

Policies and Procedures

<i>SECTION:</i> Administration	<i>NO.</i> 2.1.19		
<i>CHAPTER:</i> General Procedures	<i>ISSUED:</i> 11/29/01	<i>REV. A</i> 03/23/11	<i>REV. B</i> 04/14/15
<i>POLICY:</i> Reporting Noncompliant Conduct in Research	<i>PAGE 1 OF 4</i>		

I. PURPOSE

The primary purpose of the research compliance reporting process is to provide nonthreatening ways for employees and agents of Creighton University to report any activity or conduct that they suspect is not in compliance with the *Creighton University Research Compliance Plan* (Plan) or with applicable federal or state laws and regulations. Information received through the research compliance reporting process will be used to investigate, verify, and correct any identified noncompliant conduct in research or sponsored program activity.

II. POLICY

Employees, students, and agents of Creighton University who know or suspect that noncompliant conduct is occurring or has occurred in any research or sponsored program activities conducted and/or approved through Creighton University should report such conduct. No person shall be retaliated against by Creighton University or any of its employees, students, or agents for making a good-faith report of suspected noncompliant conduct in research or sponsored program activities.

III. SCOPE

This policy applies to all full-time and part-time faculty, administrators, staff, volunteers, students, and agents of Creighton University.

IV. PROCEDURE

Reporting Noncompliant Conduct

- 1. University research oversight committees, boards, and offices:**
Individuals who know or suspect that noncompliant conduct is occurring or has occurred should first discuss their concerns with their immediate supervisor, if appropriate. As necessary, concerned individuals should then contact the appropriate University research oversight committee, board, or office responsible for the element of research compliance in question, as described in the Plan. Concerned individuals who do not know which committee, board, or office to contact or who have a general research compliance concern should contact the Director of Research Compliance (402-280-2511).

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- 2. Research Compliance Hotline:** Creighton University shall establish and maintain a Research Compliance Hotline (855-256-0478) to allow individuals to anonymously report noncompliance in research or sponsored program activities. Any person may call the confidential Research Compliance Hotline to report any known or suspected noncompliant conduct in research or sponsored program activities. Anyone who intentionally makes a false report or misuses the Research Compliance Hotline shall be subject to discipline.

Confidentiality of Individuals Reporting Noncompliant Conduct

All reports regarding suspected noncompliant conduct shall be maintained in a confidential manner to the extent allowed by law. Persons who wish to remain anonymous may report concerns using the Research Compliance Hotline.

Individuals receiving reports of noncompliant conduct shall maintain the confidentiality of the person making the report, shall utilize the procedures in this policy to obtain information, and shall confidentially submit the information to the Director of Research Compliance for further action. Except as required by law, no one shall disclose the name of anyone making a report of noncompliant conduct without the express consent of the person making the report.

Notice of the Research Compliance Hotline Number

The Director of Research Compliance shall provide a current notice of the Research Compliance Hotline number to all University administrators to be posted in noticeable locations for employees, students, and agents working in those locations.

Procedures for Receiving Reports of Noncompliant Conduct

All reports of noncompliant conduct shall be handled in a confidential manner, according to the following guidelines:

- 1. Recording Information:** Persons receiving reports of noncompliant conduct may use the Report of Noncompliant Conduct Information Sheet (Attachment A) to obtain the information necessary for investigating the complaint. The completed Report of Noncompliant Conduct Information

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Sheet shall be forwarded to the Director of Research Compliance, who shall maintain the confidential information in a secure location.

Investigating Reports of Noncompliant Conduct

Before initiating investigation of any report of noncompliant conduct, the Director of Research Compliance shall contact the General Counsel's Office. The General Counsel's Office shall decide whether or not to oversee any investigation. If the General Counsel's Office decides not to oversee the investigation, then the Director of Research Compliance shall be primarily responsible for conducting or supervising the investigation. In most cases, the Director of Research Compliance will forward anonymous Research Compliance Hotline reports to the appropriate University research oversight committee, board, or office for further investigation and action according to its policies and procedures for addressing noncompliance. The written results of such investigations, including any corrective action taken or recommended, shall be given to the Director of Research Compliance.

After receiving the written investigation results, the Director of Research Compliance shall ensure that appropriate corrective action, if any is required, has been taken or is implemented. The Director of Research Compliance, in consultation with the General Counsel's Office, shall determine if any government or private funding agency must be notified prior to, during, or after any investigation. If the noncompliance must be reported to a federal regulatory agency and organizational officials, the Director of Research Compliance, in consultation with the General Counsel's Office, shall report the noncompliance to the appropriate federal regulatory agency and organizational officials in the time frame required by the agency or within 30 days, whichever is shorter.

V. ADMINISTRATION AND INTERPRETATIONS

Questions regarding this policy may be addressed to the Director of Research Compliance or General Counsel.

VI. AMENDMENTS OR TERMINATION

This policy may be amended or terminated at any time.

**REPORT OF NONCOMPLIANT CONDUCT
INFORMATION SHEET**

Date: _____ Time (if applicable): _____

Reporter's name (optional and confidential): _____

If anonymous, tracking number: _____

Reporter's department (optional and confidential): _____

Reporter's phone number (optional and confidential): _____

Report received and recorded by: _____

Method of contact:

- Telephone, Research Compliance Hotline
- Telephone, other
- In person
- E-mail
- Other _____

Information to obtain from reporter:

- a. Name(s) and department of individuals involved in alleged noncompliance: _____

- b. Description of suspected noncompliance, including date(s) and location(s), as applicable: _____

- c. Name(s) of any other persons who may have knowledge regarding this matter (to remain confidential for purposes of investigating the alleged misconduct): _____

- d. Has the suspected noncompliant conduct been reported to anyone else? Yes No
- e. If Yes, obtain the following information:
1. Name of person(s) reported to: _____
 2. Date the report was made: _____
 3. Was the report written or oral? _____
- f. Can the reporter provide any documentation to assist in an investigation? Yes No
- g. Is the reporter willing to meet with the Research Compliance Officer and/or the chair of the associated regulatory committee? Yes No

The following is to be completed by the Director for Research Compliance.

This report has been received by and/or forwarded to the following (check all that apply) for investigation and follow-up:

- | | |
|--|--|
| <input type="checkbox"/> Director for Research Compliance | <input type="checkbox"/> Campus Safety Committee |
| <input type="checkbox"/> Research Compliance Committee | <input type="checkbox"/> Grants Administration |
| <input type="checkbox"/> Institutional Review Board | <input type="checkbox"/> Controller's Office |
| <input type="checkbox"/> Institutional Animal Care and Use Committee | <input type="checkbox"/> General Counsel's Office |
| <input type="checkbox"/> Institutional Biosafety Committee | <input type="checkbox"/> Internal Audit Department |
| <input type="checkbox"/> Radiation Safety Committee | |

The Director for Research Compliance shall attach information related to investigation, follow-up, and any disciplinary action taken.

Date investigation and file closed: _____