

# Shepherd University Research Integrity Policy

## Introduction

Based upon its philosophy of education and ethical standards, Shepherd University expects a commitment not only to the pursuit of academic excellence, but honesty, truth, integrity, and the highest standards in all endeavors. Achieving such high standards of integrity requires researchers to provide careful supervision of all research activities, including research conducted by students; use competent methods; adhere to ethical standards of the discipline; and refuse to engage in or to condone instances of fraud or misconduct.

This policy contains the common definitions relevant to ethical research and also misconduct in research and research-related activities. Procedures for filing complaints and disciplinary actions facing any individual or groups engaging in misconduct in research are provided. For purposes of this policy the term “researcher” is defined as any Shepherd University faculty, staff member, or student conducting research as an agent or affiliate of the University conducting research on Shepherd University’s campus or with Shepherd employees or students, whether using Shepherd University facilities or not. This policy and associated procedures will be followed when an allegation of possible misconduct in scholarly research activities is received by an institutional official.

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## 1.0 General Overview of Ethical Research

### 1.1 Definition of Ethical Research

While research is discipline specific, ethical research practices entail conducting research and reporting the results of such research in accordance with the principles of professional conduct and founded by a system of moral beliefs of right and wrong.

Ethical conduct in research is expected of all members of the Shepherd University community. In addition, proposed common federal regulations governing the conduct of research funded by any federal agency were published in the Federal Register in October 1999. Working under the umbrella of the Office of Science and Technology Policy, federal agencies began to develop common definitions of misconduct in research and to establish recommendations for managing research misconduct at research institutions receiving agency support for sponsored research. The policy was published in December 2000, and agencies were given one year to implement the policy. This policy indicates that while federal agencies and academic institutions share responsibility for the research process, **institutions have the primary responsibility for monitoring the conduct of research on their campuses and ensuring the integrity of the research process.** The policy also makes clear that federal agencies supporting research may proceed to investigate allegations of misconduct under specific conditions outlined in the policy statement. Most allegations of misconduct in sponsored research fall under the

investigative authority of the agency's Office of Inspector General (OIG). Reporting requirements for findings of misconduct in sponsored research are specific to each agency.

## **1.2 Ethical Principles for Research**

Shepherd University is committed to ensuring that all students, faculty, and/or staff conducting research do so in a manner consistent with the ethical standards for their disciplines. The Office of Research Integrity is the arm of the Public Health Service that is responsible for overseeing and directing activities directly related to research integrity for all offices under the oversight of the Secretary of Health and Human Services except the Food and Drug Administration. Specific policies of different federal agencies can be found at <http://ori.dhhs.gov/policies/>. It is the responsibility of all researchers to familiarize themselves with the appropriate policies.

## **1.3 Ethical Principles for Research Involving Human Subjects**

Shepherd University is committed to ensuring that all members of the university community (students, faculty, and/or staff) that conduct any research involving human subjects do so in a manner that does not bring the integrity of the researcher or the results into question and adheres to appropriate standards as to the persons who are the subject of the research. Any Principal Investigator conducting research involving human subjects must provide certification of successful completion on NIH training within the past **five (5) years**. Researchers who have not completed this training or who need to renew their certification can do so as follows:

1. Go to <http://phrp.nihtraining.com/users/login.php> and register before starting the online training.
2. Print your certificate of completion (.pdf document) and submit it to the IRB chair.

The University policy on activities involving human subjects is to comply fully with the regulations of the [Office for Human Research Protections](#) (OHRP) and to implement the principles outlined in the [Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#). In addition, all federally-funded research conducted at this institution which involves human subjects will be in compliance with the Code of Federal Regulations (CFR) Title 45, Part 46. These regulations have been adopted by Shepherd University to cover all research activities involving human subjects. For additional information, refer to materials provided by the Shepherd University Institutional Review Board.

## **1.4. Specific Policies on Research Conducted at Shepherd University**

- 1.4.1 Research involving support from external funding agencies or Shepherd University is subject to this policy. In addition, any research involving human subjects, laboratory animals, or which is classified as exempt must adhere to the ethical practices of research described herein.

- 1.4.2 The Principal Investigator (PI) bears the primary burden to ensure that research project(s) are conducted in an ethical manner. The PI must make certain that all members of the research team have been adequately informed and/or trained before undertaking any research project(s).
- 1.4.3 Projects in graduate and undergraduate classes may be exempt from this policy. Each instructor must confirm with the IRB chair and the Research Integrity Officer that his/her class project is exempt before proceeding. If the project is deemed exempt, the expectation exists that all research will be conducted with the highest of ethical standards.
- 1.4.4 The use of electronic sources, most often the Internet, for research is increasing at a rapid rate. It is important to note that research using electronic sources is subject to the same level of scrutiny as research that does not use electronic sources. The expected level of research integrity will be applied to the use of electronic and non-electronic sources. For example, when electronic sources are used as references in a manuscript, it is expected that the same level of care will be taken when paraphrasing and citing such works.
- 1.4.3 All researchers must be able to conduct their work free of coercion or undue influence. The ability to report freely the results of research projects, unless protected by confidentiality statements, is essential to the scholarly process. This ability is central to the concept of academic freedom and its importance cannot be over looked. In addition, the freedom from coercion or undue influence must also extend to the ability to report misconduct. This protection is described in section 3.2.2 as well as the Shepherd University Conflict of Interest Policy.
- 1.4.4 All individuals involved in data collection must indicate that they are bound by considerations of confidentiality not to report the findings during the study or after the completion of a specific study. In addition, release of data that can be directly linked to an individual is not only a violation of legal statutes but also the ethical conduct of research. Only the Principal Investigator and Co-Principal Investigator may discuss data in the aggregate or give permission to include the data in scholarly publications. Confidential data will be kept in a secure environment to help ensure confidentiality is maintained. Any breach of security will be reported immediately to the appropriate University security office, the Vice President for Academic Affairs, and the Research Integrity Officer.

## **2.0 Research Practices Covered by this Policy**

### **2.1 Definition of Misconduct in Scholarly Research**

Misconduct in scholarly research includes the following:

- 2.1.1 Fabrication or falsification of research data, plagiarism, theft of ideas or intellectual property, or appropriation of another's work. While each of these are

open to some degree of interpretation the standard used in the appropriate scholarly field will be used in applying this policy.

- 2.1.2 Failure to acknowledge or recognize the contribution(s) of others, including co-researchers, students, and research assistants.
- 2.1.3 Use of the unpublished works of others without permission, or use of archival material in violation of the Copyright Act.
- 2.1.4 Abuse of supervisory power affecting collaborators, assistants, students, or others associated with the research.
- 2.1.5 Failure to account for, misapplication, or misuse of funds acquired for support of research.
- 2.1.6 Failure to comply with relevant federal and local statutes or regulations for the protection of researchers, human participants, the health and safety of the public, or welfare of laboratory animals.
- 2.1.7 Failure to comply with regulations of the relevant agency or agencies concerning the conduct of research.
- 2.1.8 Failure to reveal any material conflict of interest to Shepherd University officials, to research sponsors, and/or to those who commission work.
- 2.1.9 Failure to reveal any material conflict of interest when asked to undertake reviews of grant applications or manuscripts for publication, or to test products for sale or distribution to the public.

## **2.2 Protection of Human Participants and the Welfare of Laboratory Animals**

- 2.2.1 **Human Participants (Also Referred to as Human Subjects)**  
 Humans participating in research as research subjects are protected by federal regulations and institutional policy if the researcher obtains (1) data through intervention or interaction with the individual or (2) private information about the individual(s). All research conducted at Shepherd University that includes human participants must be reviewed and approved by the Shepherd University Institutional Review Board (IRB). Researchers affiliated with Shepherd University but conducting research involving human subjects at other sites or in collaborative research environments elsewhere are subject to IRB-HS policies at the lead institution. No human research may be conducted without an IRB-HS approval. The IRB is responsible for determining if a research proposal takes all the necessary steps to ensure the protection of human subjects involved in a particular research proposal. More information about the University's Human Subjects Policy can be found on the website <http://www.shepherd.edu/irbweb/>.

### 2.2.2 Laboratory Animals

The term *animal* is defined as any live, vertebrate animal used or intended for use in research, research training, biological testing, or for related purposes. The University has its Institutional Animal Care and Use Committee (IACUC), which is charged with overseeing issues related to the use of animals in research. Any collaborative research conducted at external sites involving animal use must have received approval from the home IACUC.

## 2.3 Conflict of Interest

It is essential to recognize situations of existing, potential, or apparent conflict of interest promptly. A conflict of interest is defined as **“any situation, whether compensated or uncompensated, in which a university employee’s intellectual independence or the university’s integrity would be compromised as a result of decisions made in the process of conducting research or in those activities associated with the research.”**

Conflict of interest is described in the Shepherd University Conflict of Interest Policy. As described in this policy, a conflict of interest arises in the following circumstances but is not limited to the following circumstances:

- 2.3.1 When the personal or business interests of the researcher, including the interests of his/her relations and associates, conflict with the researcher’s obligations to the University, including respect for the University’s policies and students or staff under his/her supervision;
- 2.3.2 When, without prior written agreement, use is made of University resources, including secretarial, office and administrative services, technical services, laboratories, premises, logo, and/or insignia, for the personal gain or benefit of the researcher or for the personal gain or benefit of others related to or associated with the researcher.
- 2.3.3 When the work of students is directed or done with a view to benefiting the personal or business purposes of the researcher, his/her associates or relations, to the detriment of the University and/or to students’ academic progress.
- 2.3.4 When the personal or business interests of the researcher, his/her associates or relations compromise the independence and impartiality necessary to perform his/her duties.
- 2.3.5 When a researcher uses confidential information that is gathered in the course of his/her duties for personal or business gain or for the gain of his/her associates or relations.
- 2.3.6 When, in the course of his/her duties, a researcher incurs an obligation to an individual or business that is likely to benefit from special treatment or favors granted by the researcher or the University.
- 2.3.7 When a researcher accepts an executive appointment, employment, or shares in any non-university organization that might reasonably expect them to disclose

confidential or proprietary information to which they have access by virtue of their University appointments. Researchers are reminded that under the Shepherd University Conflict of Interest Policy, they are required to report any potential conflict of interest as described in the policy. Examples of potential conflict of interest situations are provided in that policy.

## **2.4 Data Management Practices**

The retention of accurately recorded and retrievable results is of the utmost importance for the progress of scholarly inquiry. Researchers must have access to original results in order to respond to questions regarding their research. Errors may be mistaken for misconduct when the primary experimental results are unavailable.

- 2.4.1 Primary data should normally remain in the school or department at all times and should be preserved as long as there is a reasonable need to refer to them. Results should be recorded accurately and be retrievable for five years, or for the period of time stipulated in the terms and conditions of the award in the case of sponsored projects, following publication where the medium permits. Original primary research data should be recorded, when possible, in bound books with numbered pages or on appropriately protected electronic media. An index should be maintained to facilitate access to data. In no instance should primary data be destroyed while investigators, colleagues, or readers of published results may raise questions answerable only by reference to the data except in the case where there is a bona fide requirement for confidentiality.
- 2.4.2 Entitlement to ownership, reproduction, and publication of primary data, software, and other products of research will vary according to the circumstances under which research is conducted and is more fully articulated in the Shepherd University Intellectual Property Policy. A common, documented understanding of ownership must be reached among collaborators, supervisors, students and the University before the research is undertaken; otherwise, the University retains ownership except where superseded by federal or institutional policies/regulations.
- 2.4.3 Issues of confidentiality will arise in some disciplines and areas of research, and these issues must be appropriately addressed by the department or research unit involved prior to the research being undertaken. In all such cases, data must be in a locked area accessible only by the research team working with that data set.
- 2.4.4 Subject to any limitations imposed by the terms of grants, contracts, or other arrangements for the conduct of research, the principal investigator and all co-investigators must have free access to all original data and products of the research at all times. With the knowledge and prior written authorization of the principal investigator, a member of the research team may make copies of the primary data for his/her own use.
- 2.4.5 When a principal investigator (either faculty member or student) leaves the University, arrangements for the safekeeping of records, data, and products of

research must be made. In the case of students, the data ordinarily stays in the University. In the case of faculty members, they would normally take the data with them, however, copies of the data must be left with the University for periods of time as required by this policy and funding agencies. When this occurs, the data will be housed in the office of the appropriate school dean.

## **2.5 Mentor and Trainee Responsibilities**

A unique relationship exists between a mentor and trainee. It is of utmost importance that this relationship adheres to appropriate standards of behavior. The responsibilities of mentors and trainees include the following:

- 2.5.1 Mentors must ensure that all research is conducted to the highest possible ethical standard and with scholarly and academic integrity.
- 2.5.2 Mentors must provide their collaborators, students, staff, and assistants with information necessary to prevent misconduct as defined in this policy.
- 2.5.3 Mentors must monitor the work of students, research assistants, and any other individuals involved in the research project and oversee the designing of research methodology and the processes of acquiring, recording, examining, interpreting, and storing data. *Simply editing the results of a research project does not constitute supervision nor does supervision alone constitute a right to authorship.*
- 2.5.4 Collegial discussions among all research personnel in a research unit should be held regularly to contribute to the scholarly efforts of group members and to provide informal review of data, ongoing experiments, and the potential publications arising from current research activities.
- 2.5.5 A faculty or staff member listed as the principal investigator or co-investigator should be able to verify the authenticity of all data or other factual information generated in his/her research.

## **2.6 Collaborative Research**

Researchers increasingly collaborate with colleagues who have expertise and resources needed to carry out a project. Any project that requires more than one person working on it requires some collaboration. There is an added burden in such collaborations due to the complex roles of the relationships, common but not necessarily identical interests, diverse management requirements, and cultural differences. In some cases this collaboration may be extensive enough to warrant the establishment of Co-Principal Investigators (Co-PIs). When two or more collaborators are working as Co-PIs it is essential that the specific duties of each of the Co-PIs are identified well in advance of the onset of work.

As a result, collaborators (including Co-PIs) should:

- a. share findings with colleagues in the collaboration and be attentive to what others are doing;
- b. report and discuss findings as well as problems;
- c. make other collaborators aware of any important changes;

- d. share related news and developments so that everyone in the collaboration is equally knowledgeable about important information;
- e. have effective management plans that cover financial issues, training and supervision, formal agreements, and compliance.

## **2.7 Authorship and Publication**

- 2.7.1 In order to ensure the publication of accurate scholarly reports, two requirements must be met:
  - a. the active participation of each author in verifying and taking responsibility for the part of the manuscript to which she/he has contributed;
  - b. the designation of one author who is responsible for the validity of the entire manuscript.
- 2.7.2 The principal criterion for authorship should be that the author(s) has/have made a significant intellectual and practical contribution. The concept of “honorary authorship” is unacceptable.
- 2.7.3 Students must be given appropriate recognition for authorship or collection of data in any publication.

## **3.0 Procedures for Investigation and Resolution of Complaints of Alleged Breach of Research Integrity Policy**

This policy is applicable to all allegations of breach of the Research Integrity Policy, which include the following, but is not intended to override current policies and procedures concerned with specific research issues:

- a. Abuse of human participants and laboratory animals
- b. Conflict of interest
- c. Data collection, gathering and retention
- d. Responsibilities of supervisors and mentors
- e. Collaborative research
- f. Authorship and publication
- g. Intellectual property
- h. Copyright

## **3.1 Rights and Responsibilities**

### **3.1.1 Research Integrity Officer**

The President will appoint the Research Integrity Officer (RIO). The term of appointment shall be two years. The RIO has the following responsibilities in addition to ensuring exemption of research with the IRB Chair:

- a. after receiving an allegation of research misconduct, conduct a preliminary inquiry (“An Inquiry”) to determine if sufficient evidence exists to convene an investigation committee
- b. provide written notification and reports of inquiries and investigations to parties involved



- c. appoint the Investigation Committee and ensure that the appropriate expertise is secured to carry out a thorough evaluation of the evidence,
- d. assist the Investigation Committee in complying with applicable standards imposed by the various funding agencies,
- e. report to the sponsoring agency's Office of Research Integrity (ORI) as required by regulation and keep the ORI apprised of any developments during the course of the investigation,
- f. maintain confidentiality as described below.
- g. prepare inquiry and investigation reports as required.

### 3.1.2 Complainant

A complainant is a person who makes an allegation of scholarly misconduct. The complainant has the following rights and responsibilities. The complainant

- a. will have an opportunity to testify before the Inquiry and Investigating Committee,
- b. will be allowed to review those portions of the inquiry and investigation from his/her recorded or transcribed testimony, if any, and may provide corrections to those recorded statements,
- c. is responsible for making allegations in good faith and for maintaining confidentiality,
- d. will be protected from retaliation.

### 3.1.3 Respondent

The respondent is a person against whom an allegation of research misconduct is directed or the person who is the subject of inquiry or investigation. There can be more than one respondent in any inquiry or investigation. The respondent

- a. will be informed in writing of the allegations when an inquiry is opened and will be notified in writing of the final determinations and resulting actions.
- b. will have the opportunity to be interviewed by the Investigation Committee and present evidence to the committee,
- c. will be able to review the draft inquiry and investigation report(s) and to have advice of the respondent's own advisor or counsel,
- d. is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation,
- e. has the right to receive institutional assistance in restoring the researcher's reputation if the researcher is not found guilty of research misconduct. However, the University is not required to offer the assistance of an advocate in potentially restoring the researcher's reputation.

## 3.2 General Policies and Principles

### 3.2.1 Responsibility to Report Misconduct

All employees, students, and persons associated with Shepherd University should report observed, suspected, or apparent misconduct in research to the Research Integrity Officer. At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and will be counseled about the appropriate procedures for reporting allegations.

### 3.2.2 Protecting the Complainant

The Research Integrity Officer will monitor the treatment of individuals who bring allegations of misconduct and those who cooperate in inquiries and investigations. The Research Integrity Officer will also ensure that these persons are not the objects of retaliation. Employees should report any alleged or apparent retaliation to the Research Integrity Officer. The institution is required to protect the privacy, positions, and reputations of persons who, in good faith, make allegations. "Good faith" is defined as an intent that originates from an unbiased, honest purpose in the public interest to bring to light perceived misconduct in research endeavors.

### 3.2.3 Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation. Employees accused of research misconduct may consult with outside legal counsel to seek advice (the University's legal counsel represents the University, not individuals). The role of advisers or counsel in investigation procedures follows the University's general grievance procedure found at section 14 "Appeals/Grievances/Hearings" of the Shepherd University *Faculty Handbook*.

### 3.2.4 Preliminary Inquiry into Allegations

Upon receiving an allegation of research misconduct, the Research Integrity Officer will promptly conduct an inquiry to assess the allegation and determine whether there is sufficient evidence to warrant an investigation and will complete the Inquiry within 60 days of initial allegation, absent unavoidable exigencies. If that evidence exists, the Investigation process is initiated.

### 3.2.5 Confidentiality

To the extent allowed by law and to the extent that the conduct of the inquiry and/or investigation reasonably permits, the University shall maintain the identity of respondents and complainants securely and confidentially and shall not disclose any identifying information except to: (1) those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding, or as may be otherwise necessary in the furtherance of their duties as University employees; and (2) if relevant, to the sponsoring agency's ORI as it conducts its review of the research misconduct proceeding and any subsequent proceedings.

### **3.3 Conducting the Investigation**

#### **3.3.1 Purpose of the Investigation**

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine whether misconduct has been committed, by whom, and to what extent. If a determination is made of possible misconduct, the Research Integrity Officer will secure, inventory, and sequester all pertinent research records according to 42 CFR Section 93.305.7 and describe any relevant records and evidence not taken into custody and explain why.

#### **3.3.2 Appointment of the Investigation Committee**

The Research Integrity Officer, after satisfying the President that appropriate consultation has occurred, will appoint an Investigation Committee. The President will name a chairperson. The Investigation Committee will consist of between three and five individuals, two of whom are external to the accused's department and have familiarity with the working standards and expectations of the discipline, who do not have real or apparent conflict of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence. The RIO and President shall screen proposed individuals for any unresolved personal, professional, or financial conflict of interest with the respondent, complainant, potential witnesses, or others involved in the matter. Any such conflict that a reasonable person would consider to demonstrate potential bias shall disqualify the individual from selection. Additionally, the committee will not include the Research Integrity Officer as a member.

#### **3.3.3 Investigation Process**

The Investigation Committee will be appointed, and the process initiated within 30 calendar days of the completion of the inquiry. The investigation will normally involve examining all relevant documentation, such as research records, computer files, proposals, manuscripts, correspondence, and memoranda. Whenever possible, the committee will interview the complainant(s), the respondent(s), and other key personnel who might have information regarding the allegations. All interviews will be recorded and transcribed. The Investigation Committee shall use its best efforts to complete the investigation within 120 calendar days of the date on which it began, including all required reports and appeal processes. If it becomes apparent that the investigation cannot be completed within that time, the University shall promptly request an extension in writing from the designated ORI, if applicable to sponsored research.

#### **3.3.4 The Investigation Report**

The Investigation Committee is charged with writing an Investigation Report containing all pertinent information regarding the investigation of the alleged misconduct. The report shall contain the required elements listed in 42 CFR Section 93.312. A formal draft of the report will be made available, substantially simultaneously, to the respondent(s) and the complainant(s) for comment and rebuttal. Comments and rebuttals must be provided to the committee within 10 calendar days of receipt of the draft. Once all comments are received, the Investigation Report will be completed by the Investigation Committee.

### 3.3.5 Investigation Decision and Notification

The Investigation Report will be transmitted to the Vice President for Academic Affairs, who will make the determination of misconduct based on the findings from the investigation. The Vice President for Academic Affairs will notify the respondent and the Research Integrity Officer of his/her findings of misconduct.

### 3.3.6 Misconduct Appeal Process

Before any actions are taken in findings of research misconduct, the respondent shall have the right to appeal the University's decision. All appeal actions must be completed within five working days of the investigation unless an extension has been granted by the sponsoring ORI. In cases of non-sponsored research, the President may grant a reasonable extension period. The respondent must be given sufficient timely notice of the findings to prepare an appeal statement and must be provided with the process for appeal in writing. The Deans' Council sitting as a body shall be the final appeal authority in cases of research misconduct and will conduct an appeal based on the facts presented to the Investigation Committee. In this matter, the longest serving dean will chair the appeal process. All reasonable steps must be taken to ensure that no member of the Deans' Council has unresolved personal, professional, or financial conflicts of interest with the respondent, complainant, or others involved in the matter. Having made the determination of the charges and actions in the case, the Vice President for Academic Affairs shall recuse him/herself from these deliberations and the appeal process except as he/she may be called as a witness to the proceedings.

### 3.3.7 Actions Taken as a Result of Misconduct

Pending final appeal decisions on the charge of misconduct, the Vice President for Academic Affairs will determine what actions shall be taken against the person found to have committed misconduct in research. His/her determination shall be commensurate with University policy. The appeal process shall follow that described in the appropriate section of the *Faculty Handbook*. In cases of research misconduct findings against staff or students, the appeal processes shall be the same; however, actions taken against staff or students who have committed research misconduct shall follow applicable policies in the *Staff Manual* or the *Student Handbook*.

## 3.4 Maintenance and Custody of Research Records and Evidence

The University shall take all reasonable steps to obtain, secure, and maintain the research records and evidence pertinent to the research misconduct proceeding. Specifically, the RIO on behalf of the University shall promptly take custody of all research records and evidence needed to conduct the misconduct proceeding, inventory the materials, and sequester the materials in a secure manner.

Materials sequestered for the course of the proceedings shall be strictly monitored and supervised during access by individuals who have a need to know and are involved in the proceedings.

Additional materials related to the misconduct proceedings that come to light in the course of investigation shall also be secured as above to the extent possible.

All records and reports shall be maintained for three (3) years from the closing of the proceedings or in the case of sponsored research for seven (7) years or according to the specific requirements of the agency sponsoring the research unless these records have been transferred to the sponsoring agency or unless the sponsoring agency has advised the University in writing that the University no longer needs to retain the records.

### **3.5 Special Circumstances That May Require Protective Actions**

The university shall take appropriate interim actions in all cases that arise during the misconduct proceedings to protect public health, federal funds and equipment, and the integrity of the research process. Actions will vary according to circumstances. At any time during a research misconduct proceeding, the University shall immediately notify the appropriate ORI, if applicable, if any of the following conditions exist:

1. Health or safety of the public is at risk
2. Federal resources or interests are at risk
3. Research activities should be suspended
4. There is a reasonable indication of violations of civil or criminal law
5. Federal action is required to protect the interests of those involved in the misconduct proceedings
6. Indications of premature release of information to the public that would jeopardize the proceedings or put the evidence and/or those involved at risk
7. The University determines that the research community or public should be informed.

### **3.6 Notifying and Reporting to the ORI**

The University shall adhere to the requirements of 42 CFR Sections 93.304 - .310 in notifying, reporting, and cooperating with the ORI in cases of research misconduct investigations.

## External Resources for Researchers

- [Federal Policies and Guidelines](#)
- [Food and Drug Administration](#)
- [Data Safety and Monitoring](#)
- [Ethics and Human Participants in Research](#)
- [Related Resources](#)

## Federal Policies and Guidelines

- [IRB Guidebook](#)
- [Code of Federal Regulations - 45 CFR](#)
- [Office for Human Research Protections - OHRP | En Español](#)
- [Office for Human Research Protections \(OHRP\) 2007 International Compilation of Human Research Protections \(PDF\)](#)
- [Office for Human Research Protections/Department of Health and Human Services - Guidance on Reviewing and Reporting Unanticipated Problems and Adverse Events \(PDF\)](#)
- [Certificates of Confidentiality Kiosk - National Institutes of Health](#)
- [NIH Required Education in the Protection of Human Participants](#)
- [National Institutes of Health - FAQs regarding Human Participant Research](#)