

# ***Policies and Procedures***

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| <i>SECTION:</i><br><b>Academic Concerns</b>  | <i>NO.</i><br><b>4.2.2.</b> |                          |                           |                          |
| <i>CHAPTER:</i><br><b>Faculty</b>            | <i>ISSUED:</i><br>1/28/88   | <i>REV. A</i><br>8/31/95 | <i>REV. B</i><br>11/29/01 | <i>REV. C</i><br>2/15/06 |
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## **PURPOSE**

The purpose of this policy is to establish procedures to thoroughly, timely, objectively, and fairly evaluate, investigate and respond to allegations of research misconduct to protect the health and safety of the public and promote the integrity of biomedical or behavioral research, research training or activities related to that research or research training conducted at Creighton University and to protect federal funds and equipment, as appropriate.

## **POLICY**

Creighton University fosters a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training. Creighton University shall promptly respond to all allegations or evidence of possible research misconduct according to this policy and shall report, as required by law, any investigation and finding of research misconduct by any faculty, staff, student, or agent of Creighton University.

## **SCOPE**

This Policy applies to faculty, staff, students, and agents of Creighton University engaged in research, research training or activities related to research or research training, regardless of the funding source.

This policy applies to allegations of research misconduct in research, research training or activities related thereto, and research misconduct involving applications or proposals for funding of research, research training or activities related thereto. It also applies to any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for funding resulted in a grant, contract, cooperative agreement, or other form of support.

## **DEFINITIONS**

“Complainant” means any a person who in good faith makes an allegation of research misconduct.

“Preponderance of the evidence” means proof by information that, compared with opposing information, leads to the conclusion that the fact at issue is more probably true than not.

“Research” means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to biological causes, functions or effects, diseases, treatments, or related matters to be studied.

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“Research record” means the record of data or results that embody the facts resulting from scientific inquiry, including, but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided by the Respondent during the course of the research misconduct proceeding.

"Research Misconduct" means fabrication, falsification, or plagiarism (as those terms are defined below) in proposing, performing, or reviewing research or in reporting research results. It does not include honest error or differences of opinion.

"Fabrication" is making up data or results and recording or reporting them.

"Falsification" is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

"Plagiarism" is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

“Respondent” means the person against whom an allegation of research misconduct is made, and is the subject of a research misconduct proceeding.

## **PROCEDURES**

### **A. General Institutional Responsibilities**

1. Phases of a Research Misconduct Proceeding. Creighton University shall take the following steps in response to an allegation of research misconduct:
  - a. Allegation of Research Misconduct. A report, either written or oral, of possible research misconduct.
  - b. Institutional Inquiry. A preliminary information-gathering and fact finding process to assess whether the allegation has substance to warrant an investigation.
  - c. Notices. Notices are sent to Respondent, Complainants, the Dean, the Vice President of the involved area, and to any applicable Federal Agency of any decision to initiate an investigation of research misconduct.
  - d. Institutional Investigation. The formal development of a factual record, and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct, which may include a recommendation for corrective action or other appropriate actions.
  - e. Federal Agency Notice. Notice sent to any applicable Federal Agency who funds or has oversight of the research activity involved in the research misconduct proceedings of Institutional Investigation findings and actions related to the research misconduct proceeding.

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2. Confidentiality.

- a. Identity of Participants in Research Misconduct Proceedings. Disclosure of the identity of respondents, complainants and witnesses involved in research misconduct proceedings is limited to those who need to know, to the extent possible consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed or required by law.
- b. Records and Evidence. Except as otherwise required by law, confidentiality shall be maintained of all records and evidence from which research subjects might be identified. Disclosure of such information is limited to those who have a need to know to carry out a research misconduct proceeding.

3. Safeguards. The rights, privacy, positions and reputations of all parties involved in the research misconduct proceedings shall be protected. No one shall retaliate against any complainant, witness or committee member who, in good faith, participates in a research misconduct proceeding.

- a. All reasonable and practical efforts shall be taken to restore the position and reputation of respondents where there is no finding of research misconduct.
- b. All reasonable and practical efforts shall be taken to restore the position and reputation of any complainant, witness, or committee member and to counter potential or actual retaliation against these individuals.
- c. Disciplinary action will be taken, in accordance with University policy, against anyone who fails to act in good faith in either bringing an allegation of research misconduct, cooperating during the research misconduct proceedings (i.e. providing evidence) or serving as a member of either the Ad Hoc Inquiry or Ad Hoc Investigatory Committee. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

4. Mandatory Notice to Federal Agency during Initial Report/Inquiry or Investigation.

At any time during a research misconduct proceeding, Creighton shall immediately notify the relevant federal agency if it has reason to believe that:

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- a. Research activities should be suspended;
- b. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- c. Federal agency resources or interests are threatened;
- d. Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- e. The research community or public should be informed;
- f. There is reasonable indication of possible violations of civil or criminal law; or
- g. That the research misconduct proceedings may be made public prematurely so that the appropriate federal agency can take appropriate steps to safeguard evidence and protect the rights of those involved.

In such an instance, the Dean(s) of the School/College conducting the research misconduct proceeding shall notify the Research Compliance Officer who shall notify the appropriate federal agencies.

5. Notice to Non-Federally Funded Entities.

At any time during the research misconduct proceeding, the entity funding the activity shall be notified as required by the funding agreement. The Dean(s) of the School/College conducting the research misconduct proceeding shall notify the Research Compliance Officer who shall notify the funding entities.

B. Allegation of Research Misconduct Stage

1. Receipt of an Allegation of Research Misconduct. A good faith report of possible research misconduct may be made, either verbally or in writing, to any University official, including, but not limited to the reporting individual's supervisor, Administrator, Dean or Vice President, the Research Compliance Officer (280-2360) or the Research Compliance Hotline (280-3200). A report of possible research misconduct is not in good faith if it is made with knowing or reckless disregard for information that would negate the allegation. The report of possible research misconduct shall be documented (if not already documented by the complainant) and immediately sent to the Dean(s) of the School/College under which the research is conducted and the Research Compliance Officer. If there is more than one school/college involved in the allegation of research misconduct, then the Deans of those schools/colleges shall be jointly responsible for determining if an inquiry is warranted, setting the inquiry date and appointing members to the Ad Hoc Inquiry Committee, and where necessary, the Ad Hoc Investigation Committee.

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2. Review of Allegation by Dean(s). The Dean(s) shall review the allegation of research misconduct to determine whether or not an inquiry is warranted. An inquiry is warranted if the allegation falls within the definition of research misconduct under the “Definitions” Section of this policy and it is sufficiently credible and specific so that potential evidence of research misconduct may be identified.
  
3. Setting the Date of Institutional Inquiry and Appointment Ad Hoc Committees. If the Dean(s) determine that an inquiry is warranted pursuant to paragraph 2 above, a date(s) for the institutional inquiry shall be scheduled. The Dean(s) shall then appoint an Ad Hoc Inquiry Committee to conduct an initial review of the evidence to determine whether to conduct an investigation. If necessary, the Dean(s) shall also appoint an Ad Hoc Investigation Committee. The Dean(s) shall make every effort to appoint persons with appropriate knowledge and expertise to the Ad Hoc Committees and shall ensure that anyone appointed to either Ad Hoc Committee does not have unresolved personal, professional or financial conflicts of interest with the complainant(s), respondent(s) or witnesses. The Ad Hoc Committees shall be composed of such persons whom the Dean(s) may choose to designate to serve, provided, however, that at least two (2) members shall be from outside the affected Department/Division. It is desirable that an appropriate Associate/Assistant Dean and two tenured faculty members of the school/ college involved be appointed to the Ad Hoc Committee, but this is not a formal requirement. Members of the Ad Hoc Investigation Committee may include some or all of the members from the Ad Hoc Inquiry Committee, as well as other members as may be appointed by the Dean(s). Individuals from the department of the complainant(s) or respondent(s) should not participate in either Ad Hoc Committee. The Dean(s) shall designate one of the Ad Hoc Committee members to act as Chair for each Ad Hoc Committee. The Ad Hoc Committees may rely upon consultants with expertise or knowledge in the area of research under inquiry and/or investigation.
  
4. Notice to Respondent(s) of Allegation. The Dean(s) shall notify the presumed respondent(s), in writing, of the allegation of research misconduct prior to the start of the institutional inquiry. A copy of the notice shall be sent to the respondent’s departmental chairperson, administrator, or supervisor and the Vice President(s) of the respondent(s) area.
  
5. Custody of Research Records. On or before the date on which the respondent(s) is notified, the Dean(s) shall take all reasonable and practical steps to obtain custody of all known research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and hold them in a secure manner to be available for the research misconduct proceedings. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

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6. Ensuring Cooperation during the Research Misconduct Proceeding. Faculty, staff, students and agents, including complainant(s), respondent(s) and witnesses, shall cooperate in the research misconduct proceedings, including, but not limited to, being present as requested during the research misconduct proceeding, and providing relevant and truthful information and research records and evidence.
- C. Institutional Inquiry Stage.
1. Review by Ad Hoc Inquiry Committee. The Ad Hoc Committee shall conduct an initial review of the evidence to determine whether to conduct an investigation. A full review of the evidence related to the allegation is not required at this stage. The inquiry must be completed within 60 calendar days (including the opportunity for respondent’s review and comment, section 1.d. below) of its initiation, unless circumstances warrant a longer period, in which case the inquiry record must include documentation of the reasons for exceeding the 60-day period.
    - a. Custody of Research Records. The Dean(s) shall turn over custody of all research records and evidence collected during the Allegation stage to the Ad Hoc Inquiry Committee. The Ad Hoc Inquiry Committee shall take custody, inventory and secure those items and any additional research records or evidence discovered during the course of the inquiry, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
    - b. Respondent(s)’ Access to Research Records. Prior to and during the inquiry stage, the respondent(s) shall have the right to receive copies of or reasonable supervised access to, the research records.
  2. Criteria Warranting an Investigation. An investigation is warranted if there is:
    - A reasonable basis for concluding that the allegation falls within the definition of research misconduct under this policy and involves research, research training, or activities related to that research or research training, and
    - Preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance.
  3. Inquiry Report.

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- a. Draft Report. The Ad Hoc Inquiry Committee shall prepare a written draft report which shall include the following information:
    - The name and position of the respondent(s);
    - A description of the allegations of research misconduct;
    - The funding support, including, for example, grant numbers, grant applications, contracts, and publications listing such support;
    - The basis for recommending that the alleged actions warrant an investigation; and
  - b. Opportunity Comment. The Ad Hoc Inquiry Committee shall provide a copy of the written inquiry report to the respondent(s) for review and comment. The respondent shall have ten (10) days from receipt of the report to submit any written comments.
  - c. Final Report. The final report shall include any written comments received from the respondent(s) within the time period set forth in paragraph b above.
4. Notice of Final Inquiry Results.
- a. Notice to Respondent(s). The Ad Hoc Inquiry Committee shall give written notice to the respondent(s) of whether the inquiry found that an investigation is warranted. The notice shall include a copy of the final inquiry report along with a copy of this policy. In those cases where PHS funding is involved, the notice shall also include either a copy of, or reference to 42 CFR Part 93.
  - b. Notice to Complainant(s). The Ad Hoc Inquiry Committee may notify the complainant(s) of whether the inquiry found that an investigation is warranted. The notice may include relevant portions of the inquiry report for comment by the complainant(s).
  - c. Notice to Institutional Officials. The Ad Hoc Inquiry Committee shall promptly provide a copy of the final inquiry report to the Dean(s) who appointed the Ad Hoc Inquiry Committee, their Vice President(s) and the Research Compliance Officer. Names of complainants, witnesses and research subjects shall be redacted to maintain confidentiality.

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5. Finding that Investigation is Warranted. The Research Compliance Office shall notify any applicable federal agency funding the affected research of the decision to begin an investigation, within thirty (30) days from the date of the final inquiry report of the Ad Hoc Inquiry Committee finding that an investigation is warranted. The notice shall include a written finding by the Ad Hoc Inquiry Committee Chair and a copy of the final inquiry report, including any comments by the respondent(s) or complainant(s). Upon request, Creighton shall provide the federal agency with a copy of this policy; the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the charges for the investigation to consider. The federal agency shall be notified of any special circumstances that may exist.
  6. Finding that an Investigation is not Warranted. The Ad Hoc Committee shall sufficiently document their decision not to investigate the allegation of research misconduct and shall submit all records of the allegation and inquiry stages to the Research Compliance Officer to maintain in accordance with Section G below.
- D. Institutional Investigation Stage
1. Appointment of Ad Hoc Investigative Committee. If not already appointed, the Dean(s) shall, no later than 5 days after the issuance of the final inquiry report, appoint an Ad Hoc Investigational Committee. Such appointment shall be in accordance with the appointment requirements set forth in paragraph B.3 above.
  2. Scheduling the Investigation and Required Notices.
    - a. Time Period for Initiating and Completing the Investigation. The Ad Hoc Investigative Committee shall begin the investigation no later than 30 days after the final inquiry report of the Ad Hoc Inquiry Committee finding that an investigation is warranted. The Ad Hoc Investigative Committee shall complete all aspects of the investigation within 120 days from the date of initiating the investigation, which includes conducting the investigation, preparing the report of findings, providing the draft report to, and obtaining comments from, the respondent(s), and sending the final report to any applicable federal agency. If federal funding is involved and the Ad Hoc Investigative Committee determines that the investigation and related activities will not be complete within the 120 day period, it shall notify the Research Compliance Officer (no later than 85 days after the start of the investigation) who shall immediately submit a written request to the applicable federal agency requesting an extension. The Research Compliance Officer shall notify the Ad Hoc Investigative Committee of the federal agency's response.



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- d. Contact with Dean(s) and Research Compliance Officer. The Ad Hoc Investigative Committee shall keep the Dean(s) of the affected School/College and Research Compliance Officer apprised of any developments during the course of the investigation which disclose facts that may affect current or potential agency funding for the respondent(s) or that the funding agency needs to know to ensure appropriate use of federal funds and to otherwise protect the public interest. The Research Compliance Officer shall then notify the funding agency, as may be required by law.
  
4. Criteria for Finding of Research Misconduct. To support a finding of research misconduct, the Ad Hoc Investigative Committee must find by a preponderance of the evidence that:
  - There was a significant departure from accepted practices of the relevant research community; and
  - The misconduct was committed intentionally, or knowingly, or recklessly; and
  - The allegation was proven by a preponderance of the evidence.
  
- a. Destruction, Absence of, or Respondent(s)' Failure to Provide Research Records. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where it is established by a preponderance of the evidence that the respondent(s) intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so or maintained the records and failed to produce them in a timely manner and that the respondent(s)' conduct constitutes a significant departure from accepted practices of the relevant research community.
  
- b. Respondent(s)' Burden of Proof. Respondent(s) have the burden of proving, by a preponderance of the evidence any and all affirmative defenses or mitigating factors. The Ad Hoc Investigative Committee shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent(s).
  
5. Investigation Report.
  - a. Draft Report. The Ad Hoc Investigative Committee shall prepare a written draft investigation report which shall include the following information:
    - Allegations. A description of the nature of the allegations of research misconduct.
    - Funding. Describe the source of funding, including, for example, any grant numbers, grant applications, contracts, and publications listing funding support.

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- Institutional Charge. Describe the specific allegations of research misconduct considered during the investigation.
  - Policies and Procedures. If not already included in the inquiry report, include a copy of this policy.
  - Research records and evidence. Identity and summary of research records and evidence reviewed, as well as records and evidence taken into custody, but not reviewed.
  - Statement of Findings. Provide a finding of whether research misconduct did or did not occur for each separate allegation of research misconduct considered during the investigation. For each finding of research misconduct:
    - identify whether it was falsification, fabrication, or plagiarism;
    - identify whether it was intentional, knowing, or in reckless disregard;
    - summarize the facts and analysis which support the conclusion;
    - consider the merits of any reasonable explanation by the respondent(s);
    - identify the specific funding support;
    - identify whether any publications need correction or retraction;
    - identify the person(s) responsible for the misconduct;
    - any other corrective action recommended.
  - List any other funding support or known applications or proposals for support that the respondent(s) have pending with any federal agency or private sponsor.
- b. Opportunity for Comment.
- 1) Respondent(s). The respondent(s) shall be given a copy of the draft investigation report, along with a copy of (or supervised access to), the records and evidence on which the report is based. The respondent(s) shall have 30 days from date of receipt of the report to submit any comments to the Ad Hoc Investigative Committee.
  - 2) Complainant(s). The complainants may be given a copy of the draft investigation report or relevant portions of that report. The complainant(s) shall have 30 days from the date of receipt of the report to submit any comments to the Ad Hoc Investigative Committee.

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- c. Final Report. The Ad Hoc Investigative Committee shall issue its final report which shall contain all of the information outlined in paragraph 5.a above, any written comments received from the respondent(s) and/or complainant(s) within the time period set forth in paragraph 5.b above and the Ad Hoc Investigative Committee’s consideration of and response to any comments received from the respondent(s) or complainant(s). A copy of the final report shall be given to the respondent(s), complainant(s) and the Research Compliance Officer, redacting identities of any research subjects. A copy of the final report shall also be given to the respondent(s)’ Vice President and Dean, Administrator or Supervisor, redacting the identity of complainant(s), witnesses and any research subjects.

E. Institutional Actions

- 1. Finding of Research Misconduct. If the alleged research misconduct is substantiated by thorough investigation of the Ad Hoc Investigative Committee, the recommendations of the Ad Hoc Investigative Committee contained in the final report may be implemented and the following actions, if not already recommended by the Ad Hoc Investigative Committee in its final report, may be taken:
  - a. Restitution of funding as appropriate or if required by the agency or contract.
  - b. Withdrawal of abstracts and papers emanating from the questioned research, and notification of editors of journals and publications which published previous abstracts and papers concerning the research, if the Ad Hoc Investigative Committee concludes that substantiated research misconduct makes such abstracts and papers of questionable validity. The Dean is authorized to request/direct such actions if the researcher(s) involved fail(s) to do so within a reasonable time after the Dean directs such actions.
  - c. Appropriate action (including interim administrative actions) to terminate or alter the status of respondent(s) whose research misconduct is substantiated, or to impose other sanctions deemed appropriate under the circumstances.
  - d. The Dean, the Vice President to whom the Dean reports, and the President of the University shall consider, in consultation with General Counsel, release of information about the research misconduct to the public and/or press, particularly where public funds were used in support of the research affected by the research misconduct.
- 2. No Findings of Research Misconduct. If the Ad Hoc Investigative Committee finds that there was no research misconduct, efforts shall be undertaken as and if necessary to restore the position and reputation of the respondent(s).

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3. Cooperation with Federal Agencies. Creighton shall cooperate with any federal agency during its oversight review or administrative hearings or appeals related to any allegation of research misconduct, including, but not limited to providing all research records and evidence in our control, custody or possession, and access to all faculty, staff and students.

## F. Notices.

1. Notice to Applicable Funding Agencies of Findings and Actions. The Research Compliance Officer shall be responsible for giving notice to the applicable federal agency funding the research which is the subject of the research misconduct Investigative proceedings once they are complete. The notice shall be sent immediately after the final report is issued and shall include:
  - A copy of the final investigative report and all attachments (redacting identities of research subjects, as applicable);
  - A statement of whether or not research misconduct was found, and if so, who committed the misconduct;
  - Whether Creighton accepts the Ad Hoc Investigative Committee’s findings; and
  - A description of any pending or completed institutional actions taken against the respondent(s).
2. Other Notices to Applicable Funding Agencies. The Research Compliance Officer shall notify the applicable funding agencies, in advance, if it is planned to close a research misconduct proceeding at the inquiry or investigation stage on the basis that the respondent(s) has admitted guilt, the respondent(s) has agreed to settle the case, or for any other reason other than the closing of the case during the inquiry stage on the basis that an investigation is not warranted.

## G. Maintenance of Research Records and Evidence Related to Research Misconduct Proceedings.

1. Maintenance of Records of Research Misconduct Proceedings. Unless custody has been transferred to the applicable federal agency or the federal agency has advised, in writing, that the information no longer needs to be retained, the following records of research misconduct proceedings shall be maintained for 7 years after completion of the internal research misconduct proceeding or any federal agency proceeding involving the research misconduct, whichever is longer.

# *Policies and Procedures*

|                                              |                             |                          |                           |                          |
|----------------------------------------------|-----------------------------|--------------------------|---------------------------|--------------------------|
| <i>SECTION:</i><br><b>Academic Concerns</b>  | <i>NO.</i><br><b>4.2.2.</b> |                          |                           |                          |
| <i>CHAPTER:</i><br><b>Faculty</b>            | <i>ISSUED:</i><br>1/28/88   | <i>REV. A</i><br>8/31/95 | <i>REV. B</i><br>11/29/01 | <i>REV. C</i><br>2/15/06 |
| <i>POLICY:</i><br><b>Research Misconduct</b> | PAGE 14 OF 14               |                          |                           |                          |

- The records secured for the research inquiry and investigation, except to the extent it is subsequently determined that those records are not relevant to the inquiry or investigation or that the records duplicate other records that are being retained;
  - The documentation of the determination of irrelevant or duplicate records;
  - The inquiry report and final documents (not drafts) produced in the course of preparing the inquiry report, including the documentation of any decision not to investigate;
  - The investigation report and all records (other than drafts of the report) in support of the investigation report, including the recordings or transcriptions of each interview conducted during the investigation stage;
2. Transfer of Records to Federal Agency. Upon request of the applicable federal agency, the Research Compliance Officer shall transfer custody, or provide copies of, all institutional records relevant to a research misconduct allegation, including research records and evidence, to the requesting federal agency.

## **ADMINISTRATION**

The Dean(s) of the affected School/College and the Research Compliance Officer are responsible for administering this policy when there is an allegation of research misconduct. The Dean(s) of the affected School/College shall report any final action taken under this policy to the appropriate Administrative Vice President, General Counsel and the Research Compliance Officer.

## **AMENDMENT/TERMINATION**

Creighton University reserves the right to modify, amend, or terminate this policy at any time.