

## **PC/PCSP Office of Research Integrity**

The Research Integrity Officer for Presbyterian College (PC) and the Presbyterian College School of Pharmacy (PCSP) is:

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If you have questions concerning the Misconduct Policy or need to report an incident of Research Misconduct, please send an email to [compliance@presby.edu](mailto:compliance@presby.edu) or call (864) 938-3835

## **Introduction**

Presbyterian College and the Presbyterian College School of Pharmacy strive to develop and encourage a research environment that promotes the responsible conduct of research, research training and any activities related to research or research training. PC/PCSP discourages research misconduct and deals promptly with allegations or evidence of possible research misconduct.

For the purposes of this document, all references to “College” refer to all activity that occurs in the undergraduate College of Arts and Sciences, the graduate School of Pharmacy, and any other academic or research programs that may be offered in the future.

## **Policy Statement**

This document articulates College policy on academic integrity in research and publication and dictates procedures for impartial fact-finding and fair adjudication of allegations of research misconduct. College personnel assure quality and integrity in their research and publications by adherence to individual and professional standards. This process occurs primarily by self-regulation.

A variety of informal practices exist within the College to address questions and controversies that may arise during scholarly activities. Most problems are and should be handled by reasoned discussion or informal mediation at the level of College organization closest to the persons involved.

As a College committed to academic integrity in research and scholarship, it is imperative that we articulate institutional policies on academic integrity and provide effective procedures for institutional treatment of incidents of research misconduct that cannot be handled satisfactorily by informal or mediation procedures.

These procedures described deal with allegations of research misconduct, including research fraud, at the College. It is the intent of these procedures to insure a rapid, fair, thorough and confidential review of any allegations of misconduct.

It is also the intent of these procedures to protect the positions and reputations of good faith complainants, the researcher (in the event of a finding of no research misconduct), witnesses and committee members, and protect them from retaliation by respondents and other institutional members. The College will seek to provide confidentiality to all respondents, complainants, and research subjects identifiable from research records or evidence. These guidelines provide support to the College in administering and enforcing any administrative actions by the U.S. Department of Health and Human Services (DHHS) and to actively assure the College's compliance with all rules and regulations set forth by the DHHS.

The procedures call for two levels of investigation of allegations: a preliminary inquiry to determine the need for a formal investigation and, if necessary, a separate formal investigation.

In addition, the procedures specifically call for the appropriate notification of any entity outside the College whose relationship to the research or other activity in question might reasonably require such notification.

Although this policy focuses upon deterring unacceptable conduct, its purpose is to promote compliance with the highest scholarly standards.

## Scope

This policy and the associated procedures apply to all individuals at the College engaged in scientific or professional activities. This includes but is not limited to any person paid by, under the authority of, or affiliated with the institution, such as faculty, students, staff members, interns, graduate students, professionals, technicians, guest researchers, or collaborators at the College. The policy and associated procedures will normally be followed when an allegation of possible research misconduct is received by an institutional official. Such allegation is to be referred to the College's Research Integrity Officer.

Any change from normal procedures must ensure fair treatment to the subject of the inquiry or investigation. Upon recommendation by the Research Integrity Officer, any significant variation must be approved in advance by the Provost or, in the event that the Provost has a conflict of interest, by the President. If the Provost and the President have a conflict of interest, any variation must be approved by the Executive Committee of the Board of Trustees.

## Definitions

<b>Allegation</b>	Any written or oral statement or other indication of possible research misconduct made to an institutional official or the research integrity officer.
<b>Complainant</b>	A person who in good faith makes an allegation of research misconduct
<b>Conflict of interest</b>	Situations in which financial or other personal considerations may directly and significantly affect, or give the appearance of affecting,

	professional judgment in exercising any College responsibility or in the conducting or reporting of research.
<b>Deciding Official (DO)</b>	The institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct involvement in the institution's inquiry or investigation.
<b>Fabrication</b>	The act of making up data or results and recoding or reporting them.
<b>Falsification</b>	The act of 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.
<b>Good faith</b>	<p>Good faith when applied to the individual(s) lodging the complaint means belief in the truth of one's allegations or testimony; i.e., that a reasonable person in the complainant or witness's position could have based on the information known to the complainant or witness at the time. An allegation is not in good faith if it is made with knowing or reckless disregard for information that would negate the allegation or testimony.</p> <p>Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping the College meet its responsibilities. 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.</p>
<b>Inquiry</b>	The process of information gathering and initial fact-finding to determine whether an allegation or suspected research misconduct warrants an investigation.
<b>Investigation</b>	The formal development of a factual record and the examination of that record leading to: (1) a finding of no research misconduct, or (2) a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions.
<b>Knowing or knowingly</b>	Action by an individual in such a manner that the same individual is aware that his/her action or conduct is wrong, or is aware of the high likelihood that the action or conduct of another is wrong.
<b>Plagiarism</b>	The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
<b>Preponderance of the</b>	Proof by information that, when compared with opposing

<b>evidence</b>	information leads to the conclusion that the fact at issue is more probably true than not.
<b>Reckless or recklessly</b>	Action by an individual such that the same individual consciously disregards a substantial and unjustifiable risk or that such action involves a gross deviation from the standards of conduct that a reasonable individual would observe.
<b>Research</b>	A systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) as relates to an identified research or scholarship area by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to functions or effects, or related matters to be studied.
<b>Research Integrity Officer (RIO)</b>	The institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.
<b>Research record</b>	The record of data or results that encompass the facts resulting from research inquiry, including, but not limited to, research proposals,; laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, and any documents and materials provided to a government agency, private funding source, media, or an institutional official by a respondent in the course of the research misconduct proceeding.
<b>Respondent</b>	The person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.
<b>Retaliation</b>	An adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to a good faith allegation of research misconduct; or good faith cooperation with a research misconduct proceeding.
<b>Research misconduct</b>	Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion. A finding of research misconduct requires that there be a significant departure from accepted practices of the relevant research community; that the misconduct be committed intentionally, knowingly, or recklessly; and that the allegation be proven by a preponderance of the evidence.

## **RESPONSIBILITIES**

### **Research Integrity Officer**

The Research Integrity Officer (RIO) will have primary responsibility and authority for implementation of the procedures set forth in this document. The RIO will be a high level College employee who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The RIO 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 RIO 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 government or other external funding sources as required by regulation and keep them apprised of any developments during the inquiry or investigation that may affect current or potential funding for the individual(s) under investigation or that the government agency needs to know to ensure appropriate use of public funds and otherwise protect the public interest.

### **Complainant**

The complainant will have an opportunity to testify before the inquiry and investigation committees, 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 RIO has determined that the complainant may be able to provide pertinent information on any portions of the draft inquiry and investigation reports, these portions will be given to the complainant for comment.

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

### **Respondent**

The respondent will be informed in writing of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will have the right to be interviewed by and present evidence to the inquiry committee and the 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 an inquiry or investigation. If the respondent is not found guilty of research misconduct, the institution will undertake reasonable efforts to restore his or her reputation.

## **Deciding Official**

The Provost of Presbyterian College will serve as the Deciding Official. S/he will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. S/he will consult with the RIO and determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions consistent with this policy.

If an Inquiry is indicated, the Provost will instigate inquiry proceedings by the following:

The Provost will instruct the Chair of the Senior Faculty Counsel or, as appropriate, the Dean of the Pharmacy School, to appoint, with the Research Integrity Officer as consult, the inquiry committee. If upon completion of the inquiry process, and if subsequently needed, a separate investigation committee will be appointed, with the Chair of the Senior Faculty Counsel, the Provost, and the Research Integrity officer ensuring 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 serve as the repository of all investigative materials and attempt to ensure that confidentiality is maintained.

## **PROCEDURES**

### **Responsibility to Report Misconduct**

It is **the explicit duty** of any member of the faculty, staff or student body or other individuals associated with the College to report observed, suspected, or apparent misconduct in research to the appropriate Department Chair, Dean of the Pharmacy School, or finally the RIO. The RIO is in turn responsible for reporting the allegations to the DO (Provost).

In the event that a fraud or other misconduct allegation shall be made against the Dean or Provost, duties and responsibilities assigned herein shall be transferred to that individual's higher academic report; i.e. duties and responsibilities to the Dean of the Pharmacy School shall be transferred to the Provost, and; duties assigned herein to the Provost shall transfer to the President.

In the event that a fraud or misconduct allegation shall be made against the President, duties assigned to the President will transfer to the Executive Committee of the Board of Trustees.

In the event that a fraud or misconduct allegation shall be made against the RIO, duties assigned to the RIO will transfer via the Provost to an external consultant Research Integrity Officer with the appropriate background and training.

With the exception of the specified line of reporting and on a need to know basis by other institutional officials such as College legal counsel, all allegations shall be held in absolute confidentiality. The allegations should usually be made in the form of a written, signed statement which states the allegation and specifies the evidence on which the allegation is based.

If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may call the Research Integrity Officer 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 may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer, a department chair, Dean or Provost, and will be counseled concerning appropriate procedures for reporting allegation.

### **Preliminary Assessment of Allegations**

Upon receiving an allegation of research misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry. An inquiry is warranted if the allegation (1) falls within the definition of research misconduct; (2) involves applications, proposals for government support or PHS supported biomedical or behavioral extramural or intramural research, or involves research training or activities related to research or research training, such as the operation of cell, tissue, and data banks and the dissemination of research information regardless of whether an application for government support resulted in a grant, contract, cooperative agreement or other form of government support, and (3) is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

### **Protecting the Complainant**

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, Provost, and Vice President for Human Resources will ensure that no retaliatory actions will be taken against these persons 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, Provost or the Vice President for Human Resources. In the event that involvement of the Provost is indicated, employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer, Vice President for Human Resources, or the President.

The College 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 College will attempt 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, the complainant's name will be revealed to the respondent. The institution is required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

## **Protecting the Respondent**

Inquiries and investigations will be conducted in a way 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 the thorough conduct of the inquiry or investigation.

The respondent shall have the right to have an advisor (including legal counsel) present when appearing before the inquiry committee. The advisor cannot be a principal or witness in the case. The advisor may quietly offer advice to the respondent during the meeting apart from suggesting areas of inquiry to the committee.

## **Cooperation with Inquiries and Investigations**

College faculty, students and employees shall cooperate with the Research Integrity Officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the Research Integrity Officer or other institutional officials on misconduct allegations.

## **CONDUCTING THE INQUIRY**

### **Initiation and Purpose of the Inquiry**

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up and falls under the definition of research misconduct, then he or she will immediately initiate the inquiry process.

In initiating the inquiry, the Research Integrity Officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to conduct an initial review of the evidence to determine whether to conduct 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.

### **Sequestration of the Research Records**

On or before the date on which the respondent is notified of the allegation or the inquiry begins, whichever is earlier, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are immediately inventoried and secured. The College shall also undertake all reasonable and practical efforts to take custody of additional research records or evidence that is discovered during the course of a research misconduct proceeding. Where research records encompass research or scientific instruments shared by a number of users, custody may be limited to copies of the data on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. Where appropriate, the College shall give the respondent copies of, or reasonable supervised access to, the research records.



## **Appointment of the Inquiry Committee**

The Chair of the Senior Faculty Council or the Dean of the Pharmacy School, in consultation with the Research Integrity Officer and other institutional officials as appropriate, will appoint an inquiry committee and committee chair within 10 working days of the initiation of the inquiry. The inquiry committee should consist of three tenured faculty members who have no real or apparent personal, professional or financial conflicts of interest with the complainant(s), respondent(s), witnesses or anyone otherwise involved 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. In the event that such expertise is not available in either the College or the Pharmacy School, the College may elect to ask tenured faculty of another institution with the appropriate expertise to serve on the inquiry committee.

The Research Integrity Officer will notify the respondent of the allegation and of the proposed committee membership. If the respondent submits a written objection to any appointed member of the inquiry committee based on bias or conflict of interest within 5 working days, the Research Integrity Officer will determine whether to replace the challenged member with a qualified substitute.

## **Charge to the Committee and the First Meeting**

The Research Integrity Officer will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment. The charge will state that the purpose of the inquiry 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 Research Integrity Officer will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, 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.

## **Inquiry Process**

All the meetings of the committee shall be closed. The Inquiry Committee will ordinarily interview the complainant, the respondent, and key witnesses as well as examine relevant research records and materials. The inquiry committee will then evaluate the evidence and testimony obtained during the inquiry.

The committee shall meet with the respondent unless that person specifically refuses. It is the prerogative of the respondent to request an immediate implementation of an investigation if on learning of the allegations the respondent wishes to forego the inquiry process.

The committee shall afford the respondent every opportunity to refute the allegation including provision of any and all pertinent records of the research or other activity in question.

The committee shall have the power to require the complainant, the respondent or other institutional officials to provide such records as any of its members believe is necessary for the consideration of the allegations.

If the respondent or the complainant refuse to appear or provide information before the committee, or for any reason fail to do so, the committee shall proceed with its inquiry in a manner it deems to be proper and make its decision based on the information available. The committee shall not divulge the complainant's name to the respondent, but both the complainant and the respondents should be explicitly informed that should an investigation ensue the identity of the complainant will be made known to the respondent. If at any time during the inquiry the possibility of criminal violations arises, the committee shall immediately notify the Research Integrity Officer who is responsible for informing the appropriate federal office within 24 hours if federal funding is involved.

After consultation with the Research Integrity Officer and institutional counsel, committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. An investigation is warranted if (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and (2) preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

## **THE INQUIRY REPORT**

### **Elements of the Inquiry Report**

The Committee shall prepare a written inquiry report that states the name and title of the committee members, the allegations, the research support, 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, 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.

If the opinion of the committee is divided, written reports shall be provided to the Research Integrity Officer detailing the several opinions and the basis for them. College counsel will review the report for legal sufficiency.

### **Comments on the Draft Report by the Respondent and the Complainant**

The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report, with the complainant's name redacted, and complainant with portions of the draft report that address information provided by the complainant in the inquiry for comment.

## **Confidentiality**

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report.

## **Receipt of Comments**

Within 10 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 submit will become part of the final inquiry report and record. Based on the comments, the Inquiry Committee may revise the report as appropriate. A copy of the final inquiry Committee report with the complainant's name redacted will be provided to the Respondent.

## **INQUIRY DECISION AND NOTIFICATION**

### **Decision by Deciding Official**

The Research Integrity Officer 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.

If the opinion of the inquiry committee is unanimous in finding that an investigation is warranted, it is incumbent on the Deciding Official to initiate an investigation within 20 working days of the receipt of the report. If the committee agrees unanimously that the accusation is without merit, the Deciding Official shall dismiss the matter without further action.

If the committee is not unanimously agreed, the Deciding Official may either remand the matter to the committee for further consideration for a period not to exceed 10 working days, terminate the proceedings, or convene an investigation as the Deciding Official in his/her discretion shall determine to be appropriate based on the report provided.

The inquiry is completed when the Deciding Official makes this determination, which will be made within 10 working days of the receipt of the report from the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file. If the respondent acknowledges the allegations, the Deciding Official will decide on the appropriate actions to be taken.

### **Notification**

The Research Integrity Officer will notify the respondent in writing of the Deciding Official's decision as to whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to any applicable government rules and regulations and the College's policies and procedures regarding allegations of research misconduct.

The Research Integrity Officer may notify the complainant who made the allegation whether the inquiry found that an investigation is warranted. The Research Integrity Officer may provide relevant portions of the report to the complainant for comment.

The Research Integrity Officer will also notify all entities whose relationship to the research or other activity in question is known and who might reasonably be expected to require such notification. Based on the report of the committee, the Research Integrity Officer shall be empowered to take interim administrative actions, as appropriate, to protect federal or nonfederal funds and ensure that the purposes of the financial assistance are carried out.

Under extraordinary circumstances the Deciding Official shall be empowered to direct the Research Integrity Officer to initiate an inquiry in the absence of a specific individual willing to make written allegations. The Deciding Official or Research Integrity Officer may for good cause authorize modifications or deviations from these Procedures. Such deviations, however, should be rare and only invoked for good cause on account of circumstances not anticipated in these Procedures and should in any case maintain the rights of both complainant and the respondent, maintain confidentiality, and shall follow the spirit and intent of these policies.

### **Time Limit for Completing the Inquiry Report**

The College must complete the inquiry within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes longer than 60 days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period. The respondent also will be notified of the extension.

### **Reporting to ORI on the decision to initiate an investigation**

Within 30 days of finding that an investigation is warranted for grant funded projects, the College's RIO must provide the Office of Research Integrity (ORI) of the U.S. Department of Health and Human Services with the written finding by the responsible College official and a copy of the inquiry report which includes the following information:

- Name and position of the respondent
- Description of the allegations of research misconduct
- List of PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;
- Basis for recommending that the alleged actions warrant an investigation; and
- Comments on the report by the respondent or the complainant.

Upon request, the College's RIO must provide the following information to ORI:

- College policies and procedures under which the inquiry was conducted.
- Research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
- Charges for the investigation to consider.

The College must keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the College decided not to conduct an investigation. The College must keep these records in a secure manner for at least 10 years after the termination of the inquiry, and upon request, provide them to ORI or other authorized DHHS personnel.

In addition, the College will keep records and report annually through its NIH BRAD grant report any instances of research misconduct, whether grant funded or not.

## **CONDUCTING THE INVESTIGATION**

### **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 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, the general public or College employees 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.

### **Sequestration of the Research Records**

The Research Integrity Officer will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. Where the research records encompass research or scientific instruments shared by a number of users, custody may be limited to copies of the data on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. 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**

At the instruction of the DO, the Research Integrity Officer, in consultation 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 normally consist of five individuals who were not involved in the inquiry process. Members of the Investigation Committee should be tenured faculty who

have no real or apparent personal, professional or financial conflicts of interest with the complainant(s), respondent(s), witnesses or anyone otherwise involved in the case, are unbiased, and have as far as practicable 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, subject matter experts, or other qualified persons. Whenever practicable, one member of the Investigation Committee shall be a faculty member or scientist from outside the College.

The Research Integrity Officer will notify in writing the complainant and respondent of the proposed committee membership. If either submits a written objection within 5 working days to any appointed member of the investigation committee or expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

### **CHARGE TO THE COMMITTEE AND THE FIRST MEETING**

The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegation and related issues identified during the inquiry, define research misconduct, and identify the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation to determine in good faith 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 Research Integrity Officer, who will determine whether it is necessary to expand the scope of the investigation and notify the respondent of the new subject matter or to provide notice to additional respondents.

#### **The First Meeting**

The Research Integrity Officer 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 federal funding is involved, the federal regulation.

#### **Investigation Process**

The Research Integrity Officer must notify the respondent in writing of the allegations within a reasonable amount of time after determining that an investigation is warranted, but before the investigation begins. The Research Integrity Officer must 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 investigation committee will be appointed and the process initiated within 30 days of a finding that an investigation is warranted.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, voice mail files, and notes of telephone calls. The committee shall have the power to require testimony from the complainant(s), the respondent(s), 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. All interviews shall be tape recorded and transcribed. Summaries or transcripts of the interviews should be prepared, provided to the interview party for comment or revision as to accuracy of the contents, and included as part of the investigatory file.

The committee is empowered to have the complainant and the respondent present at the same meeting. The respondent shall be entitled to confront the complainant if the committee does not so insist. The respondent shall have the right to have an advisor (including legal counsel) present when appearing before the committee or when confronting the complainant. The advisor shall not be permitted to examine witnesses, make any statement, or otherwise participate in the proceedings apart from suggesting areas of inquiry to the committee. The advisor may quietly offer advice to the respondent during the meeting. If the respondent refuses to appear before the committee or for any reason fails to do so, the committee shall proceed with its investigation in a manner it deems to be proper.

#### **Research misconduct, evidentiary standards:**

The College or Department of Health and Human Services has the burden of proof for making a finding of research misconduct by a preponderance of the evidence. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the College establishes by a preponderance of the evidence that the respondent 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.

The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether the College has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent. The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding.

## **REPORT OF THE INVESTIGATION COMMITTEE**

### **Elements of the Investigation Committee Report**

Within 90 working days of notice to the Respondent of its appointment, the committee shall present its Report in writing to the Deciding Official.

The Report must include:

- Allegations - Describe the nature of the allegations of research misconduct.
- Extramural support - Describe and document the extramural support (if any), including, for example, any grant numbers, grant applications, contracts, and publications listing extramural support.
- College charge - Describe the specific allegations of research misconduct for consideration in the investigation.
- Policies and Procedures - Include the institutional policies and procedures under which the investigation was conducted.
- Research records and evidence - Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.
- Statement of findings.

For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so the following supporting documentation:

- Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing or reckless disregard;
- Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
- Identify the specific government support (if any);
- Identify whether any publications need correction or retraction;
- Identify the person(s) responsible for the misconduct; and
- List any current support or known applications or proposals for support that the respondent has pending with Federal agencies.

The Report must also contain Comments - Include and consider any comments made by the respondent and complainant on the draft investigation report.

The Report must also maintain and provide records - Maintain and provide to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews. If the Committee's Report concludes that one or more violations have been substantiated, the Report may recommend what sanctions, if any, should be imposed upon the Respondent and what corrective action, if any, should be taken.



## **Comments on the Draft Investigation Report**

### **Respondent**

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The comments of the respondent, if any, must be submitted within 30 working days of the date on which the respondent received the draft investigation 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 Research Integrity Officer may provide the complainant a copy of the draft investigation report or relevant portions of that report. The comments of the complainant, if any, must be submitted within 30 working days of the date on which the complainant received the draft investigation report or relevant portions of it.

### **College Counsel**

The draft investigation report will be transmitted to the College legal counsel for a review of its legal sufficiency.

### **Confidentiality**

In distributing the draft report, or portions thereof, to the respondent and complainant, the Research Integrity Officer will inform the recipients of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality.

### **Institutional Review and Decision**

The Deciding Official will proceed as follows:

If the majority of the investigation committee finds that research fraud or other misconduct did occur, it is incumbent on the Deciding Official to initiate appropriate sanctions against the respondent. If the majority of the investigation committee finds that the accusation is without merit, the Deciding Official shall dismiss the matter without further action.

The Deciding Official may also return the report to the investigation committee with a written request for further fact-finding or analysis when: a) there is new evidence that may be sufficient to alter a finding or recommendation that was not considered by the committee and such evidence or facts were not known to the committee, complainant or respondent at the time of the original proceedings; or b) the committee's proceedings were not conducted in substantial conformity with the prescribed procedures; or c) the decision does not appear to be based on substantial evidence, that is, the facts as detailed in the report were not sufficient to establish or support a finding that a violation occurred.

Upon receipt of the Deciding Official's written request, the investigation committee will conduct additional proceedings and deliberations and forward a supplemental investigational report to the Deciding Official. The Deciding Official will review the final findings of the investigation committee's supplemental report and take appropriate action as outlined in this policy.

When a final decision on the case has been reached, the Research Integrity Officer 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. The Deciding Official shall report the final decision and administrative action to the President and other appropriate institutional officials as warranted.

### **Transmittal of the Final Investigation Report**

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 Research Integrity Officer.

### **Time Limit for Completing the Investigation Report**

An investigation should ordinarily be completed within 90 working 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 finding, making the draft report available to the subject of the investigation for comment and submitting the report to the Deciding Official for approval. If the Research Integrity Officer approves a time extension for good cause, 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.

### **Notices to ORI of institutional findings and actions**

The Research Integrity Officer must give ORI the following:

- Investigation Report - Include a copy of the report, all attachments, and any appeals.
- Final institutional action - State whether the College found research misconduct, and if so, who committed the misconduct.
- Findings - State whether the College accepts the investigation's findings.
- Institutional administrative actions - Describe any pending or completed administrative actions against the respondent.

## **Policy Enforcement**

### **INSTITUTIONAL ADMINISTRATIVE ACTIONS**

#### **Completion of the Research Misconduct Process**

The College must carry inquiries and investigations through to completion and must pursue diligently all significant issues. The College must notify ORI in advance if the college 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.

The College will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated. The Deciding Official shall also have the right to terminate all proceedings based upon the recommendation of a majority of the committee.

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 reviewing the recommendation(s) of the Investigation Committee and after consultation with the Research Integrity Officer and the General Counsel. All decisions involving disciplinary actions will be in accordance with applicable policies covering faculty, staff or students, and with any contractual rights that the respondent may have. Subject to those limitations, the actions may include but are not limited to:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was determined.
- 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 or enrollment;
- Restitution of funds to funding organization or agency as appropriate.

The investigation committee's final factual findings and determination that research fraud or other misconduct occurred will be treated as conclusive and binding in any grievance or other internal College proceedings, including those conducted by any faculty committee or body charged with determining whether termination or rank reduction proceedings should be continued against a faculty member. Notwithstanding the foregoing, in any case where the termination of a faculty member is being sought, the procedure in the appropriate Faculty Handbook or other applicable document concerning termination shall be followed de novo, with the final reports of the investigation committee and the Deciding Official to be submitted as evidence and given whatever weight the officials in charge of the termination decision deem appropriate.

## **OTHER CONSIDERATIONS**

### **Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation**

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

### **Restoration of the Respondent's Reputation**

If the institution finds no misconduct and after consulting with the respondent, the Research Integrity Officer and Deciding Official will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer will normally notify those individuals aware of or involved in the investigation of the final outcome, publicize the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunge all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must be in consultation with the Deciding Official.

### **Protection of the Complainant and Others**

Regardless of whether the institution determines that research misconduct occurred, the Research Integrity Officer and Deciding Official will undertake reasonable efforts to protect complainants who made allegations of research misconduct in good faith and others who cooperated in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Research Integrity Officer will determine, after consulting with the complainant, what steps, if any, are needed to prevent or counter any potential or actual retaliation and restore the position or reputation of the complainant, witnesses or committee members.

### **Allegations Not Made in Good Faith**

If relevant, the Research Integrity Officer 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 Research Integrity Officer will recommend to the Deciding Official whether any administrative action should be taken against the complainant. The Deciding Official shall consult the appropriate University administrators to determine the appropriateness of the action.

## **Interim Administrative Actions**

Institutional officials will take interim administrative actions, as appropriate, if:

- an immediate health hazard is involved;
- an immediate need to protect a sponsor's funds or equipment is noted;
- 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 is noted;
- it is probable that the alleged incident is going to be reported publicly; or
- a reasonable indication of possible criminal violation exists.

## **Notifying ORI of special circumstances**

At any time during a research misconduct proceeding, the College must notify ORI immediately if it has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- College resources or interests are threatened;
- Research activities should be suspended;
- Reasonable indication of possible violations of civil or criminal law exists;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The College believes the research misconduct proceeding may be made public prematurely so that the College may take appropriate steps to safeguard evidence and protect the rights of those involved;
- The research community or public should be informed. (Code of Federal Regulations, 93.318).

## **RECORD RETENTION**

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file that includes:

- Records that the College secures for the research misconduct proceedings, except to the extent the College subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained;
- The documentation of the determination if irrelevant or duplicate records;

- The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate;
- The investigation report and all records in support of that report, including the recordings or transcriptions of each interview conducted; and
- The complete record of any institutional appeal.

The Research Integrity Officer will maintain records of research misconduct proceedings in a secure manner for seven years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation.

## **9. REFERENCE DOCUMENTS**

Presbyterian College’s Research Integrity policy and its administrative regulations regarding research misconduct is based on the OSTP (Office of Science and Technology Policy) “The Federal Policy of Research Misconduct” which became effective December 6, 2000.

DHHS (Department of Health and Human Services) adopted the policy on June 15, 2005 (42 CFR 93). In addition, this document also draws upon policies from other academic institutions.

### NOTES:

1.42 C.F.R. § 50.102.

2.42 C.F.R. § 50.102.

3.42 C.F.R. § 50.102.

4.42 C.F.R. § 50.103(d)(12).

5.42 C.F.R. § 50.103(d)(13).

6.42 C.F.R. § 50.103(d)(2).

7.42 C.F.R. § 50.103(d)(13).

8.42 C.F.R. § 50.103(d)(3).

9.42 C.F.R. § 50.103(d)(1).

10.42 C.F.R. § 50.103(d)(1).

11.42 C.F.R. § 50.103(d)(1).

12.42 C.F.R. § 50.103(d)(8).

13.42 C.F.R. § 50.103(d)(7).

14.42 C.F.R. § 50.103(d)(7).  
15.42 C.F.R. § 50.103(d)(7).  
16.42 C.F.R. § 50.103(d)(7).  
17.42 C.F.R. § 50.104(a)(4); 18.42 C.F.R. § 50.104(a)(2).  
19.42 C.F.R. § 50.104(a)(2).  
20.42 C.F.R. § 50.104(a)(1).  
21.42 C.F.R. § 50.104(a)(1).  
22.42 C.F.R. § 50.103(d)(15).  
23.42 C.F.R. § 50.104(a)(3).  
24.42 C.F.R. § 50.104(a)(5).  
25.42 C.F.R. § 50.104(a)(3).  
26.42 C.F.R. § 50.104(b)(1).  
27.42 C.F.R. § 50.104(b)(2).  
28.42 C.F.R. § 50.104(b)(3).  
29.42 C.F.R. § 50.104(b)(4).  
30.42 C.F.R. § 50.104(b)(5).  
31.42 C.F.R. § 50.103(d)(14).  
32.42 C.F.R. § 50.103(d)(14).  
33.42 C.F.R. § 50.103(d)(11).  
34.42 C.F.R. § 50.103(d)(10).  
42 C.F.R. § 50.103(d)(15).