Regis University

Research Integrity Policy

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I. Introduction

A. General Policy

Regis University, a Jesuit Catholic institution of higher education, supports a scholarly environment that promotes the highest ethical standards and discernment in the conduct of research**.** Additionally, the University has a duty to ensure the integrity of research and, in keeping with its mission, the University will respond promptly and fairly to any allegation of misconduct.

B. Scope

This policy and the associated procedures apply to all individuals at the University engaged in research, including research supported by PHS. The PHS regulation at 42 CFR Part 93 applies to any research, research-training or research-related grant or cooperative agreement with PHS. This policy applies to any person paid by, under the control of, or affiliated with the University, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at the University.

The policy and associated procedures will normally be followed when an official of the University receives an allegation of possible misconduct in research. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of the University and the federal funding entity. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the Vice President for Academic Affairs.

II. Definitions

A. *Allegation* means a disclosure of possible research misconduct through any means of communication. This includes any written or oral statement or other communication made to an institutional official.

B. *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

C. *Deciding Official* means the institutional official (Vice President for Academic Affairs) who makes final determinations on allegations of research misconduct and any responsive institutional actions.

*Sections that are based on requirements of the PHS regulations codified at CFR Ch. 1 (10-1-06 Edition) Part 93 have endnotes that indicate the applicable sections number, e.g., 42 C.F.R. '50.103(d)(1).

D. *Good Faith allegation* means an allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation. Good faith as applied to a committee member means cooperating with the research misconduct proceedings by carrying out duties assigned impartially to committee members 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.

E. *Inquiry* means preliminary gathering of information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

F. *Investigation* means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

G. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the research misconduct and research integrity activities of the U. S. PHS.

H. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.

I. *PHS regulation* means the PHS regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 CFR Ch 1 (10-1-06) Part 93, entitled "Responsibility of PHS Awardees and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science."

J. *PHS support* means PHS grants, subgrants, contracts, subcontracts or cooperative agreements or applications under those PHS funding instruments; or salary or other payments under PHS grant, cooperative agreements or contracts.

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

L. *Research Integrity Officer (RIO)* means the Appropriate Faculty Member appointed by the institutional official (Vice President for Academic Affairs) responsible for assessing

allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

M. *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) by establishing, discovering, developing, elucidating, or confirming information about, or the underlying mechanism relating to matters to be studied.

N. *Research record* means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to prove evidence for information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of research misconduct. A research record includes, but is not limited to the following: grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

O. *Respondent* means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation.

P. *Retaliation means* any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has, in good faith, made an allegation of research misconduct or of inadequate institutional response thereto or has cooperated in good faith with an inquiry or an investigation of such allegation.

Q. *Research misconduct or misconduct in research* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, performing or reviewing research, or in reporting research results.

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

2. 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.

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

4. Research misconduct does not include honest error or differences of opinion. A finding of research misconduct made under this part requires that –

   (a) There be a significant departure from accepted practices of the relevant research community; and

   (b) The misconduct be committed intentionally, knowingly, or recklessly; and

   (c) The allegation be proven by preponderance of the evidence.

R. *Complainant* means a person who makes an allegation of research misconduct.

III. Rights and Responsibilities

A. Research Integrity Training

Training is critical to the successful operation of an institution's research integrity program. The following describes how faculty, staff and students at the University may become involved with training systems available. For specific information regarding these programs individuals should contact the Office of Academic Grants.

CITI Training

Regis University recognizes the value of the multiple methodological approaches taught and employed at Regis University. Central to all these methods is the integrity of scholarship and the rights of researchers who participate in our research and learning. Based on Federal guidelines and, moreover, the basic grounding principle of Regis University, "How ought we to live?" Regis University outlines the following available* training:

1. CITI – Collaborative Institutional Training Initiative - http://citiprogram.org
2. U.S. Office Research Integrity website – http://ori.hhs.gov/

The following Responsible Conduct in Research CITI modules in Social Behavioral Research (SBR) are recommended:

1. Introduction to Responsible Conduct of Research (no quiz)
2. Research Misconduct Basic Module (quiz)
3. Responsible Conduct of Research with Human Subjects (quiz)

*Be aware some funding agencies may require this training (such as NSF and NIH). In the case where students or personnel involved in a research project requiring training, the PI or faculty leading the project are responsible to assure these agency rules are met.

B. Research Integrity Officer

The Vice President for Academic Affairs shall appoint an appropriate Faculty Member as the Research Integrity Officer who will have primary responsibility for implementation of the procedures set forth in this document.

The Research Integrity Officer will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained. The Research Integrity Officer will limit the disclosure of the identity of the complainant and respondent to those who need to know, consistent with a through, competent, objective, and fair research misconduct proceeding.

The Research Integrity Officer will assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The Research Integrity Officer will report to ORI if PHS support is involved as required by regulation and keep the ORI apprise of any developments during the course of the inquiry or investigation that may affect current or potential PHS support for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

The Research Integrity Officer is also the Deciding Official.

C. Complainant

The complainant will have an opportunity to testify before the Inquiry and Investigation Committee, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the Research Integrity Officer has determined that the complainant may be able to provide pertinent information on any portions of the draft report, these portions of the draft report; will be given to the complainant for comment.

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry or investigation.

D. Respondent

The institution will notify the respondent of the allegations through good faith effort in writing at the time of or before beginning an inquiry; the respondent will be notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed and present evidence to the Inquiry and Investigation Committee, to review the draft inquiry and investigation reports, and to have the advice of counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of and inquiry or investigation. If the respondent is not found guilty of research misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.

E. Deciding Official

The Vice President for Academic Affairs will serve as the Deciding Official. The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent for the complainant on the draft report. The Deciding Official will consult with appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions [see section X].

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with the University should report observed, suspected, or apparent misconduct in research to the Vice President for Academic Affairs. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may call the Deciding Official at 303-458-1843 to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of research misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an employee or University members may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and/or the Vice President for Academic Affairs and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

University members will cooperate with the Research Integrity Officer and other University members in the review of allegations and the conduct of inquiries and investigations. University members, including the respondent, have an obligation to provide evidence relevant to research misconduct allegations to the Research Integrity Officer or other institutional officials.

C. Confidentiality

The Research Integrity Officer shall, as required by 42 CFR § 93.108: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective, and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The Research Integrity Officer should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information

D. Protecting the Complainant, Witnesses, Committee Members

The Research Integrity Officer will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer.

The University will protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the complainant requests anonymity, the institution will limit the disclosure of the identity of the complainant to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding. The institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The complainant will be advised that if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity may no longer be guaranteed. Institutions are required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

E. 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 and confidentiality to the extent possible

without compromising public health and safety or thoroughly carrying out the inquiry or investigation. The institution will limit the disclosure of the identity of the respondent to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding.

University employees accused of research misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice. During the research misconduct proceeding, the Research Integrity Officer is responsible for ensuring that respondents receive all the notices and opportunities provided in 42 CFR 93 and policies and procedures of the institution.

F. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceedings, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds, and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the Research Integrity Officer will, in consultation with other institutional officials and RIO, take appropriate interim action to protect against such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

-Health or safety of public is at risk, including an immediate need to protect human or animal subjects;

-HHS resources or interests are threatened;

-Research activities should be suspended;

-There is reasonable indication of possible violations of civil or criminal law;

-Federal action is required to protect the interests of those involved in the research misconduct proceedings;

-The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or

-The research community or public should be informed.

G. Cooperation with Inquires and Investigations

University employees will cooperate with the RIO and other University officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the RIO or other institutional officials on misconduct allegations.

H. Preliminary Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether there is sufficiently credible and specific evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of research misconduct.

The assessment period shall be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted within the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The Research Integrity Officer shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester research records and evidence needed to conduct the research misconduct proceedings.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the RIO determines that the allegation provides sufficient information to allow specific follow-up, and/or involves PHS support, and falls under the PHS definition of research misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the RIO should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose of the inquiry is **not** to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

B. Notice to the Respondent

At the time of or before beginning the inquiry, the University must make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry further identifies additional respondents, the University must notify them as well.

C. Criteria Warranting an Inquiry

An inquiry is warranted if the allegation falls within the definition of research misconduct under the definition section of this policy, and the allegation is sufficiently credible and specific so that the potential evidence of research misconduct may be identified.

D. Securing Evidence and Records

After determining that an allegation falls within the definition of misconduct in research, the RIO must take prompt measures to ensure that all original research records, evidence, and materials relevant to the allegation are immediately secured. However, 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 instrument. If PHS funding is involved, The RIO may consult with ORI for advice and assistance in this regard.

E. Creating the Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within 15 working days of the initiation of the inquiry. The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution.

The RIO will notify the respondent of the proposed committee membership in 15 working days. If the respondent has an objection to any of the committee members, the respondent must submit a written objection of any appointed member of the inquiry committee or expert, based on bias or conflict of interest within 5 working days the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

F. Charge to the Committee and the First Meeting

The RIO will prepare a charge for the inquiry committee that sets forth the time for completion of the inquiry, describes the allegations and any related issues identified during the allegation assessment. The charge will state the purpose of the inquiry, which is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose is not to determine whether research misconduct definitely occurred or who was responsible.

At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry. The RIO will also assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The Research Integrity Officer and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

G. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent(s), and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the RIO and institutional counsel, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and position of the committee members and experts, if any; the allegations; the PHS support, if any; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Institutional counsel will review the report for legal sufficiency.

B. Opportunity for Comment

The RIO will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the complainant, if he or she is identifiable, with portions of the draft inquiry report or a summary of the inquiry findings that address the complainant's role and opinions in the investigation. The RIO should also supply the respondent with a copy of the University’s policies and procedures.

Confidentiality

The RIO may establish reasonable conditions for review to protect the confidentiality of the draft report.

Receipt of Comments

Within 14 working days of their receipt of the draft report, the complainant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the complainant or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

Inquiry Decision and Notification

Decision by Deciding Official

The RIO will transmit the final report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 calendar days of the first meeting of the inquiry committee, unless circumstances clearly warrant a longer period.

Notification

The RIO will notify both the respondent and the complainant in writing of the Deciding Official's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The RIO will also notify all appropriate University officials of the Deciding Official's decision.

Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the RIO no more than 60 calendar days following its first meeting, unless the RIO approves an extension for good cause. If the RIO approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent also will be notified of the extension.

VII. Conducting the Investigation

Evidentiary Standards

The University must prove research misconduct by a preponderance of the evidence

The University has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent’s failure to provide research records adequately documenting the questioned research is evidence of research misconduct when the University has established by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain such 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 significant departure from accepted practices of the relevant research community.

The respondent has the burden of proving by a preponderance of the evidence any and all affirmative defenses and/or any mitigating factors that are relevant to the finder of fact. The finder of fact shall give due consideration to admissible, credible evidence of honest error or differences of opinion presented by the respondent.

Initiation and Purpose of the Investigation

The initiation must begin within 30 calendar days after the determination by the Deciding Official that an investigation is warranted. The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

Notifying ORI and Respondent; Sequestration of the Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and 2) notify the respondent in writing of the allegations to be investigated. The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation

The RIO will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 working days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they

may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee. Reasonable steps will be taken to ensure an impartial and unbiased investigation to the maximum extent practicable.

The RIO will notify the respondent of the proposed committee membership within 10 working days. If the respondent submits a written objection to any appointed member of the investigation committee or expert within 10 working days, the RIO will determine whether to replace the challenged member or expert with a qualified substitute.

A. Charge to the Committee and the First Meeting

1. Charge to the Committee

The RIO will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry. The RIO will also define research misconduct, and identify the name of the respondent(s). The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the RIO, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.
The committee will also interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation.

The committee will also pursue any leads on any significant issues which are discovered and are determined relevant to the investigation.

2. The First Meeting

The RIO, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulation.

B. Investigation Process

The investigation committee and the Research Integrity Officer must use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation. Also,

reasonable steps should be taken to ensure an impartial and unbiased investigation to the maximum extent practical. Each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspect of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation. Finally, the committee and the RIO shall diligently pursue all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

VIII. Investigation Report

Elements of the Investigation Report

The final report submitted to the Deciding Official (Vice President for Academic Affairs) must describe the policies and procedures, under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution. If PHS funding is involved, a final report must be submitted to ORI (See Requirements for Reporting to ORI When PHS Funding is involved below).

Comments on the Draft Report

Respondent

The RIO will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 10 working days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

Complainant

The RIO will provide the complainant; if he or she is identifiable, with those portions of the draft investigation report that address the complainant's role and opinions in the investigation. The report should be modified, as appropriate, based on the complainant's comments.

The University Counsel

The draft investigation report will be transmitted to University Counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

Confidentiality

In distributing the draft report, or portions thereof, to the respondent and complainant, the Research Integrity Officer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

A. Institutional Review and Decision

Based on a preponderance of the evidence, the Deciding Official (Vice President for Academic Affairs) will make the final determination whether to accept the investigation report, its findings, and the recommended actions. If this determination varies from that of the investigation committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the investigation committee. If PHS funding is involved, such explanation shall be included in Regis University's letter transmitting the report to ORI. The Deciding Official's explanation should be consistent with the definition of research misconduct, the University's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official may also return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the RIO will notify both the respondent and the complainant in writing. In addition, the Deciding Official will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

B. Transmittal of the Final Investigation Report to ORI When PHS Funding is involved

After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and complainant's comments, to the Deciding Official, through the RIO.

C. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Deciding Official for approval, and submitting the report to the ORI as required.

IX. Requirements for Reporting to ORI When PHS Funding is Involved

A. If the ORI is involved, the University will notify the ORI in writing within 30 calendar days that an investigation is warranted and upon completion of the inquiry report, the University will promptly provide ORI with an official copy of the inquiry report which includes the following:

1. Name and position of respondent;
2. A description of the allegations of research misconduct;
3. The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support
4. The basis for recommending that the alleged actions warrant an investigation; and,
5. Any comments on the report by the respondent of complainant.

The following must be provided to ORI on request:

1. The University's policies and procedures under which the inquiry was conducted;
2. The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and,
3. The charges of the investigation to consider.

ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

If the Deciding Official decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

B. If the University plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the RIO will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

C. If the University determines that it will not be able to complete the investigation in 120 days, the RIO will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.

D. When PHS funding or applications for funding are involved and an admission of research misconduct is made, the RIO will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence

and extent of misconduct. When the case involves PHS support, the University cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

The RIO will notify ORI at any stage of the inquiry or investigation if:

A. There is an immediate health hazard involved;

B. There is an immediate need to protect Federal funds or equipment;

C. There is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;

D. It is probable that the alleged incident is going to be reported publicly; or

E. The allegation involves a public health sensitive issue, *e.g.*, a clinical trial; or

F. There is a reasonable indication of possible criminal violation. In this instance, the University must inform ORI within 24 hours of obtaining that information.

ORI expects the University to carry inquiries and investigation through to completion and to pursue diligently all significant issues. The University must notify ORI in advance if the University plans to close a case at the inquiry, investigation or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage which must be reported to ORI.

X. The University's Administrative Actions

The University will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- Restitution of funds as appropriate.

XI. Other Considerations

A. Termination of University Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's employment with the University, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent’s Reputation

If the University finds no misconduct and, if PHS funding is involved and ORI concurs, after consulting with the respondent, the Research Integrity Officer will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunging all reference to the research misconduct allegation from the respondent's personnel file. Any action by the University to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Complainant and Others

Regardless of whether the University or ORI determines that research misconduct occurred, the RIO will undertake reasonable efforts to protect complainants who made allegations of research misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Deciding Official will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of the complainant. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The RIO will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the complainant.

D. Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine whether the complainant's allegations of research misconduct were made in good faith. If an allegation was not made in good faith, the

Deciding Official will determine whether any administrative action should be taken against the complainant.

E. Interim Administrative Actions

University officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.

XII. Record retention

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the RIO or committees. Unless custody has been transferred to another institution or HHS, or ORI has advised the University in writing that it no longer needs to retain the records, the RIO will keep the file for 7 years after completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will be given access to the records upon request.