



*Research and
Sponsored Programs*

Compliance Plan

Creighton
UNIVERSITY

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Table of Contents

1.0	INTRODUCTION	1
1.1	Purpose	1
1.2	Mission Statement	1
2.0	RESEARCH CODE OF CONDUCT	2
2.1	Compliance with Federal and State Laws, Regulations, and University Policies	2
2.2	Research Activities	2
2.2.1	Protection of Human Subjects, Animal Welfare, and Biohazardous Agents	2
2.2.2	Environmental Health and Safety in Research Activities	3
2.2.3	Radiation Safety in Research Activities	3
2.3	Research Integrity	4
2.3.1	Authorship	4
2.3.2	Disclosure of Financial Support	4
2.3.3	Peer Review	4
2.3.4	Data Management	5
2.3.5	Research Misconduct	5
2.4	Fiscal Stewardship	5
2.4.1	Research and Sponsored Program Funds	5
2.4.2	Conflict of Interest	5
2.5	Other Related University Compliance Programs, Policies, and Procedures	6
2.5.1	Health Sciences Plan for Billing and Patient Services	6
2.5.2	Intellectual Property	6
3.0	SCOPE AND DEFINITIONS	7
3.1	Scope	7
3.2	Definitions	7
4.0	COMPLIANCE STRUCTURE	9
4.1	University President	9

4.2	Research Advisory Committee	9
4.3	Research Compliance Committee	9
4.4	Research Compliance Office	9
	4.4.1 Research Compliance Officer	9
	4.1.1.1 Responsibilities	10
4.5	Research Compliance Education Coordinator	10
4.6	Research Compliance Auditor/Monitor	10
4.7	University Research Oversight Committees, Boards, and Offices	11
	4.7.1 Institutional Review Board (402-280-2126)	11
	4.7.2 Institutional Animal Care and Use Committee (402-280-2082)	11
	4.7.3 Institutional Biosafety Committee (402-280-4098)	11
	4.7.4 Radiation Safety Committee (402-280-5570)	11
	4.7.5 Campus Safety Committee (402-280-6400)	11
	4.7.6 Grants Administration (402-280-2064)	12
	4.7.7 Conflict of Interest Review Committee (402-280-1830)	12
	4.7.8 Internal Audit Department (402-280-3502)	12
	4.7.9 Controller's Office (402-280-2190 or 402-280-2289)	12
5.0	COMMUNICATING AND REPORTING RESOURCES	13
5.1	Helplines	13
5.2	Anonymous Research Compliance Hotline (402-280-3200)	13
5.3	Employee Exit Interview	14
5.4	Non-Retaliation Policy	14
6.0	DEVELOPMENT AND IMPLEMENTATION OF POLICIES AND PROCEDURES	15
7.0	EDUCATION AND TRAINING PROGRAMS	16
7.1	Training or Research Plan	16
7.2	Specific Training	16
7.3	Modes of Training	16
7.4	Attendance	16
8.0	EFFECTIVE MONITORING OF RESEARCH COMPLIANCE	17
8.1	Risk Assessment	17
8.2	Monitoring and Auditing Activity of Research Oversight Committees	17
	8.2.1 Monitoring Activity	17
	8.2.2 Auditing Activity	17

8.3	Monitoring and Auditing Activity of the Research Compliance Office	18
8.3.1	Monitoring and Auditing Program	18
8.3.2	Monitoring Activity	18
8.3.3	Auditing Activity	18
9.0	RESPONDING TO RESEARCH NONCOMPLIANCE	19
9.1	Violations and Investigations	19
9.2	Reporting Requirements	19
10.0	CORRECTIVE ACTION	20

Acronyms

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

1.0 Introduction

1.1 PURPOSE

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

1.2 MISSION STATEMENT

The mission of the Research Plan is to provide guidance to the Creighton 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 Jesuit Catholic University. These standards include honesty, justice, integrity, respect, and a sense of responsibility to others. Creighton 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 Jesuit Catholic University.

2.0 Research Code of Conduct

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

Research Personnel 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 Creighton University.

Those involved in research and sponsored programs activities at or through Creighton 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 Creighton 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 Creighton 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.

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.

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).

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.

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.

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 to appropriate regulatory committees according to the guidelines of the funding agency or sponsor.

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.

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, University Policy No. 4.2.2, *Research Misconduct* (for further information see <http://www.creighton.edu/President/PresOfc/GuideToPolicies/Guide.pdf>), and this Research Plan. Creighton University will not tolerate misconduct in any research or sponsored program activities conducted and/or approved through the University.

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 (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.

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 Creighton University policies as applicable:

- *Externally Sponsored Projects Financial Conflict of Interest*, Policy No. 3.1.10
- *Conflict of Interest Policy for All Employees*, Policy No. 3.1.11
- *Conflict of Interest Policy for Officers and Senior Administrators*, Policy No. 3.1.12

The complete text of the *Guide to Policies of Creighton University* is available at <http://www.creighton.edu/President/PresOfc/GuideToPolicies/Guide.pdf>.

2.5 OTHER RELATED UNIVERSITY COMPLIANCE PROGRAMS, POLICIES, AND PROCEDURES

2.5.1 Health Sciences Plan for Billing and Patient Services

Research Personnel providing clinical treatment to human subjects are expected to comply with the University's Health Sciences Plan for Billing and Patient Services (Billing Compliance Plan) and relevant policies and procedures for any health care items and/or services that are billed to the patient and/or his/her third-party payer. The University's Billing Compliance Plan is available at <http://www.creighton.edu/GeneralCounsel/compliance.html>.

2.5.2 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 University Policy No. 4.2.3, *Intellectual Property*, at <http://www.creighton.edu/President/PresOfc/GuideToPolicies/Guide.pdf>.

3.0 Scope and Definitions

3.1 SCOPE

This Research Plan applies to all Creighton 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 Creighton 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 *Research Misconduct*, No. 4.2.2, Guide to Policies, at: <http://www2.creighton.edu/fileadmin/user/president/docs/Guide.pdf>
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 *Externally Sponsored Projects Financial Conflict of Interest*, No. 3.1.10, Guide to Policies:
<http://www2.creighton.edu/fileadmin/user/president/docs/Guide.pdf>

4.0 Compliance Structure

4.1 UNIVERSITY PRESIDENT

The Research Plan was established at the request of the University President to ensure appropriate oversight of research and sponsored program activities conducted at or through Creighton University. The President serves as the Institutional Official for the University. The Research Compliance Officer (RCO) and the Research Compliance Committee (RCC) report to the University President.

4.2 RESEARCH ADVISORY COMMITTEE

The Research Advisory 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 developing, implementing, and overseeing the Research Plan. The RCC is composed of the RCO; a representative 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) Grants Administration, (7) Controller's Office, (8) Human Resources, (9) General Counsel's Office (nonvoting), and (10) Internal Audit Department (nonvoting); and a faculty member who is active in research from each of the following colleges and schools: (11) College of Arts and Sciences, (12) School of Pharmacy and Allied Health Professions, (13) School of Dentistry, (14) School of Medicine, and (15) School of Nursing. The RCC meets at least once each month, unless otherwise determined by the RCO.

4.4 RESEARCH COMPLIANCE OFFICE

4.4.1 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, Grants Administration) to ensure compliance with the regulatory requirements related to research activity conducted at and/or approved through Creighton University.

4.4.1.1 Responsibilities

The RCO, with input and assistance from the RCC and General Counsel, 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 General Counsel 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 President Health Sciences and the University President. The RCO serves as the interface between the RCC and the Research Advisory Committee.

4.5 RESEARCH COMPLIANCE EDUCATION COORDINATOR

The Research Compliance Education Coordinator 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 AUDITOR/MONITOR

The Research Compliance Quality Assurance Auditor/Monitor directly evaluates and monitors the quality of research, the protection of human subjects, and use of animals in research. The Research Compliance Auditor/Monitor 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 (402-280-2126)

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.creighton.edu/researchcompliance/IRB/index.htm>

4.7.2 Institutional Animal Care and Use Committee (420-280-2082)

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

Website: <http://www.creighton.edu/researchcompliance/IACUC/index.htm>

4.7.3 Institutional Biosafety Committee (402-280-4098)

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

Website: <http://www.creighton.edu/researchcompliance/Biosafety/index.htm>

4.7.4 Radiation Safety Committee (402-280-5570)

The [Radiation Safety Committee](#) (RSC) reviews and approves the use of radiation generating equipment (therapeutic, diagnostic, and analytic), radioactive materials, and lasers for clinical, research, and educational purposes. It represents Creighton University in regulatory matters with federal and state agencies responsible for the use and transport of radioactive materials.

Website: http://www.creighton.edu/researchcompliance/Radiation_Safety/index.htm

The Human Subject Research Committee of the RSC reviews and approves protocols with radiation use involving human subjects as a consultant for the IRB, and the [Radioactive Drug Research Committee](#) (RDRC) reviews and approves use of radioactive drugs by human subjects enrolled in an approved IRB protocol.

Website: <http://www.creighton.edu/researchcompliance/RDRC/index.htm>

4.7.5 Campus Safety Committee (402-280-6400)

The [Campus Safety Committee](#) (CSC), mandated by state law, addresses environmental, health, safety, and risk issues for Creighton University. Its members, which include representatives from each Vice Presidential area, represent both management and labor

and are appointed by the University President. The Committee is chaired by the Director of Environmental Health and Safety.

Website: http://www.creighton.edu/researchcompliance/Campus_Safety/index.htm

4.7.6 Grants Administration (402-280-2064)

[Grants Administration](#) provides 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.creighton.edu/researchcompliance/Grants/index.htm>

4.7.7 Conflict of Interest Review Committee (402-280-1830)

The [Conflict of Interest Review Committee](#) (CIRC) reviews disclosed financial interests and has 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.creighton.edu/researchcompliance/Conflict_of_Interest/COI_index.htm

4.7.8 Internal Audit Department (402-280-3502)

The [Internal Audit Department](#) functions in an advisory capacity, providing information, analysis, and guidance to Research Personnel to help them fulfill their roles and responsibilities in a responsible, effective, and efficient manner. The Department participates in auditing and monitoring, and recommends actions to improve systems for financial reporting and to ensure compliance with laws, regulations, and internally developed policies and procedures.

Website: <http://www2.creighton.edu/administration/president/internalaudit/>

4.7.9 Controller's Office (402-280-2190 or 402-280-2289)

The [Controller's Office](#) is responsible for many of the financial and 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, 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.creighton.edu/Controllers/>

5.0 Communication and Reporting Resources

Creighton 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 Creighton University. This information is published on the Research Compliance Website, in this Research Plan and on various materials distributed by the research oversight committees, boards, and offices.

5.1 RESEARCH HELPLINES

Research Personnel are encouraged to first address their questions or concerns regarding research or sponsored programs activity to their immediate supervisor, 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 RCO (402-280-2360) or use the Research Compliance Hotline (Section 5.2 below).

5.2 CONFIDENTIAL RESEARCH COMPLIANCE HOTLINE (402-280-3200)

Research Personnel are expected to report any known or suspected noncompliant conduct related to research or sponsored program activities conducted and/or approved through Creighton University, as described in the University Policy No. 2.1.19, *Reporting Noncompliant Conduct in Research or Sponsored Programs*. The confidential **Research Compliance Hotline (402-280-3200)** is available for any individual who wishes to remain anonymous and/or has found other available reporting mechanisms to be ineffective. The Research Compliance Hotline:

- 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 Hotline 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.

- Any Employee or Agent who makes an intentionally false report of research noncompliance or who misuses the Research Compliance Hotline, shall be subject to discipline and/or termination of his/her affiliation with Creighton University.

5.3 EMPLOYEE EXIT INTERVIEW

All employees shall meet with a representative of Human Resources prior to leaving their employment at Creighton University. This meeting will allow employees the opportunity to raise any concerns they may have regarding research activities conducted at or through Creighton 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 Creighton University or any of its employees or agents for making a good-faith report of suspected noncompliant conduct in research or sponsored program activities. Anyone who intentionally makes a false report or misuses the Research Compliance Resources and/or Research Compliance Hotline shall be subject to discipline.

6.0 Development and Implementation of Policies and Procedures

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 General Counsel's Office, RCC, and Research Advisory 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 before submission to the President's cabinet for approval.

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 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.

7.0 Education and Training Programs

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 PLAN

The RCO is responsible for ensuring 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 Creighton University.

7.2 SPECIFIC TRAINING

Each research oversight committee, board or office is responsible for developing, implementing, reviewing and updating training materials and programs for Research Personnel subject to their research oversight activities. The RCO may, upon request, assist in providing specific training required 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.

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

8.1 RISK ASSESSMENT

The RCO, with assistance from General Counsel, shall conduct on-going risk assessments related to research and sponsored program activity at or through Creighton University. Information obtained from these on-going risk assessments shall be utilized by the RCC and Research Oversight Committees to focus their policies, training and monitoring activities to minimizing identified risks.

8.2 MONITORING AND AUDITING ACTIVITY OF RESEARCH OVERSIGHT COMMITTEES

8.2.1 Monitoring Activity

Research Oversight Committee 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 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 audit activity that must be reported to a federal agency and/or private sponsor shall be reported to the RCO or other appropriate University official.

8.2.2 Auditing Activity

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

In addition, the Research Oversight Committee may conduct an audit 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 audit activity shall be reported to the RCO or other appropriate University official.

8.3 MONITORING AND AUDITING ACTIVITY OF THE RESEARCH COMPLIANCE OFFICE

8.3.1 Monitoring and Auditing Program

The Research Compliance Office shall develop, with input from General Counsel, Internal Audit and the RCC, a written program, which will outline the methods and means of conducting monitoring and auditing activity. The written monitoring and auditing program shall be periodically reviewed and updated to ensure that it adequately meets the needs of the Research Plan.

8.3.2 Monitoring Activity

Each year, the Research Compliance Office, with input from General Counsel and the RCC will identify and prioritize projects and activities to monitor during the year utilizing the procedures outlined in the written monitoring and auditing 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, Creighton University policies and procedures, and adherence to research and sponsored program contract requirements.

8.3.3 Auditing Activity

The Research Compliance Office may conduct audits based on information obtained as a result of Research Compliance activities, including, but not limited to Helplines and/or Hotline calls. Such audits shall be focused on the identified areas of concern. The Research Compliance Office may use internal resources (i.e., Research Quality Monitor) and/or external resources (i.e., Research Oversight Committee; Internal Audit Department), as appropriate to conduct such audits.

9.0 Responding to Research Noncompliance

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, General Counsel's office 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

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

Corrective action may be addressed through one or more venues, including but not limited to, the applicable Research Oversight Committee(s), Institutional Administration, General Counsel, the University President and/or Board. 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.