.jmu.edu/JMUpolicy/1104.shtml>

### **4.7.2 Institutional Animal Care and Use Committee (Chair, 540.568.3047 or 540.568.3558)**

The Institutional Animal Care and Use Committee (IACUC), appointed by the University President, supervises all vertebrate animal use at James Madison University as required by Federal regulations to ensure all practices are humane and legal.

Website: <http://www.jmu.edu/sponsprog/iacuc.html>

Policy No. 2202: <http://www.jmu.edu/JMUpolicy/2202.shtml>

### **4.7.3 Institutional BioSafety Committee (Chair, 540.568.2776)**

The Institutional BioSafety Committee (IBC) reviews and approves the use of recombinant DNA and other biohazardous agents in research activities.

Website: <http://www.jmu.edu/sponsprog/biosafety.html>

Policy No. 2204: <http://www.jmu.edu/JMUpolicy/2204.shtml>

### **4.7.4 Radiation Safety Committee (540.568.6678)**

The (RSC) reviews and approves the use of radiation generating equipment (therapeutic, diagnostic, and analytic), radioactive materials, and lasers for research, and educational purposes. It represents James Madison University in regulatory matters with federal and state agencies responsible for the use and transport of radioactive materials.

The Radiation Safety Committee for Research is appointed by the Dean, College of Science and Mathematics. The Committee consists of representatives from the disciplines engaged in radiation research activities. The Radiation Officer can be reached at 540.568.6678.

Website: <http://www.jmu.edu/safetyplan/radiology/advisorycommittee.shtml>

Policy No. 3108: <http://www.jmu.edu/JMUpolicy/3108.shtml>

Policy No. 1104: <http://www.jmu.edu/JMUpolicy/1104.shtml>

The Institutional Review Board and as needed the RSC reviews and approves protocols with radiation use involving human subjects as a consultant for the IRB and reviews and approves use of radioactive drugs by human subjects enrolled in an approved IRB protocol.

Website: <http://www.jmu.edu/sponsprog/irb.html>

#### **4.7.5 Comprehensive Safety Program (Fire/Safety/Environmental – (540.568.6765) and Campus Safety Committee (540.568.6764)**

The Health and Safety Policy No. 3108, addresses environmental, health, safety, and risk issues for James Madison University. This policy provides guidelines and instructions to assist university officials in their compliance with applicable provisions of the Occupational Safety and Health Act as well as pertinent state health and safety laws. The Campus Safety Committee is appointed by the President and chaired by the Chief of Public Safety.

See - *James Madison University's Comprehensive Safety Plan*

Website: <http://www.jmu.edu/safetyplan/index.shtml>

Policy No: <http://www.jmu.edu/JMUpolicy/3108.shtml>

#### **4.7.6 Sponsored Programs Administration and Accounting (540.568.6872)**

Sponsored Programs Administration and Accounting (SPAA) provide services in collaboration with faculty and administration to identify, obtain, and administer extramural funding in support of the mission of the University. Website:

<http://www.jmu.edu/sponsprog/>

Policy No.: 2201 <http://www.jmu.edu/JMUpolicy/2201.shtml>

#### **4.7.7 Conflict of Interest Review Committee (540.568.7025?)**

The Conflict of Interest Review Committee (CIRC) reviews disclosed financial interests and have responsibility for managing, reducing or eliminating financial interests that raise an actual or potential conflict of interests in research or educational activities.

Website: <http://www.jmu.edu/sponsprog/conduct.html>

Policy No. <http://www.jmu.edu/JMUpolicy/2203.shtml> - see 6.6 of the policy

#### **4.7.8 Audit and Management Services (540.568.6400)**

The Internal Audit conducts independent audits of research and sponsored programs and associated University Research Oversight Committees, Boards, and Offices in accordance with the *International Standards for the Professional Practice of Internal Auditing* consistent with an annual service plan and long-term research and sponsored programs audit initiative approved by the University President (Institutional Official) and the Audit Committee of the Board of Directors. The Audit and Management Services Department also functions in an advisory capacity, providing information,

analysis, and guidance to the university community to assist them to fulfill their roles and responsibilities in a responsive, effective, and efficient manner. University Policy 1108 (Internal Controls- <http://www.jmu.edu/JMUpolicy/1108.shtml>) Assigns primary responsibility for maintaining adequate internal controls to Academic and Administrative department heads with division heads having ultimate responsibility for their divisions.

Website: <http://www.jmu.edu/audit/>

Policy No. 1108: <http://www.jmu.edu/JMUpolicy/1108.shtml>

#### **4.7.9 Sponsored Programs Accounting Office (540.568.3725)**

The Sponsored Programs Accounting Office is responsible for the financial and fiscal post-award functions for research and sponsored program activities including, but not limited to, review of research charges and journal entries to ensure that the expenses are allowable, timely, and charged to the appropriate fund; coordinating the Effort Reporting function, coordinating and assisting with the annual A-133 audit conducted by Commonwealth of Virginia Auditors for Public Accounts, assisting departments with financial matters relating to research or sponsored program activities, and ensuring compliance with federal, state, and local laws relating to grants and contracts.

Website: <http://www.jmu.edu/acadaffairs/grants.shtml>

Policy No. 2201: <http://www.jmu.edu/JMUpolicy/2201.shtml>

## 5.0 Communication and Reporting Resources

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James Madison University has various resources available to Research Personnel who have questions related to any area of research compliance or to report compliance issues related to research and sponsored program activities at James Madison University. This information is published on the Research Compliance Website, <http://www.jmu.edu/sponsprog/complianceplan.html> in this Research Plan and on various materials distributed by the research oversight committees, boards, and offices.

### 5.1 RESEARCH HELP LINES

Research Personnel are encouraged to first address their questions or concerns regarding research or sponsored programs activity to their immediate supervisor or department head, whenever appropriate. As necessary, Research Personnel should contact the appropriate University research oversight committee, board, or office (Section 4 above) primarily responsible for the area of research compliance in question. Research Personnel may also raise their research compliance related questions or concerns to the Research Compliance Office (RCO) Help Line (540.568.7025) See Section 5.2 below.

### 5.2 CONFIDENTIAL RESEARCH COMPLIANCE (540.568.7025)

Research Personnel are expected to report any known or suspected noncompliant conduct related to research or sponsored program activities conducted and/or approved through James Madison University, as described in the University Policy No. 2205, *Misconduct in Research and Other Scholarly Work at* <http://www.jmu.edu/JMUpolicy/2205.shtml> The Research Compliance Help Line (540.568.7025) is available for any individual who wishes to remain anonymous and/or has found other available reporting mechanisms to be ineffective. The Help Line:

- Allows callers to anonymously report concerns regarding research or sponsored program activities without fear of retaliation or retribution. Anonymity will be maintained to the extent allowed by law. Calls to the Research phone will not be traced or recorded unless the caller chooses to leave a message on the voice-mail system; any message left on the voice-mail system will be erased immediately after it is retrieved.
- Provides an alternative reporting mechanism for reporting information about known or suspected noncompliant conduct in research or sponsored program activities.

### **5.3 EMPLOYEE EXIT INTERVIEW**

All employees may meet with a representative of Human Resources prior to leaving their employment at James Madison University. This meeting will allow employees the opportunity to raise any concerns they may have regarding research activities conducted at or through James Madison University. Any items of non-compliance raised during the exit interview will be forwarded to the RCO who shall distribute to the appropriate research oversight committee, board, or office.

### **5.4 NON-RETALIATION POLICY**

No person shall be retaliated against by James Madison University or any of its employees or agents for making a good-faith report of suspected noncompliant conduct in research or sponsored program activities. All persons making reports of compliance concerns are assured that such reports will be treated as confidential to the extent permitted by law. Such reports will be shared with others only on a bona fide need-to-know basis. The University will take no adverse action against persons making such reports in good faith. Anyone who intentionally makes a false report or misuses the Research Compliance Resources shall be subject to discipline.

## 6.0 Development and Implementation of Policies and Procedures

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Several policies currently exist within the University to ensure compliance with various federal laws and regulations relating to research activities. The RCO shall work with the Policy and Legal Affairs Advisor, Research Compliance Committee, and Faculty Research Committee to ensure that University-wide policies relating to research compliance activities are developed, implemented, reviewed and updated as appropriate. University wide policy must be approved by the appropriate University Committees and the University Policy Committee before submission to the Division Heads for approval by the President.

Each research oversight committee, board, or office is responsible for developing, implementing, distributing, reviewing and updating policies and procedures related to its research oversight responsibilities. The RCO is available as a resource to assist each research oversight committee, board, or office in developing, implementing, distributing, reviewing, and updating such policies and procedures, including those required by federal or state law and regulation. Policies and procedures shall be easily found and accessible to all Research Personnel. The most current policies and procedures shall be posted on the University's Website, and whenever possible, shall be available to Research Personnel, either in paper form or through the internet. See JMU Administration Policies and Procedures at <http://www.jmu.edu/JMUpolicy/administration.shtml>

### 6.1 REVISIONS TO COMPLIANCE PLAN

This compliance plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Director of Research Compliance shall review the plan at least annually to assure that it remains current and effective. Changes to the plan may be proposed by members of the Research Compliance Committee, departments, or individual employees. All changes to the compliance plan must be consistent with the JMU Policies and Procedures of the University.

## 7.0 Education and Training Programs

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The RCO and/or members of University research oversight committees, boards, or offices shall identify areas of research education and training needed to ensure compliance with federal agency requirements and applicable federal, state, and local laws.

### 7.1 TRAINING ON RESEARCH

The RCO is responsible for monitoring that Research Personnel receive general orientation on the Research Plan and that identified Research Personnel receive training on specific training on the Research Plan related to their research and sponsored programs activity by or through James Madison University.

### 7.2 SPECIFIC TRAINING

The RCO in conjunction with the appropriate board or committee chair shall be provided the resources for developing, implementing, reviewing and updating training materials and programs for Research Personnel subject to their research oversight activities. The RCO may, upon request, provide specific training and provide the required training by a research oversight committee, board or office. Training materials, such as copies of PowerPoint slides and other documents should be available to participants of training sessions. [http://www.jmu.edu/sponsprog/research\\_compliance/conducttraining.html](http://www.jmu.edu/sponsprog/research_compliance/conducttraining.html)

**Educational Materials** - JMU has entered into the Collaborative Institutional Training Initiative (CITI). This program provides the mandated training for (1) Research Ethics and Responsible Conduct of Research, (2) Human Subjects Research, and (3) Lab Animal Welfare.

CITI has developed a course on the responsible conduct of research (RCR) that is available on-line. The course covers the core RCR instructional areas including data management, conflict of interest, publication, authorship, peer review, collaboration, mentoring, and research misconduct. In addition, there are courses on Human Subject Research, and on Lab Animal Welfare, which must also be completed depending on your research.

[http://www.jmu.edu/sponsprog/research\\_compliance/conducttraining.html](http://www.jmu.edu/sponsprog/research_compliance/conducttraining.html)

### 7.3 MODES OF TRAINING

Training can be provided through various modalities and from various resources. Training may be created internally or may be available through outside resources.

While live training is preferred whenever possible, it is not the exclusive means of providing the required training. If live training is not possible, training may be provided through video/DVD/CD recordings; internet or Web-based training; and internal or external publications.

#### **7.4 ATTENDANCE**

Attendance at mandatory training sessions shall be tracked. Failure to complete mandatory training within the stated time frame may result in suspension of research and/or sponsored programs activity related to that mandatory training.

## 8.0 Effective Monitoring of Research Compliance

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### 8.1 RISK ASSESSMENT

The RCO shall conduct periodic risk assessments related to research and sponsored program activity at or through James Madison University. Information obtained from these periodic risk assessments shall be utilized by the RCO and the RCC to focus their policies, training and monitoring activities to minimizing identified risks.

### 8.2 MONITORING AND EVALUATING ACTIVITY OF RESEARCH OVERSIGHT COMMITTEES

#### 8.2.1 Monitoring Activity

The RCO with input from the RCC may conduct routine monitoring of activities related to its research oversight responsibilities. Any such monitoring activity should be focused on compliance with applicable laws and regulations, as well as institutional policies/procedures. Results of routine monitoring activity shall be utilized by each research oversight committee(s) to identify potential risk areas, ascertain the need for revised or additional policies, training and or monitoring.

Any confirmed research or sponsored program non-compliance identified during such monitoring activity that must be reported to a federal agency and/or private sponsor shall be reported to the RCO.

#### 8.2.2 Evaluating Activity

The RCO may request that a Research Compliance Committee evaluate activity subject to its oversight responsibilities for purposes of an internal/external investigation. In those instances, the RCC will work with the RCO, as well as any other required University staff, to timely conduct the Evaluation.

In addition, a specific research oversight committee may conduct an assessment of a specific risk area identified through the routine risk assessment or through other any other means.

Any confirmed research or sponsored program non-compliance identified during such assessment activity shall be reported to the RCO. If financial fraud is determined Policy No. 1603 Reporting of Suspected Fraudulent Transactions

<http://www.jmu.edu/JMUpolicy/1603.shtml> If research misconduct is determined, Policy No. 2205 Research Misconduct in Research and other Scholarly work will apply <http://www.jmu.edu/JMUpolicy/2205.shtml>

## **8.3 MONITORING AND ASSESSING ACTIVITY OF THE RESEARCH COMPLIANCE OFFICE**

### **8.3.1 Monitoring and Evaluating Program**

The Research Compliance Office shall develop, with input from Policy and Legal Affairs Advisor and the RCC, a written program, which will outline the methods and means of conducting monitoring and evaluating activity. The written monitoring and evaluating program shall be periodically reviewed and updated to ensure that it adequately meets the needs of the Research Plan.

### **8.3.2 Monitoring Activity**

The Research Compliance Office, with input from the RCC will identify and prioritize projects and activities to monitor during the year utilizing the procedures outlined in the written monitoring and quality assurance program plan. The monitoring function shall focus primarily on quality control and monitoring for compliance with regulatory requirements. Monitoring results will be used to evaluate the overall effectiveness of the Research Plan and update research related policies and on-going education and training programs as necessary. Selected projects will be evaluated for compliance with established criteria including applicable laws and regulations, James Madison University policies and procedures, and adherence to research and sponsored program grant/contract requirements.

### **8.3.3 Research Oversight Review Activity**

The Research Compliance Office may conduct research oversight reviews based on information obtained as a result of Research Compliance activities, including, but not limited to Helpline calls. Such Reviews shall be focused on the identified areas of concern. The Research Compliance Office may use internal resources (i.e., Research Oversight Committee(s); Internal Audit Department), as appropriate to conduct such reviews.

## 9.0 Responding to Research Noncompliance

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### 9.1 VIOLATIONS AND INVESTIGATIONS

Every credible allegation, inquiry, complaint, or other evidence of research noncompliance or misconduct is investigated in accordance with established policies and procedures. When appropriate, Policy and Legal Affairs Advisor shall be advised as soon as possible of any allegation of research noncompliance or misconduct. If the investigation results in sufficient evidence of noncompliance with applicable laws, regulations or applicable institutional policies, appropriate corrective action shall be taken in accordance with such laws, regulations and/or institutional policies, including Section 10 of this Research Plan and may require reporting to federal agencies/authorities.

### 9.2 REPORTING REQUIREMENTS

Any conduct that violates criminal, civil, or administrative laws shall be reported to the appropriate agency/authority within a reasonable period of time.

## 10.0 Corrective Action

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Anyone who fails or refuses to comply with this Research Plan shall be subject to appropriate corrective action. Corrective action, for those employed by James Madison University, shall be in accordance with the employee's status (i.e., faculty, administrator, and staff) and in accordance with any Employment agreement with James Madison University. Corrective action shall be in accordance with the Employment agreement, which may include termination of the contract.

In addition to corrective action at the institutional level, individuals may be subject to corrective action under local, state, and/or federal laws or regulations for their action or inaction resulting in non-compliant conduct.

Corrective action shall be taken against the following:

- Those involved in noncompliant conduct related to research or sponsored program activities.
- Those who were aware or should have been aware of noncompliant conduct and failed to take necessary steps to achieve compliance under this Research Plan.