Research Misconduct

PURPOSE

The purposes of this Research Misconduct Policy are:

- To ensure that research activities conducted or supported by VERSITI are performed in accordance with the highest ethical and scientific standards.
- To foster a research environment that promotes the responsible conduct of research, discourages Research Misconduct, and deals promptly with allegations or evidence of possible Research Misconduct.
- To establish a consistent written process for addressing allegations of Research Misconduct in a thorough, competent, objective and fair manner.
- To protect good faith complainants, witnesses and others who participate in the Research Misconduct review process from retaliation.
- To ensure compliance with applicable laws and regulations.

SUMMARY

VERSITI relies on all VERSITI research staff members to establish and maintain the highest standards of ethical practices in research. This Policy describes the ongoing obligations of VERSITI research staff to promote an environment that supports ethical research, and the process by which concerns related to research are identified, investigated, addressed, reported, and documented.

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POLICY

1. DEFINITIONS

For the purposes of this Policy, capitalized terms shall have the meanings set forth below.

"Complainant" means an individual or entity who makes a good faith allegation of Research Misconduct.[1]

"EVP of Research" means the VERSITI Executive Vice President of Research, or his/her designee.

"Inquiry" means a preliminary information gathering and preliminary fact-finding process to determine whether there is sufficient evidence of possible Research Misconduct to warrant a formal Investigation. A full review of all of the evidence related to the possible Research Misconduct is not required in the event the Inquiry does not

determine an allegation warrants a formal Investigation.[2]

"Investigation" means the formal development of a factual record and the examination of that record leading to (i) a decision not to make a finding of Research Misconduct; or (ii) a recommendation for a finding of Research Misconduct, which may include a recommendation for other appropriate actions, including administrative actions.[3]

"Office of Research Integrity" or **"ORI"** means the Office that oversees and directs Public Health Service (PHS) research integrity activities and research misconduct issues on behalf of the Secretary of Health and Human Services (with the exception of the regulatory research integrity activities of the Food and Drug Administration). ORI is located within the Office of the Assistant Secretary for Health (OASH) within Office of the Secretary of Health and Human Services (OS) in the Department of Health and Human Services (HHS).

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

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

"Research Staff Member" means an individual, regardless of title or position, who is responsible for the design, conduct, or reporting of research conducted or supported by VERSITI (or, in the case of PHS contracts, a research project) (including a fellow and graduate student, project director, Principal Investigator, collaborator, or consultant or other staff member who is responsible for the design, conduct, or reporting of research).

"Research Misconduct" includes any of the activities below undertaken during the process of proposing, performing, or reviewing research, or in reporting research results, if: (i) there is a significant departure from accepted practices of the relevant research community; (ii) the misconduct is committed intentionally, knowingly, or recklessly; and (iii) the allegation of misconduct is proven by a preponderance of the evidence:[4]

- **Fabrication** (making up data or results and recording or Reporting them);
- **Falsification** (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), and/or
- **Plagiarism** (appropriation of another person's ideas, processes, results, or words without giving appropriate credit).

Research Misconduct does not include honest errors or differences of opinion.[5]

"Research Misconduct Proceeding" means any action related to alleged Research Misconduct, including but not limited to, allegation assessments, inquiries, Investigations, and hearings.[6]

"Research Record" means the record of data or results that embody the facts resulting from scientific Inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress Reports, abstracts, theses, oral presentations, internal Reports, journal articles, and any documents and materials provided by a Respondent in the course of the Research Misconduct proceeding.[7]

"Respondent" means the person against whom an allegation of Research Misconduct is directed, or who is the subject of a Research Misconduct proceeding.[8]

"Retaliation" means an adverse action taken against a Complainant, witness, or committee member or other individual or entity who participates in the Reporting or review of allegations related to Research Misconduct.[9]

For purposes of this Research Misconduct policy, the definitions found in 42 CFR Part 93 shall apply in addition to the definitions above. To the extent the definitions are restricted to U.S. Public Health Service research, VERSITI hereby adopts the definitions to apply to all research misconduct regardless of funding source.

2. RESEARCH INTEGRITY

2.1 Promoting Research Integrity

> *The scientific research enterprise, like other human activities, is built on a foundation of trust. Scientists trust that the results reported by others are valid. Society trusts that the results of research reflect an honest attempt by scientists to describe the world accurately and without bias. The level of trust that has characterized science and its relationship with society has contributed to a period of unparalleled scientific productivity. But this trust will endure only if the scientific community devotes itself to exemplifying and transmitting the values associated with ethical scientific conduct.*
>
> National Academy of Sciences, On Being a Scientist (1995)
> http://www.nap.edu/readingroom/books/obas/preface.html

Accepted practices for the responsible conduct of research can and do vary from discipline to discipline and even from laboratory to laboratory. There are, however, some important shared values for the responsible conduct of research that bind all researchers together, such as:

HONESTY — conveying information truthfully and honoring commitments ACCURACY

— reporting research findings precisely and taking care to avoid errors EFFICIENCY —

using resources wisely and avoiding waste

OBJECTIVITY— letting the facts speak for themselves and avoiding improper bias[10]

2.2 Ongoing Obligations of Versiti Research Staff Members

VERSITI relies on all VERSITI Research Staff Members to establish and maintain the highest standards of ethical practices in research and provides both formal and informal training. Each individual Research Staff Member is expected to:

2.2.1 support and contribute to the ongoing maintenance of a research environment that promotes the shared values described above, adheres to the highest standards of ethical practice, and inspires confidence and trust in research findings;

2.2.2 regularly attend sessions at which research data is presented and actively participate in the rigorous examination of research data and developments;

2.2.3 attend formal and informal training in ethical research practices provided by VERSITI and other entities;

2.2.4 ensure that all research data is properly documented;

2.2.5 encourage free and open exchange of research materials and new ideas,

2.2.6 maintain a high standard of personal and corporate accountability, and

2.2.7 acknowledge and respect the intellectual contributions of others in the greater research community; and

2.2.8 remain in full compliance with all applicable statutes, regulations, and VERSITI policies.

3. REPORTING RESEARCH MISCONDUCT CONCERNS

3.1 Communicating Concerns

VERSITI staff and non-VERSITI personnel who know or suspect that a VERSITI staff member has engaged in Research Misconduct are strongly encouraged to immediately Report such circumstances to the VERSITI Executive Vice President of Research or the Compliance Officer. Individuals may also Report concerns to VERSITI's third-party compliance hotline provider (refer to VERSITI's Whistleblower Policy for contact information). Complainants are encouraged to provide as much information and documentation as possible, including any presentations, publications, or other documents that may be affected by the alleged misconduct.

3.2 No Retaliation

The EVP of Research will take all reasonable and practical steps to protect the positions and reputations of good faith Complainants, Respondents, witnesses and committee members who participate in the review process.[11] All VERSITI representatives are strictly prohibited from engaging in any form of retaliation against any individual (or entity) who: (i) communicates a good faith concern related to Research Misconduct (regardless of whether such concern reflects actual wrongdoing); or (ii) cooperates in any Inquiry or Investigation regarding such concern. Prohibited retaliatory behavior includes any negative action that would deter a reasonable person in the same situation from communicating or participating in the Investigation of a concern related to VERSITI practices or conduct. Examples of retaliatory behavior include, but are not limited to, discharging, demoting, suspending, threatening, harassing, disciplining, changing a job or shift assignment, or in any other manner discriminating or retaliating against any person or entity involved in the good faith communication or Investigation of a concern. VERSITI Personnel who engage in Retaliatory Behavior in violation of this Policy will be subject to disciplinary action, up to and including termination. The EVP of Research will undertake all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in Research Misconduct, but against whom no finding of Research Misconduct is made.[12]

3.3 Confidentiality

To the maximum extent possible given legal requirements and the need to conduct effective Research Misconduct Proceedings, the identity of Respondents, Complainants, research subjects, and others who participate in Research Misconduct proceedings will be kept confidential.[13]

3.4 False Allegations

This Policy is also intended to protect individuals against false allegations of Research Misconduct. Any communication that proves to be both unsubstantiated and made with malice or with knowledge of its falsity is not protected by this Policy. VERSITI Personnel who (i) knowingly or with reckless disregard for the truth give false information, (ii) knowingly make a false Report of wrongful conduct, or (iii)

knowingly submit a false Report of retaliation, will be subject to disciplinary action, up to and including termination. As stated in Section 3.2 above, allegations that are not substantiated, yet are made in good faith, are not subject to corrective action or any form of retaliation.

4. OFFICE OF RESEARCH INTEGRITY REPORTS

If Research Misconduct allegations relate to PHS-funded research, the EVP of Research will notify the Chief Executive Officer, the Compliance Officer and ORI in the following circumstances. All other references to ORI notification in this Policy shall apply only if the allegations relate to PHS-funded research.

4.1 Threat to Health or Safety; Public Awareness

The EVP of Research will notify the Office of Research Integrity and if applicable, the funding agency (i.e. NIH) immediately if he/she has reason to believe that any of the following special circumstances exist:[14]

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

4.1.2 HHS/PHS resources or interests are threatened;

4.1.3 Research activities should be suspended;

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

4.1.5 Federal action is required to protect the interests of those involved in the Research Misconduct proceeding;

4.1.6 The EVP of Research believes the Research Misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved; or

4.1.7 The research community or public should be informed.

4.2 Research Misconduct Proceedings

The EVP of Research will:

4.2.1 Notify ORI if Inquiry warrants an Investigation (see Section 7.4)[15]

4.2.2 Notify ORI of Final Investigation findings (see Section 9.4).[16]

4.2.3 Provide information to ORI upon request, including institutional policies, transcripts or recordings of any interviews, copies of relevant documents, and charges for the investigation to consider.

4.2.4 Cooperate with ORI during its oversight review or any subsequent administrative hearings or appeals. This includes providing all research records and evidence under VERSITI's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

4.3 Admission of Guilt; Settlement

The EVP of Research will notify the Office of Research Integrity if VERSITI plans to close a case at the Inquiry or Investigation 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.[17]

4.4 Annual Report

The EVP of Research will file annual compliance Reports with the Office of Research Integrity.[18]

5. PRELIMINARY ASSESSMENT; CUSTODY OF RESEARCH RECORDS

5.1 Preliminary Assessment

Within one (1) week of his/her receipt of allegation(s), the EVP of Research, in consultation with the Chief Executive Officer and the Compliance Officer, will assess the allegation(s) to determine whether an Inquiry is warranted. An Inquiry is warranted if: (1) the allegation(s), if true, would constitute Research Misconduct; and (2) the allegations are sufficiently credible and specific so that potential evidence of Research Misconduct may be identified.[19] The EVP of Research's findings at the conclusion of the preliminary assessment will be summarized in a Preliminary Assessment Report. If the EVP of Research determines that an Inquiry is warranted, the EVP of Research will notify the Chief Executive Officer and the Inquiry process will proceed as described in Section 6.

5.2 Obtaining Custody of Research Records

The EVP of Research will promptly take all reasonable and practical steps to obtain custody of all Research Records and evidence needed to conduct Research Misconduct Proceedings. The EVP of Research shall inventory the Research Records and evidence, and sequester them in a secure manner.[20] If there are Research Records or other evidence that 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.[21] Whenever possible, the EVP of Research will take custody of the Research Records: (1) before or at the time the EVP of Research notifies the Respondent of the allegations, Inquiry or Investigation; and (2) whenever additional documentation becomes known or relevant.[22]

5.3 Respondent's Access to Research Records

If appropriate, the EVP of Research will give the Respondent copies of, or reasonable supervised access to, the Research Records.[23]

5.4 Failure to Provide Records

The destruction, absence of, or Respondent's failure to provide research records adequately documenting the questioned research is evidence of Research Misconduct if a preponderance of the evidence indicates that:

5.4.1 the Respondent intentionally, knowingly, or recklessly had research records and destroyed the records, 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

5.4.2 the Respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.[24]

6. CONDUCTING AN INQUIRY

6.1 Inquiry Time Limitations

If the EVP of Research determines that an Inquiry is warranted, the Inquiry process must be completed within sixty (60) calendar days of the Inquiry Initiation Date, unless circumstances clearly warrant a longer period. The Inquiry initiation date shall be the date upon which notice of the Inquiry is sent to the Respondent (the "Inquiry Initiation Date"). If the Inquiry takes longer than sixty (60) days to complete, the Inquiry record will include documentation of the reasons for exceeding the 60-day period.[25]

6.2 Sequestration of Research Records

On or before the date upon which the Respondent is notified of the Inquiry, the EVP of Research will promptly take all reasonable and practical steps to obtain custody of all the Research Records and other evidence needed to conduct Research Misconduct Proceedings. See Section 5.2.

6.3 Appointment of the Inquiry Committee

The EVP of Research will appoint an Inquiry Committee. The Inquiry Committee shall include at least three (3) members 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 Inquiry. Inquiry Committee Members may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside VERSITI. Non-VERSITI Inquiry Committee Members will be required to sign conflict of interest and confidentiality statements prior to serving on the Inquiry Committee. The Inquiry Committee may consult with outside legal counsel as necessary.

6.4 Notice to Respondent of Inquiry

The EVP of Research will provide the Respondent with written notice of the pending Inquiry, before or at the time of Inquiry initiation. The written notice will include: (1) of the nature of the allegations; (2) the composition of the Inquiry Committee; (3) a copy of this Policy; and (4) a copy of the applicable federal regulations (42 CFR Part 93).[26] If the Respondent objects to the participation of any Inquiry Committee member based upon allegations of bias or conflict of interest, the Respondent will inform the EVP of Research of such objections in writing within five (5) business days of the Respondent's receipt of the Inquiry notice. The EVP of Research will determine if the Respondent's objections have merit and replace any challenged member with a qualified substitute, if necessary. If the inquiry subsequently identifies additional Respondents, VERSITI must notify them.

6.5 Conducting the Inquiry

The Inquiry Committee shall conduct the Inquiry by examining available evidence and interviewing the Complainant, Respondent, key witnesses (the Inquiry Committee will record or transcribe all interviews). The purpose of the Inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible; therefore, a full review of all of the evidence is not required.[27] 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 a formal Investigation.

6.6 Inquiry Warrants 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 process indicates that the allegation may have substance.[28] The Inquiry Committee will prepare an Inquiry Report (see Section 7)

7. INQUIRY REPORT AND NOTIFICATIONS

7.1 Draft Inquiry Report

Within thirty (30) days of the Inquiry Initiation Date, the Inquiry Committee will prepare a draft written Inquiry Report that includes all of the following information:

7.1.1 Respondent's name and position;

7.1.2 Description of the allegations of Research Misconduct;

7.1.3 Information regarding PHS and extramural support, if any (e.g., grant numbers, grant applications, contracts, and publications listing PHS support);

7.1.4 Title of Inquiry Committee members and experts consulted (if any);

7.1.5 The Inquiry Committee's determination as to whether an Investigation is recommended and the basis for such determination. If the Inquiry declines to recommend a formal Investigation, the Report must include sufficiently detailed documentation to permit a later assessment of the reasons the Inquiry Committee decided not to conduct an Investigation by the ORI;[29] and

7.1.6 Any other actions recommended by the Inquiry Committee.

7.2 Opportunity to Comment

The EVP of Research will provide the Respondent with a copy of the draft Inquiry Report for review and comment.[30] The Complainant may also be provided relevant portions of the draft Inquiry Report for comment. If any Complainant wishes to remain anonymous, their names will be redacted from the copy of the draft Inquiry Report provided to the Respondent. The Respondent and Complainant must provide his/her comments to the draft Inquiry Report (if any) to the Inquiry Committee within five (5) business days of his/her receipt of the draft Inquiry Report.[31]

7.3 Final Inquiry Report

Any comments that the Respondent or Complainant submits on the draft Inquiry Report will become part of the Final Inquiry Report and record. Based on the comments, the Inquiry Committee may revise the draft Report as appropriate. The Inquiry Committee will prepare a written Final Inquiry Report that includes all of elements identified in Section 7.1 and comments to the Report by the Respondent and Complainant.

7.4 Inquiry Notifications

7.4.1 Chief Executive Officer. The EVP of Research will provide the Chief Executive Officer with a copy of the Inquiry Report.

7.4.2 Notice to Respondent. The EVP of Research will send written notice to the Respondent which includes: (a) a description of the allegations; (b) whether the Inquiry Committee found that an

Investigation is warranted; (c) a copy of the Inquiry Report; and (d) a statement that a copy of this Policy and the applicable federal regulations (42 CFR Part 93) were provided in the Inquiry notice, but are available upon request.[32]

7.4.3 Notice to Complainants. The EVP of Research may notify the Complainant who made the allegation whether the Inquiry Committee found that an Investigation is warranted. Notice to ORI. Before the Investigation begins and/or within thirty (30) days of finding that an Investigation is warranted, the EVP of Research will: (1) notify the ORI of the decision to begin an Investigation, and (2) provide ORI a copy of the Final Inquiry Report and any comments on the Report by the Respondent or Complainant.[33]

7.4.4 Notice to Funding Agency. If applicable, the EVP of Research must notify the funding agency in the event VERSITI finds, learns of, or suspects research misconduct that impacts or might impact the conduct or performance of a government-funded project(s) (i.e. NIH). This includes research misconduct occurring at VERSITI (grant recipient organization) or at third-party subrecipient organizations. VERSITI must work with the funding agency to assess the effects and ability to continue the project as originally approved by the funding agency. If VERSITI determines that a change of scope or a change of Principal Investigator or other senior/key personnel is required, the institution must promptly obtain approval from the appropriate personnel at the funding agency.

7.4.5.1 NIH funding projects require approval from the NIH Funding Institute or Center Grants Management Officer.

8. CONDUCTING AN INVESTIGATION

8.1 Investigation Time Limitations

If the Inquiry Committee determines that an Investigation is warranted, the Investigation must begin within thirty (30) days of the date upon which the EVP of Research provided the Respondent with written notice of the Investigation.[34] All aspects of the Investigation must be completed within 120 days of beginning the Investigation, including conducting the Investigation, preparing the final Investigation Report, and sending the final Report to ORI.[35] If VERSITI is unable to complete the an Investigation related to PHS-funded research in 120 days, the EVP of Research must ask ORI for an extension in writing.[36] If ORI grants an extension, it may direct the EVP of Research to file periodic progress Reports.[37]

8.2 Sequestration of Research Records

To the extent the EVP of Research has not already done so at the allegation or Inquiry stages, the EVP of Research shall take all reasonable and practical steps to obtain custody of, inventory, and sequester Research Records and other evidence as provided in Section 5 above.

8.3 Appointment of the Investigation Committee

The EVP of Research, in consultation with the Chief Executive Officer and the Compliance Officer, will appoint an Investigation Committee and a Committee Chair. The Investigation Committee will consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the Investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or

outside VERSITI. Individuals appointed to the Investigation Committee may also have served on the Inquiry Committee. Members of the Investigation committee will be required to sign conflict of interest and confidentiality statements prior to serving on the Investigation committee.

8.4 Notice to the Respondent of Investigation

Within a reasonable amount of time after determining that an Investigation is warranted, but before the Investigation begins, the EVP of Research will provide the Respondent with written notice of the pending Investigation. The written notice will include: (1) a description of the allegations (including any new allegations); (2) the composition of the Investigation Committee; (d) a statement that a copy of this Policy and the applicable federal regulations (42 CFR Part 93) were provided in the Inquiry notice, but are available upon request.[38] If the Respondent objects to the participation of any Investigation Committee member based upon allegations of bias or conflict of interest, the Respondent will inform the EVP of Research of such objections in writing within five (5) business days of the Respondent's receipt of the Investigation notice. The EVP of Research will determine if the Respondent's objections have merit and replace any challenged member with a qualified substitute, if necessary.

8.5 Responsibilities of the Investigation Committee

8.5.1 Documentation. The Investigation Committee will use diligent efforts to ensure that the Investigation is thorough, sufficiently documented, and includes examination of all Research Records and evidence relevant to reaching a decision on the merits of the allegations.[39]

8.5.2 Standard and Burden of Proof. A finding of Research Misconduct must be proved by a preponderance of the evidence [40]. VERSITI has the burden of proof for making a finding of Research Misconduct.[41] 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 VERSITI 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.[42]

8.5.3 Ensuring a fair Investigation. The Investigation Committee 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.[43]

8.5.4 Interviews. The Investigation 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. The Investigation Committee will 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.[44] The Respondent may be accompanied by legal counsel or other advisor during the interview, but must provide the Investigation Committee with at least five (5) days prior written notice of his/her intent to bring legal counsel.

8.5.5 Pursue Leads. The Investigation Committee 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.[45]

8.5.6 Develop an Investigation Report and Recommendations. The purpose of the Investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether Research Misconduct has been committed and by whom. The Investigation Committee will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations and/or additional Respondents. This is particularly important where the alleged Research 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. It is critically important that the scope of the Investigation be sufficient, within reason, so as to detect all instances of Research Misconduct in the research record, in particular in research publications, so that the EVP of Research can pursue appropriate means to correct the scientific record. The findings and recommendations of the Investigation Committee will be set forth in an Investigation Report

9. INVESTIGATION REPORT

9.1 Draft Investigation Report

The Investigation Committee will prepare a draft Investigation Report that describes:[46]

9.1.1 The nature of the allegations of Research Misconduct.

9.1.2 Any PHS support (e.g., grant numbers, grant applications, contracts, and publications listing PHS support);

9.1.3 The specific allegations of Research Misconduct considered in the Investigation;

9.1.4 The VERSITI policies and procedures under which the Investigation was conducted;

9.1.5 A summary of the Research Records and evidence reviewed, including any evidence taken into custody but not reviewed;

9.1.6 Statement of findings for each separate allegation of Research Misconduct identified during the Investigation, including whether Research Misconduct did or did not occur, and if so:

a. Whether the Research Misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;

b. A summary of the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the Respondent;

c. Identify the specific PHS support, if any;

d. Identify whether any publications need correction or retraction;

e. Identify the person(s) responsible for the misconduct; and

f. List any current support or known applications or proposals for support that the Respondent has pending with non-PHS Federal agencies.

g. Include and consider any comments made by the Respondent and Complainant on the draft Investigation Report. (See Section 9.2 below.)

9.2 Opportunity to Review and Comment

9.2.1 By Respondent. The EVP of Research will give the Respondent a copy of the draft Investigation

Report and, concurrently, a copy of, or supervised access to, the evidence on which the draft Report is based.[47] The comments of the Respondent on the draft Report, if any, must be submitted within thirty (30) business days of the date on which the Respondent received the draft Investigation Report.

9.2.2 By Complainant. The EVP of Research 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 thirty (30) days of the date on which the Complainant received the draft Investigation Report or relevant portions of it.

9.3 Final Investigation Report

The Investigation Committee will consider and address the comments to the draft Investigation Report made by the Respondent and/or Complainant (if any) before issuing the final Investigation Report.[48] The Investigation Committee will prepare a final Investigation Report that includes all of elements identified in Section 9.1 and comments to the Report by the Respondent and/or Complainant (if any).

9.4 Investigation Notifications

9.4.1 Notice to Respondent. The EVP of Research will send written notice to the Respondent which includes: (a) a description of the allegations; (b) whether the Investigation Committee found that Research Misconduct occurred; (c) a copy of the Final Investigation Report; (d) a statement that a copy of this Policy and the applicable federal regulations (42 CFR Part 93) were provided in the Inquiry notice, but are available upon request.

9.4.2 Notice to the Chief Executive Officer. The EVP of Research will submit a copy of the final Investigation Report to the Chief Executive Officer. The EVP of Research and Chief Executive Officer will determine whether VERSITI accepts the final Investigation Report.[49]

9.4.3 Notice to the Audit and Compliance Committee. The EVP of Research will submit a copy of the final Investigation Report to the Compliance Officer and the VERSITI Audit and Compliance Committee Chairperson.

9.4.4 Notice to Funding Agency. The EVP of Research must notify the funding agency in the event VERSITI learns or suspects that falsified, fabricated, or plagiarized information has affected the integrity of government-funded research, including but not limited to, applications for funding and progress reports, or published research or research products supported by government funds. VERSITI must immediately provide information on the affected research to the appropriate personnel at the funding agency.

9.4.4.1 NIH funded projects require notification to the NIH Office of Extramural Research – Research Integrity (OER-RI), in a manner consistent with the ORI confidentiality regulations.

9.4.5 Notice to ORI. The EVP of Research will send written notice to the ORI which includes: (a) a copy of the Final Investigation Report and all attachments; (b) a summary of the findings of the Investigation Committee, whether the Committee concluded that Research Misconduct occurred, and if so, who committed the Misconduct; (c) whether VERSITI has accepted the Final Investigation Report; and (d) any pending or completed administrative actions against the Respondent.[50]

10. RECORDKEEPING

After completion of a case and all ensuing related actions, the EVP of Research will prepare a complete file, including the records of any Inquiry or Investigation and copies of all documents and other materials furnished to the EVP of Research or Committees. The EVP of Research will keep the file for seven (7) years after completion of the case.

11. POLICY REVIEW, EDUCATION, VIOLATIONS

11.1 Policy Review

The EVP of Research and the Corporate Compliance Committee will review this Policy every two years. Questions regarding the implementation of this Policy should be directed to VERSITI's EVP of Research or Corporate Counsel/Compliance Officer.

11.2 Education

VERSITI will make this Policy available to all VERSITI Research Staff on its Internet. New BCW Research Staff Members will complete a training session that addresses the content of this Policy. Thereafter, VERSITI Research Staff Members will repeat the required training: (1) at least every four (4) years; and (2) if and when VERSITI materially revises this Policy.[51]

11.3 Violations

A finding of Research Misconduct and/or failure to comply with the provisions of this Policy may result in discipline, up to an including termination of employment.

REPLACES:	Version 2012 08 01
REVIEW PERIOD:	As needed, and every two years
UPDATED:	December 12, 2018
EFFECTIVE DATE:	December 12, 2018

References

[1] 42 CFR § 93.203.
[2] 42 CFR § 93.212; 42 CFR § 93.307(c).
[3] 42 CFR § 93.215.
[4] 42 CFR § 93.104.
[5] 42 CFR § 93.103(d).
[6] 42 CFR § 93.223.
[7] 42 CFR § 93.224.
[8] 42 CFR § 93.225.
[9] 42 CFR § 93.226.
[10] See U.S. Department of Health and Human Services, Office of Research Integrity, Introduction *to the Responsible Conduct of Research* (August, 2007) available at http://ori.hhs.gov/documents/rcrintro.pdf
[11] 42 CFR § 93.300(d).
[12] 42 CFR § 93.304 (k)
[13] 42 CFR § 93.108; 42 CFR § 93.300(e); 42 CFR § 93.304(a).
[14] 42 CFR § 93.304(i); 42 CFR § 93.318
[15] 42 CFR § 93.304(d).
[16] 42 CFR § 93.315.
[17] 42 CFR § 93.316(a).
[18] 42 CFR § 93.302(b).
[19] 42 CFR § 93.307(a).
[20] 42 CFR § 93.305(a), (c)-(d); 42 CFR § 93.310(d).
[21] 42 CFR § 93.307(b).
[22] 42 CFR § 93.310(d).
[23] 42 CFR § 93.305(b).
[24] 42 CFR § 93.106(b).
[25] 42 CFR § 93.307(g)
[26] 42 CFR § 93.307(b).
[27] 42 CFR § 93.307(c).
[28] 42 CFR § 93.307(d).
[29] 42 CFR § 93.309(c).
[30] 42 CFR § 93.307(f).
[31] 42 CFR § 93.304(e).
[32] 42 CFR § 93.308(a).
[33] 42 CFR § 93.309(a).
[34] 42 CFR § 93.310(a).
[35] 42 CFR § 93.311(a).
[36] 42 CFR § 93.311(b).
[37] 42 CFR § 93.311(c).
[38] 42 CFR § 93.310(c).
[39] 42 CFR § 93.310(e).
[40] 42 CFR § 93.219.
[41] 42 CFR § 93.106(b).

[42] 42 CFR § 93.106(b)(2).
[43] 42 CFR § 93.310(f).
[44] 42 CFR § 93.310(g).
[45] 42 CFR § 93.310(h).
[46] 42 CFR § 93.313(a)-(g).
[47] 42 CFR § 93.312(a).
[48] 42 CFR § 93.304(f).
[49] 42 CFR § 93.315(c).
[50] 42 CFR § 93.315.
[51] 42 CFR § 93.302(a)(2)(i).