

Research Compliance Office

Creighton University
Research Compliance Plan



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Creighton University

Mission Statement

Creighton is a Catholic and Jesuit comprehensive university committed to excellence in its selected undergraduate, graduate, and professional programs.

As Catholic, Creighton is dedicated to the pursuit of truth in all its forms and is guided by the living tradition of the Catholic Church.

As Jesuit, Creighton participates in the tradition of the Society of Jesus, which provides an integrating vision of the world that arises out of a knowledge and love of Jesus Christ.

As comprehensive, Creighton's education embraces several colleges and professional schools and is directed to the intellectual, social, spiritual, physical, and recreational aspects of student's lives and to the promotion of justice.

Creighton exists for students and learning. Members of the Creighton community are challenged to reflect on transcendent values, including their relationship with God, in an atmosphere of freedom of inquiry, belief, and religious worship.

Service to others, the importance of family life, the inalienable worth of each individual, and appreciation of ethnic and cultural diversity are core values of Creighton.

Creighton faculty members conduct research to enhance teaching, to contribute to the betterment of society, and to discover new knowledge. Faculty and staff stimulate critical and creative thinking and provide ethical perspectives for dealing with an increasingly complex world.

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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
RSC	Radiation Safety Committee
RSO	Radiation Safety Office

1.0 Introduction

1.1 PURPOSE

The Creighton University Research 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 ethical standards of a Jesuit Catholic University 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, radiation, 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 must be reviewed by Creighton University's Institutional Review Board (IRB) before the research project is initiated. 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 the 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).

Any research protocol involving the use of radiation (material or x-ray) must be reviewed and approved by the Radiation Safety Committee (RSC).

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, 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 Safety Data Sheets (SDS) for all chemicals on hand within the facility must be easily accessible 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. Investigators using radioactive material must apply for and receive a permit from the Radiation Safety Committee (RSC) before 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 complies 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, provide final approval of the finished work before its publication, and 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 non-sponsored 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 www.creighton.edu/generalcounsel/cupolicies/); and this Research Plan. Creighton University will not tolerate misconduct in any research or sponsored program activities conducted and/or approved by or 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 protocols) 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:

- *Financial Conflict of Interest in Research*, 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 www.creighton.edu/generalcounsel/cupolicies/.

2.5 OTHER RELATED UNIVERSITY COMPLIANCE PROGRAMS, POLICIES, AND PROCEDURES

2.5.1 Health Sciences Schools Billing and Patient Services Compliance Plan

Research Personnel providing clinical treatment to human subjects are expected to comply with the University's Compliance Plan for Health Sciences Schools Billing (Billing Compliance Plan) and Patient Services Compliance Plan (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/billingcompliance/>.

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: www.creighton.edu/generalcounsel/cupolicies/.

2.5.3 Export Controls

Research Personnel are expected to comply with state and federal regulations regarding export controls. Please contact the Office of Research and Compliance with questions regarding export controls. For further information see:

<http://www.creighton.edu/researchservices/exportcontrol/>.

3.0 Scope and Definitions

3.1 SCOPE

This Research Plan applies to all employees and agents of Creighton University, including 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: www.creighton.edu/generalcounsel/cupolicies/.
5. **Research data** are the data originally recorded by or for Research Personnel, and are 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, 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 a funded research project. See *Financial Conflict of Interest in Research*, No. 3.1.10, Guide to Policies, at: www.creighton.edu/generalcounsel/cupolicies/.

4.0 Compliance Structure

4.1 PROVOST/ASSOCIATE VICE PROVOST FOR RESEARCH & SCHOLARSHIP

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 Associate Vice Provost for Research & Scholarship serves as the Institutional Official for the University. The Associate Vice Provost for Research & Scholarship has delegated the oversight of day-to-day activities of the Research Compliance Office and all associated boards, committees, and offices to the Director for Research Compliance. The Research Compliance Officer (RCO) and the Research Compliance Committee (RCC) report to the Associate Vice Provost for Research & Scholarship.

4.2 UNIVERSITY RESEARCH COUNCIL

The University Research Council 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. The Associate Vice Provost for Research & Scholarship serves as the Chair of the University Research Council.

4.3 RESEARCH COMPLIANCE COMMITTEE

The Research Compliance Committee (RCC) assists the Research Compliance Officer (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) Sponsored Programs Administration, (7) Controller's Office, (8) Human Resources, (9) General Counsel's Office (nonvoting), (10) Internal Audit Department (nonvoting), (11) Animal Research Facility (nonvoting), and (12) Quality Assurance Monitor/Auditor (nonvoting); and a faculty member who is active in research from each of the following colleges and schools: (13) College of Arts and Sciences, (14) School of Pharmacy and Allied Health Professions, (15) School of Dentistry, (16) School of Medicine, and (17) School of Nursing. The RCC meets once each quarter, unless otherwise determined by the RCO.

4.4 RESEARCH COMPLIANCE OFFICE

4.4.1 Research Compliance Officer (402-280-2511)

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) 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;
- Require and review annual reports from specific elements of research and compliance (i.e., IRB(s), IACUC, Sponsored Programs Administration, Clinical Research Office, Education Coordinator, Quality Assurance Monitor Auditor);
- Review and respond to internal or external reports of alleged research noncompliance;
- Coordinate investigation of matters related to noncompliance 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 Associate Vice Provost for Research & Scholarship. In addition, the Associate Vice Provost for Research & Scholarship has the authority to communicate personally to the University's Board of Directors or its designated

subcommittee (A) promptly on any matter involving criminal conduct or potential criminal conduct, and (B) no less than annually on the implementation and effectiveness of the Research Plan. The RCO serves as the interface between the RCC and the University Research Council.

4.5 RESEARCH COMPLIANCE EDUCATION COORDINATOR (402-280-2680)

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 (402-280-2322)

The Research Compliance Quality Assurance Auditor/Monitor directly evaluates and monitors the quality of research, 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 Associate Vice Provost for Research & Scholarship, 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/researchservices/rcocommittees/irb/>

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

The Institutional Animal Care and Use Committee (IACUC), appointed by the Associate Vice Provost for Research & Scholarship, 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/researchservices/rcocommittees/iacuc/>

4.7.3 Institutional Biosafety Committee (402-280-3208)

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

Website: <http://www.creighton.edu/researchservices/rcocommittees/ibc/>

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) and radioactive materials, as well as lasers for clinical, research, and educational purposes. It also serves as a resource for laser users. It represents Creighton University in regulatory matters with federal and state agencies responsible for the receipt, use, disposal, and transport of radioactive materials, as well as the use of radiation-generating equipment.

Website: <http://www.creighton.edu/researchservices/rcocommittees/radiationsafety/>

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, who include representatives from each 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/admin/facilities/committees/campussafetycommittee/>

4.7.6 Sponsored Programs Administration (402-280-2064)

Sponsored Programs 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/researchservices/grants/>

4.7.7 Conflict of Interest Review Committee (402-280-3074)

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

Website: <http://www.creighton.edu/researchservices/rcocommittees/circ/>

4.7.8 Internal Audit Department (402-280-3026)

The Internal Audit Department conducts independent audits of University departments, programs, activities, policies, plans, procedures, and systems, including University research oversight committees, boards, and offices, in accordance with the *International Standards for the Professional Practice of Internal Auditing* consistent with a risk-based annual service plan and multi-year audit approach approved by the University President and the Audit and Compliance Committee of the Board of Trustees. The Internal Audit Department also functions in an advisory capacity, providing information, analysis, and

guidance to Research Personnel to assist them in fulfilling their roles and responsibilities in a responsive, effective, and efficient manner.

Website: <http://www.creighton.edu/administration/internalaudit/>

4.7.9 Accounting Services (402-280-3986)

Accounting Services 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 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: <https://www.creighton.edu/finance/sharedservices/home/>

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 wish to report compliance issues related to research and sponsored program activities at Creighton University. This information is published on the Research and 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 (402-280-2511) or use the Research Compliance Hotline (Section 5.2 below).

5.2 CONFIDENTIAL RESEARCH COMPLIANCE HOTLINE (855-256-0478)

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 (855-256-0478 or <https://secure.ethicspoint.com/domain/media/en/gui/43718/>)** 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 people 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 and/or emails to the Research Hotline will not be traced or recorded.
- 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 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 noncompliance 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.

5.5 AUTONOMY OF RESEARCH OVERSIGHT COMMITTEES FROM UNDUE INFLUENCE

In order to fulfill its ethical obligations to protect research participants and the research itself, Creighton University research oversight committees, boards, and offices (IRB, IACUC, IBC, Sponsored Programs Administration, and CIRC) must exercise autonomy and judiciousness in their thinking and decision-making. They must refrain from showing bias toward or against any investigators based on factors such as scoring by funding agencies or the relative power and influence amongst investigators submitting protocols for review.

A request by an investigator to hasten the review of a submission is not presumed to be an attempt at undue influence.

Any offers of special monetary incentives, favors in kind, or other rewards by investigators to oversight committees, committee members, or support staff for the guaranteed approval of a submission is presumed to be an attempt at undue influence and must be reported to the RCO. Furthermore, if a Creighton University official attempts to influence oversight committee members based on the power of his or her position, it is also presumed to be an attempt at undue influence and should be reported to the RCO.

The RCO shall first determine whether an inappropriate and unethical inducement was presented by an investigator to an oversight committee, committee member, or support

staff, such as special monetary incentives, favors in kind, or other rewards for the guaranteed approval of a submission.

If the action by the investigator is determined not to presumptively constitute undue influence, the RCO shall then determine whether the action in question is reasonable or justified.

Any support staff or committee members who may be vulnerable to attempts by investigators to unduly influence their prioritization of assignments or actions must report any such attempts to the RCO. Any cases in which a committee director, chair, or vice chair is perceived as acting as an agent of an investigator attempting to unduly influence the committee or staff must be reported to the RCO. The RCO will investigate the situation carefully and make reasonable and good faith efforts to protect the autonomy of the committee and support staff in fulfilling their responsibilities, and to mitigate any damage caused by attempts at undue influence.

6.0 Development and Implementation of Policies and Procedures

Several policies currently exist within the University to ensure compliance with various state and federal laws and regulations relating to research activities. The RCO shall work with the General Counsel's Office, the RCC, and the University Research Council to ensure that University-wide policies relating to research compliance activities are developed, implemented, reviewed, and updated as appropriate, including updating them as necessary to reflect revisions to state or federal laws. 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 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 electronically.

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 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 training session participants.

7.3 MODES OF TRAINING

Training can be provided by various means 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 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

A record of attendance at and completion of mandatory training will 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 ongoing risk assessments related to research and sponsored program activity at or through Creighton University. Information obtained from these ongoing risk assessments shall be utilized by the RCC and research oversight committees to focus their policies, training, and monitoring activities on minimizing identified risks.

8.2 MONITORING AND AUDITING ACTIVITY OF RESEARCH OVERSIGHT COMMITTEES

8.2.1 Monitoring Activity

Research oversight committees 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 and ascertain the need for revised or additional policies, training, and or monitoring.

Any confirmed research or sponsored program noncompliance identified during such monitoring activity that must be reported to a governmental 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 conduct the audit in a timely fashion.

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

Any confirmed research or sponsored program noncompliance 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 has developed, with input from General Counsel, Internal Audit, and the RCC, a written program that outlines 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 ongoing education and training programs, as necessary. Selected projects will be evaluated for compliance with established criteria, including applicable laws and regulations and 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, Helpline 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., Quality Assurance Auditor) 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, as required by law or as determined necessary by the University.

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 the University 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 that results in noncompliant conduct. Corrective action may include restitution of identifiable victims (including, but not limited to, reimbursement of grant funds).

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.

In the event of detected noncompliance, the RCO will also assess and modify the Research Plan as necessary.

Credo of Creighton University

Creighton, a Jesuit University, is convinced that the hope of humanity is the ability of men and women to seek the truths and values essential to human life. It aims to lead all its members in discovering and embracing the challenging responsibilities of their intelligence, freedom, and value as persons.

We therefore profess, and pledge ourselves to teach in the perspectives of, the following creed:

We believe in God, our loving Creator and Father.

We believe in the intrinsic value of the human being as created in God's image and called to be his child. This includes all persons and excludes any form of racism and other discrimination.

We believe that the deepest purpose of each man and woman is to create, enrich, and share life through love and reverence in the human community. This motivates our open and relentless pursuit of truth. For this reason we foster reverence for life in all its human potential.

We believe that we should support all persons in their free and responsible life-sharing through family and social systems, and through political, scientific, and cultural achievements.

We believe that we must strive for a human community of justice, mutual respect, and concern. In this context we must cultivate respect and care for our planet and its resources.

We believe that laws exist for the benefit and well-being of individual persons, that legal systems must express the common good, and that all government must be subject to the courageous, though respectful and loyal, criticism of intelligent and responsible citizens.

We believe that the law of justice and love must regulate the personal, family, economic, political, and international life of all persons if civilization is to endure.

We believe in the teachings and example of Jesus Christ.