



Research Compliance Quality Assurance Program

Creighton
UNIVERSITY

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1.0 Introduction

1.1 PURPOSE

The Research Compliance Quality Assurance Program is a component of Creighton University's Research Compliance Program. The purpose of the Research Compliance Quality Assurance Program is to benefit and support the research programs at Creighton University involving human subjects and animals to:

- Achieve quality, performance and efficiency;
- Ensure compliance with University policies and federal laws and regulations;
- Identify education/training initiatives for Investigators, their research staff and others; and
- Assist in obtaining and maintaining accreditation for research programs that involve the:
 - 1) protection of human subjects in research.
 - 2) use of animals in research activities (Association for Assessment and Accreditation of Laboratory Animal Care International, AAALAC).

The goal of this Program is to promote a working relationship among the Principal Investigator, his/her research staff, the applicable University oversight Committee, (Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC)) and the Research Compliance Office. It is designed to identify regulatory noncompliance and protect human and animal subjects and research animals at Creighton University.

2.0 Research Compliance Quality Assurance Program Structure

2.1 DESCRIPTION OF PROGRAM STRUCTURE

The Research Compliance Quality Assurance Program consists of three elements:

- Directed “For Cause” Investigations,
- Routine “Not For Cause” Investigations
- Research Compliance Continuous Education for Quality Assurance

Descriptions of each component are contained in sections 3.0 and 4.0 below.

2.2 ROLE OF THE RESEARCH COMPLIANCE AUDITOR

The Research Compliance (RC) Auditor directly evaluates and monitors the Research Compliance Quality Assurance Program. The Research Compliance Auditor arranges and performs monitoring visits (on-site or off-site), performs protocol reviews or reviews of the consent process, and oversees the continuous education for quality assurance in research at the University. The Research Compliance Auditor will assist in the selection of research protocol(s) for quality assurance monitoring or review and may make recommendations to the Research Compliance Officer and the applicable (IRB or IACUC) for protocol(s) follow-up quality assurance monitoring. The Research Compliance Auditor directly reports to the Research Compliance Officer. At the discretion of the Research Compliance Officer, the Research Compliance Auditor will work with the University’s Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and/or Research Compliance Committee to monitor the quality of research, the protection of human subjects and use of animals in research. In addition, the Research Compliance Auditor will work with the Internal Audit Department in conjunction with the Research and Sponsored Project audits involving human subjects.

3.0 Quality Assurance Program Elements

3.1 DIRECTED “FOR CAUSE” INVESTIGATIONS

The QA Monitor conducts Directed “For Cause” Investigations at the request of the Research Compliance Officer, the HRPP, IRB or IACUC for reasons including, but not limited to:

- Receipt of an internal complaint (i.e. Research Compliance Hotline, anonymous report) or internal concern (i.e., human subject or family member, research staff or personnel) of possible protocol violation or regulatory non-compliance;
- Receipt of an external complaint (i.e., OHRP, the FDA, Sponsor, OLAW or USDA) of potential protocol violation or regulatory non-compliance;
- Increase of added risk to the human research subjects (i.e. serious adverse events);
- Investigator history of poor adherence to University policies/procedures or regulatory requirements.

The Directed “For Cause” Investigation may be conducted on-site or off-site and may consist of a full record or partial record review, or a review of the consent process. Directed “For Cause” Investigations require the participation of the Principal Investigator and/or the Designated Research Personnel.

3.2 ROUTINE “NOT FOR CAUSE” INVESTIGATIONS

The Research Compliance Auditor conducts Routine “Not for Cause” Investigations at the direction of the Research Compliance Officer to evaluate on-going research compliance. Routine reviews may include, but are not limited to, reviews of:

- Oversight Committee (IRB or IACUC) records and activities to ensure that its policies and procedures are consistent with regulatory requirements and federal assurances.
- Risk areas identified during periodic risk assessments of the Research Compliance Program and Human Research Protection Program.
- Risk areas identified during directed “for cause” investigations.
- Protocols randomly selected by the Research Compliance QA Monitor for on-site review.
- Observation of consenting a potential subject or group of subjects.

The Routine "Not for Cause" audits may be conducted on-site or off-site and may consist of a full record or partial record review, or a review of the consent process. Routine "Not for Cause" audits require the participation of the Principal Investigator and/or the Designated Research Personnel.

The goal of the monitoring is to ensure compliance with all University policies including those of the Research Compliance office, HRPP, IRB and IACUC but also to educate investigators and provide educational opportunities. The objectives of this program are:

- Risk reduction
- Increased compliance
- Increased awareness by the research and staff
- Increased awareness of possible misconduct violations and the appropriate procedure for handling those
- General education
- Ability to create open dialogue between compliance office and investigators

This program will be measured by review of the reports submitted by the RC Auditor to the Director of Research Compliance and the respective board.

Responsibilities of the Principal Investigator and Oversight Committee Chairs

The Principal Investigator and/or Oversight Committee Chair or their designees shall meet with the Research Compliance Auditor at the beginning of any Directed "For Cause" Investigation or Routine "Not for Cause" Audit to answer any questions. The Principal Investigator shall receive a copy of the final RC Auditor's report as it relates to his/her research protocol.

3.3 ACCESS TO DOCUMENTS, RECORDS AND STAFF

The Research Compliance Auditor shall have access to all documents and information maintained by the Investigator and/or applicable oversight Committee (IRB/IACUC) as part of any Directed "For Cause" Investigation or Routine "Not for Cause" Investigation. The Research Compliance Auditor shall have access to any research project, staff, Committee members or Committee oversight staff to conduct interviews as part of any Directed "For Cause" Investigation or Routine "Not for Cause" Audit.

3.4 QUALITY ASSURANCE MONITOR'S REPORT

The Research Compliance Auditor will submit a report of his/her findings to the Research Compliance Officer, with a copy to the Investigator and applicable oversight Committee. The report will state any identified violations or areas of research non-compliance, including the basis of any identified violations and/or areas of non-compliance. The report, where appropriate, shall

list areas that demonstrate quality research compliance and provide recommendations for quality and/or compliance improvement.

3.5 THE RESEARCH COMPLIANCE OFFICER’S RESPONSE TO THE QUALITY ASSURANCE MONITORING REPORT.

In conjunction with the applicable oversight committee, the Director of Research Compliance shall take appropriate action to address any violations or areas of research non-compliance identified in the RC Auditor’s Report. Such action may include, but is not limited to notification of the appropriate Department Chair, Dean, Provost, University President, the research sponsor and/or federal agencies. The Director of Research Compliance shall consult with the Associate General Counsel regarding any reporting requirements to federal agencies and/or research sponsors. Based on the results of a Directed “For Cause” Investigation, the Research Compliance Officer may require additional monitoring activity pursuant to Section 3.2 above.

4.0 Research Compliance Continuous Education For Quality Assurance

4.1 “SELF-MONITORING” BY THE PRINCIPAL INVESTIGATOR AND/OR THE DESIGNATED RESEARCH PERSONNEL

Principal Investigators and/or the Designated Research Personnel will be offered the opportunity to voluntarily “self-monitor” their own research programs or protocols for research compliance quality assurance. The Research Compliance Auditor’s working documents will be available on line or can be requested by the Principal Investigator and/or the Designated Research Personnel at the Research Compliance office.

Once the “self-monitoring” working documents are completed, the Principal Investigator and/or the Designated Research Personnel can contact the Research Compliance Auditor to discuss any “self-monitoring” questions or to request recommendations in research compliance quality assurance. To protect the confidentiality of the voluntary information provided from the Principal Investigator and/or the Designated Research Personnel no written documentation will be arranged or exchanged with the Research Compliance Auditor. The interaction between the Research Compliance Auditor and the Principal Investigator and/or the Designated Research Personnel may occur by telephone conference or a consultation visit.

4.2 Research Compliance Education

Research Compliance Education already exists at our University and is offered to Principal Investigators and/or Research Personnel as outlined by the Research and Sponsored Programs Compliance Plan. The Research Compliance Quality Assurance Program may offer additional, voluntary programs or seminars at the University to discuss hot topics in research compliance or research quality improvement.

5.0 Reporting External Monitoring

Other external groups may monitor or evaluate research programs or protocols for regulatory compliance i.e. a federal or state agency, or a sponsor. Principal Investigators that receive adverse reports noting research violations of regulatory standards from an external evaluator must notify the applicable oversight committee. Independently or in conjunction with the with the Director of Research Compliance, the applicable oversight committee (IRB or IACUC) may determine if the protocol requires monitoring under the Research Compliance Quality Assurance Program.