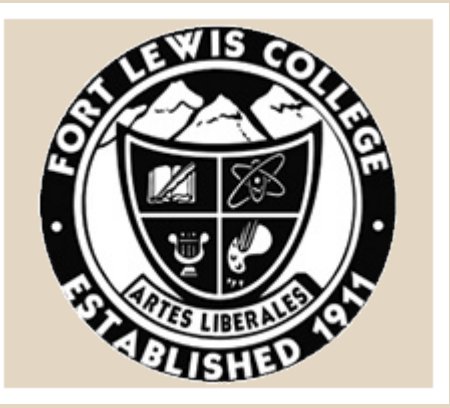
SPON-006 Policy for Responding to Allegations of Research Misconduct

	Policy identification number: **SPON-0006** File: **Other Operational Policies / Sponsored Research & Federal Relations**	
	Policy for Responding to Allegations of Research Misconduct	
	Policy summary **Allegations of research misconduct by institutional members engaged in research supported by any Public Health Service (PHS) funding will normally be addressed following this policy and its associated procedures.**	
Policy Owner **Provost and Vice President for Academic Affairs**	Approval Date **December 17, 2014**	Effective Date **December 17, 2014**
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I. Introduction[a]

A. General Policy

No set of rules or professional code can either guarantee or take the place of a scholar's personal integrity. The College accepts the following specific excerpt from the "Statement on Professional Ethics" of the American Association of University Professors, as defining what is meant by professional ethics:

"Professors, guided by a deep conviction of the worth and dignity of the advancement of knowledge, recognize the special responsibilities placed upon them. Their primary responsibility to their subject is to seek and to state the truth as they see it. To this end professors devote their energies to developing and improving their scholarly competence. They accept the obligation to exercise critical self-discipline and judgment to using, extending, and transmitting knowledge. They practice intellectual honesty. Although professors may follow subsidiary interests, these interests must never seriously hamper or compromise their freedom of inquiry."

Fort Lewis College (FLC) seeks to foster a research environment promoting the responsible conduct of research, research training, and activities related to that research or research training (hereafter referred to as research), and discourages research misconduct. The College deals promptly with allegations or evidence of possible research misconduct (93.300 (c)).

All members of the FLC community participating in research or applying for support from any Public Health Service (PHS) funding component are informed about the College's policies and procedures for responding to allegations of research misconduct, and about the College's commitment to compliance with these policies and procedures (93.302 (a)(2)(i)).

B. Scope

This policy and the associated procedures apply to all individuals at Fort Lewis College engaged in biomedical or behavioral extramural or intramural research, research training, or activities related to that research or research training that is supported by or for which support is requested from the Public Health Service (PHS). This includes allegations of plagiarism of research records produced in the course of PHS supported research, research training or activities relating to that research or research training. The PHS regulation at 42 (Code of Federal Regulations) CFR Part 93 applies to any biomedical or behavioral extramural or intramural research, research-training or research-related grant, contract or cooperative agreement with PHS. This policy applies to any person paid by, under the control of, or affiliated with the institution, such as scientists, trainees, technicians, and other staff members, students, fellows, guest researchers, or collaborators at Fort Lewis College (93.102).

The policy and associated procedures will normally be followed when an allegation of possible research misconduct is received by an institutional official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interest of FLC and PHS. Any change from the 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 Director of Sponsored Research and Federal Relations.

The policy applies only to research misconduct occurring within six years of the date HHS or FLC receives an allegation of research misconduct, except in the following instances:

1) *Subsequent use*: The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized;

2) *Health or safety of the public:* If ORI or FLC, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public; and,

3) *Grandfather:* If HHS or FLC received the allegation of research misconduct before the effective date of this policy (93.105).

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[a] Sections that are based on requirements of the PHS regulations codified at 42 CFR Part 93 have endnotes that indicate the applicable section number, e.g. (93.300(b)).

II. Definitions (42 CFR 93.103, 93.200-93.227*)*

A. ***Allegation*** means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to a Fort Lewis College institutional or HHS official (93.201).

B. ***Complainant*** means a person who in good faith makes an allegation of research misconduct (93.203).

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

D. ***Deciding Official*** means 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 prior involvement in the institution's inquiry, investigation, or allegation assessment. The Deciding Official will be appointed by the Provost upon request by the Research Integrity Officer.

E. ***Evidence*** means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact (93.208).

F. ***Fabrication*** means making up data or results and recording or reporting them (93.103).

G. ***Falsification*** means 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 (93.103).

H. ***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 the facts that would disprove the allegation (93.210).

I. ***Inquiry*** means preliminary information-gathering and preliminary fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation (93.212).[1]

J. ***Institutional member or members*** means a person who is employed by, is an agent of, or is affiliated by contract or agreement with Fort Lewis College. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and subawardees, and their employees (93.214).

K. ***Investigation*** means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions (93.215).[2]

L. ***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 scientific misconduct and research integrity activities of the U.S. Public Health Service (93.217).

M. ***PHS*** means the U.S. Public Health Service, an operating component of the DHHS (93.220).

N. ***PHS regulation*** means the Public Health Service regulation establishing standards for an institution's inquiries and investigations into allegations of research misconduct, which is set forth at 42 CFR 93, entitled "Public Health Service Policies on Research Misconduct."

O. ***PHS support*** means PHS grants, contracts, or cooperative agreements or applications therefore (93.221).

P. ***Plagiarism*** means the appropriation of another person's ideas, processes, results, or words without giving appropriate credit (93.103).

Q. ***Research Integrity Officer*** means the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

R. ***Research misconduct proceeding*** means any actions related to alleged research misconduct taken under 92 CFR 93 "Public Health Service Policies on Research Misconduct," including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearing, and administrative appeals (93.223).

S. ***Research record*** means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding (93.224).

T. ***Research misconduct*** means fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or honest differences in interpretations or judgments of data (93.103).[3]

U. ***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. There can be more than one respondent in any inquiry or investigation (93.225).

V. ***Retaliation*** means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or one of its members because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation (93.226).

III. Rights & Responsibilities

A. Research Integrity Officer

The Director of Sponsored Research will serve 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 be an institutional official 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 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 inquiry or investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained.

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 as required by regulation and keep ORI appraised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding 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.[4]

B. 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 or 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 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.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, 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.

D. Deciding Official

The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. The Deciding Official will consult with the Research Integrity Officer or other 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 Fort Lewis College should report observed, suspected, or apparent research misconduct to the Research Integrity Officer and/or Provost. 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 at (970) 247-7695 to discuss the suspected misconduct informally. If the circumstances described by the individual fall under 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 and will be counseled about appropriate procedures for reporting allegations.

Fort Lewis College will take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and evidence (93.300 (f)).

B. Competence and Fairness of Proceedings

Fort Lewis College will respond to each allegation of research misconduct for which the institution is responsible in a thorough, competent, objective and fair manner, including taking precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved personal, professional or financial conflicts of interest with the complainant, respondent or witnesses (93.300 (b) and 93.304 (b)).

C. 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 will ensure that these persons will not be retaliated against at the institution and will review instances of alleged retaliation for appropriate action (93.300 (d)).

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

Fort Lewis College will protect the privacy of those who report misconduct in good faith[6] to the maximum extent possible. For example, if the complainant requests anonymity, the College 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. Fort Lewis College is required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations (93.108, 93.300 (d)).

D. 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.

Institutional 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 and may bring the counsel or personal adviser to interviews or meetings on the case.

E. Cooperation with Inquiries and Investigations

Institutional employees will 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.

F. 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, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of research misconduct.

V. Conducting the Inquiry

A. Criteria Warranting an Inquiry

An inquiry is warranted if the allegation:
(1) Falls within the definition of research misconduct (see section II.T.);
(2) Is within the Scope as defined in this policy (see section I. B.); and,
(3) Is sufficiently credible and specific so that potential evidence of research misconduct may be identified (93.307 (a) 1-3).

B. 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, involves PHS support or non support, and falls under the PHS definition of research misconduct, 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 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. Therefore, an inquiry does not require a full review of all the evidence related to the allegation. 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 (93.307 (c)).

At the time of, or before beginning an inquiry, the Research Integrity Officer will make a good faith effort to notify in writing the presumed respondent, if any. If the inquiry subsequently identifies additional respondents, the Research Integrity Officer will notify them (93.307 (b)).

C. Securing of Research Records

After determining that an allegation falls within the definition of research misconduct and involves PHS funding, the Research Integrity Officer will ensure that all original research records and materials relevant to the allegation are immediately secured (93.307 (b)).

Either before or when the institution notifies the respondent of the allegations, inquiry or investigation, the Research Integrity Officer will promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments (93.304 (g) and 93.305 (a)).

In addition, the Research Integrity Office will 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, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments (93.304 (g) and 93.305(c)). The Research Integrity Officer may consult with ORI for advice and assistance in this regard.

Fort Lewis College will protect the confidentiality of respondents, complainants, and research subjects identifiable from research records or evidence (93.304 (g)).

D. Appointment of Inquiry Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within ten 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 Research Integrity Officer will notify the respondent of the proposed committee membership in ten days. The respondent has five days after being notified of the proposed committee membership to object to any of its members. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within five days, the Research Integrity Officer will determine, also in five days, whether to replace the challenged member or expert with a qualified substitute.

E. Charge to the Committee

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 and states 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 scientific misconduct to warrant an investigation as required by the PHS regulation. 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.

F. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent 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 Research Integrity Officer 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 title of the committee members and experts, if any; the allegations; the PHS 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. Institutional counsel will review the report for legal sufficiency.

B. 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 for comment and rebuttal and will provide the complainant, if he or she is identifiable, with portions of the draft inquiry report that address the complainant's role and opinions in the investigation (93.305 (b)).

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

b. Receipt of Comments
Within 20 calendar 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 (93.307 (f)).[9] Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

a. 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. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

b. Notification
The Research Integrity Officer 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 Research Integrity Officer will also notify all appropriate institutional officials of the Deciding Official's decision. The notice will include a copy of the inquiry report and include a copy of or refer to Part III HHS 42 CFR 93, entitled "Public Health Service Policies on Research Misconduct" as well as Fort Lewis College's policies and procedures for responding to allegations of research misconduct (93.308 (a) (b)).

D. An investigation is warranted if there is:

a. A reasonable basis for concluding that the allegation falls within the definition of research misconduct (see Part II, Definitions, T) and involves PHS supported biomedical or behavioral research, research training or activities related to that research or research training; and,

b. Preliminary information-gathering and preliminary fact-fining from the inquiry indicates that the allegation may have substance (93.307 (d) (1-2)).

E. Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the Research Integrity Officer no more than 60 calendar days following its first meeting, [10] unless the Research Integrity Officer approves an extension for good cause. If the Research Integrity Officer approves an extension, the reason for the extension will be entered into the records of the case and report.[11] The respondent also will be notified of the extension (93.307 (g)).

F. Reporting to ORI on the Decision to Initiate an Investigation

Within 30 days of finding that an investigation is warranted, Fort Lewis College will provide ORI with the written finding by the Deciding Official and a copy of the inquiry report which includes the following information: the name and position of the respondent; a description of the allegations of research misconduct; the PHS support, including for example, grant numbers grant applications, contracts, and publications listing PHS support; the basis for recommending that the alleged actions warrant an investigation; and any comments on the report by the respondent or the complainant. On request, Fort Lewis College will provide ORI with the institutional policies and procedures under which the inquiry was conducted; the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and the charges for the investigation to consider (93.307 (e) and 93.309 (a) and (b)).

G. Retention of Records of the Inquiry

The records of 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 will be retained for seven (7) years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation, whichever is later (93.317 (a) (3) and (b)).

H. Documentation of Decision not to Investigate

Fort Lewis College will keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the reason why the institution decided not to conduct an investigation if such a decision results from the inquiry. The College will keep this documentation for at least seven (7) years after the termination of the inquiry and upon request, provide them to ORI or other authorized HHS personnel (93.309 (c)).

VII. Conducting the Investigation

A. 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 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.

B. Securing of Research Records

The Research Integrity Officer 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 (93.310 (d)).

C. Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within ten 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.[12] 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.

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

D. Charge to the Committee and the First Meeting

a. Charge to the Committee
The Research Integrity Officer 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, define research misconduct, and identifies the name of the respondent. 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 Research Integrity Officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

b. The First Meeting
The Research Integrity Officer 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.

E. Investigation Process

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation (93.310 (a)).[13]

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, and notes of telephone calls or email communications.[14] The committee will 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 (93.310 (g)).

The College will 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 the allegations (93.310 (e)).

The College will pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion (93.310 (h)).

The College will take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry or investigation (93.310 (f)).

The College will 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 College will 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 investigation (93.310 (c)).

The College will complete all aspects of an investigation within 120 days of beginning it, including conducting the investigation, preparing the repot of findings, providing the draft report for comment, and sending the final report to ORI. If the institution's procedures provide for an appeal by the respondent that could result in a reversal of modification of the findings of research misconduct in the investigation report, Fort Lewis College will complete any such appeal within 120 days if it's filing. Appeals from personnel or similar actions that would not result in a reversal or modification of the findings of research misconduct are excluded from the 120-day limit. If unable to complete appeals within 120 days, Fort Lewis College will ask ORI for an extension in writing and provide an explanation for the request (93.311 (a); 93.314).

VIII. The Investigation Report

A. Elements of the Investigation Report

At the conclusion of the investigation, the investigative committee will prepare a report which will be submitted to ORI which will include all attachments and any appeals; state whether Fort Lewis College found research misconduct, and if so, who committed the misconduct; state whether the institution accepts the investigation's findings, and describe any pending or completed administrative actions against the respondent (93.315 (a-d)).

B. Comments on the Draft Report

1. Respondent

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed five 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.

2. Complainant

The Research Integrity Officer 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.

3. Institutional Counsel

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

4. 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 Research Integrity Officer may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

C. Institutional Review and Decision

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.

Based on a preponderance of the evidence, the Deciding Official will make the final determination whether to accept the investigation report, its findings, and the recommended institutional 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 in the institution's letter transmitting the report to ORI. The Deciding Official's explanation should be consistent with the PHS definition of research misconduct, the institution'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 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.

D. Restoring Reputations and Protection Against Retaliation

All reasonable and practical efforts, if requested and as appropriate, will be made by the institution to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no funding of research misconduct is made (93.304 (k)).

All reasonable and practical efforts to protect or restore the position and reputation of any complainant(s), witness (es), or committee members will be made by the institution. The College will also counter potential or actual retaliation against these complainants, witnesses, and committee members (93.304 (l)).

E. Transmittal of the Final Investigation Report to ORI

The final institutional investigation report will be submitted to ORI by the Research Integrity Officer in writing and will include:

1. a description of the specific allegations of research misconduct investigated;
2. a detailed description, including documentation, of PHS support, such as any grant numbers, grant applications, contracts, and publications listing PHS support, and the PHS support related to each specific allegation;
3. a description of the specific allegations of research misconduct for consideration in the investigation;
4. a copy of the institutional policies and procedures used in the investigation (if not already provided to ORI with the inquiry report) and identify any evidence taken into custody but not reviewed;
5. a summary of the records and evidence reviewed;
6. an analysis of each specific allegation of research misconduct identified during the investigation and provide a finding as to whether research misconduct did or did not occur, the evidence that supports the finding, and any reasonable explanation by the respondent;
7. an analysis of whether the misconduct was fabrication, falsification, or plagiarism;
8. the names of the persons responsible for the misconduct;
9. a description of the criteria warranting a finding of misconduct such that (a) there be a significant departure from accepted practices of the relevant research community, (b) the misconduct be committed intentionally, knowingly, or recklessly, and (c) the allegation be proven by a preponderance of the evidence (93.104 (a) (b) (c));
10. a summary of whether any publications need correction or retraction (93.313 (f)(4));
11. a list of any current support or known applications or proposal for support that the respondent has pending with non-PHS federal agencies (93.313 (f) (6));
12. inclusion and consideration of any comments made by the respondent and complainant on the draft investigation report (93.312);
13. the notice to ORI of institutional findings and actions (see VIII A.)(93.315); and
14. maintain custody and retention of records as described in sections V. C., VI. B. and G (93.305).

F. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 days of its initiation,[18] 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.[19]

IX. Requirement for Reporting to ORI

A. An institution's decision to initiate an investigation must be reported in writing to the ORI Director on or before the date the investigation begins.[20] At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of research misconduct, and PHS applications or grant number(s) involved.[21] ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report.[22] Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

B. If Fort Lewis College plans to terminate 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 reason without completing all relevant requirements of the PHS regulation, (except for closing a case at the inquiry stage on the basis that an investigation is not warranted or due to a finding of no misconduct at the investigation stage which must be reported to ORI), the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination (93.316 (a)).[23]

C. If the institution determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer 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.[24]

D. When PHS funding or applications for funding are involved and an admission of research misconduct is made, the Research Integrity Officer 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 funds, the institution cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.[25]

E. The Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:

1. the health and safety of the public is at risk, including an immediate need to protect human or animal subjects;[26]

2. HHS resources or interests are threatened;

3. research activities should be suspended;

4. there is reasonable indication of possible violations of civil or criminal law;

5. Federal action is required to protect the interest of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his or her co-investigators and associates, if any;[28]

6. it is probable that the alleged incident is going to be made public prematurely;[29]

7. the research community or public should be informed (93.318 (a-g)).

X. Institutional Administrative Actions

Fort Lewis College will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.[31]

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 consulting with the Research Integrity Officer. 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 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.

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. Protection of the Complainant and Others [32]

Regardless of whether the institution or ORI determines that research misconduct occurred, the Research Integrity Officer 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 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 Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the complainant.

C. 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, such as reduction in rank or other consequences.

D. Interim Administrative Actions

Institutional 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. [33]

XII. Record Retention

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will keep the file for seven (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. The information provided will not be disclosed as part of the peer review and advisory review processes, but may be used by the Secretary in making decisions about the award or continuation of funding (93.309 (c) and 93.401 (c)).

Revision History

This policy revises policy 12-6: Responding to Allegations of Scientific Misconduct approved July 2012. That policy revised policy 11-11: Research Misconduct approved June 2003.