Information

Responding to Allegations of Research Misconduct

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See B.Scope

Administrative Authority

Executive Vice President for Research and Innovation

Responsible Unit

Research Integrity Program
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Policy For Responding To Allegations Of Research Misconduct

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In case of any conflict between the Approved Policy and 42 CFR Part 93, the regulation shall prevail.

The University of Louisville is committed to the highest standards of integrity in all its research endeavors and will not tolerate conduct that imperils this mission by violating those standards. This commitment governs the conduct of faculty

members, staff, and students engaged in scholarly and scientific research activities. This policy and procedures promote these objectives by establishing a framework of methods and principles for assessing, and conducting inquiries and investigations regarding allegations or incidents of "research misconduct."

This policy is intended to carry out University of Louisville's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93.[1] This policy applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving:

·An individual who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with this institution;[1] This includes any person paid by, under the control of, or affiliated with the University, and including but not limited to individuals involved in research (including those involved in the design, conduct, reporting, or management of research) for which the University is responsible, scientists, physicians, nurses, trainees, technicians, undergraduate and graduate students, gratis faculty who conduct research, fellows and residents , guest researchers, collaborators, and research support staff ; and

·(1) PHS support biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information, (2) applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training, or (3) plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.[2]

This policy and the associated procedures do not apply to order of authorship, authorship credit or collaboration disputes and apply only to allegations of research misconduct that occurred within six years of the date the institution or HHS received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b). They do not apply to other types of violations of University research policy or misconduct in research.

This policy and associated procedures will be followed when the University receives an allegation of possible misconduct. The Executive Vice President for Research must approve any significant variation in procedure prior to its initiation. Any change from normal procedures must ensure fair treatment to the subject of the inquiry or investigation.

This policy and procedures are intended to protect the rights and reputations of those alleged to have committed research misconduct and those who make such allegations, while at the same time ensuring that the substance of all allegations will be assessed fairly and conscientiously. Because the integrity of all research is of paramount concern to the University, those with knowledge of possible acts of research misconduct are encouraged to report. Protections, especially against retaliation, will be provided to those who make allegations in good faith.

These policies and procedures also provide for reporting research misconduct investigations and institutional actions to the U. S. Office of Research Integrity, and for cooperating with the Office of Research Integrity in its review of institutional actions and reports.

All individuals involved - whether making allegations or the object of allegations, or otherwise participating in inquiries and investigations -- are cautioned to familiarize themselves with the specific requirements promulgated by federal agencies, especially the National Institutes of Health/Office of Research Integrity (NIH/ORI) and the National Science Foundation (NSF), responsible for oversight of the research misconduct assessment process. These requirements, which may apply to certain determinations made under these policies and procedures (e.g. evidentiary standards, bases for findings and conclusions, etc.), can be found at:

NIH/ORI: https://ori.hhs.gov/research-misconduct-0

NSF: https://oig.nsf.gov/home/group/investigations/page/research-misconduct

II. Definitions

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 an institutional or HHS official.[3]

B. Business Day means a day in which the Institution is operating, regardless of whether classes are in session.[2]

C. Complainant means a person who in good faith makes an allegation of research misconduct.[4]

D. Conflict of interest in the context of research misconduct proceedings means the real or apparent possibility that the interests of one person may compromise or affect the interests of another person due to prior or existing personal, familial, financial, or professional relationships.

E. Deciding Official (DO) means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Executive Vice President for Research and Innovation at the University of Louisville is the Deciding Official for purposes of these "Policies and Procedures For Responding To Allegations of Research Misconduct" and for purposes of satisfying federal PHS (ORI) policy requirements established in 42 CFR Part 93 for the handling of allegations or instances of research misconduct.

F. 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.[5]

G. Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if it is made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the purpose of helping an institution meet its responsibilities under 42 CFR Part 93. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the

research misconduct proceeding.[6]

H. HHS means the United States Department of Health and Human Services.

I. Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 CFR §§ 93.307-93.309.[7] It is intended to allow a careful look into a situation without tainting reputations of possibly innocent individuals.

J. Inquiry Committee refers to the three- (3)-person committee that is charged with conducting an inquiry. The *Research Integrity Ombudsperson*, shall make the appointments, in consultation with other institutional officials as appropriate.

K. Institutional member means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. 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 sub-awardees, and their employees.[8]

L. 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.[9] An investigation is a formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct. There are generally three aspects to an investigation: the gathering and reviewing of evidence and testimony (which may include a hearing); the formulation of findings of fact and conclusions regarding the commission of research misconduct; the preparation of a written report.

M. Investigation Committee refers to the five-(5)-member committee that is charged with conducting an investigation. The *Research Integrity Ombudsperson* shall make the appointments, in consultation with other institutional officials as appropriate. One of the five Investigation Committee members may be appointed from another institution.

N. Office of Research Integrity or *ORI* means the office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.[10]

O. Preliminary assessment and review refers to an informal assessment or review of facts to determine only whether an allegation or set of circumstances has sufficient evidence to support an inquiry into research misconduct. The assessment or review, which may take place, if at all, prior to the initiation of an *inquiry*, will usually be conducted by the *Research Integrity Ombudsperson*, in consultation with such others as he or she may believe appropriate. A preliminary assessment or review should be conducted only to determine whether to proceed with an inquiry, not to substitute for an inquiry, and should be conducted in such a manner as not to compromise the integrity of any subsequent inquiry.

P. 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.[11]

Q. Public Health Serviceor *PHS* means the unit within HHS that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.[12]

R. PHS support means PHS funding, or applications or proposals therefore, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: PHS

grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.[13]

S. Records of research misconduct proceedings means: (1) the research records and evidence secured for the research misconduct proceeding pursuant to this policy and 42 CFR §§ 93.305, 93.307(b), and 93.310(d), except to the extent the Research Integrity Ombudsperson determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that have been retained; (2) the documentation of the determination of irrelevant or duplicate records; (3) 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, as required by 42 CFR § 93.309(c); (4) the investigation report and all records (other than drafts of the report) in support of the report, including the recordings or transcripts of each interview conducted; and (5) the complete record of any appeal within the institution from the finding of research misconduct.[14]

T. Researchmeans a systematic investigation designed to develop or contribute to knowledge, and includes both sponsored research and non-sponsored research, that involves use of University personnel, patients, students, facilities or resources, or the expenditure of University or affiliated corporation funds. The term includes clinical and health-related research, and behavioral and social science research, and encompasses basic and applied research and product development.

U. Research Integrity Ombudsperson means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; and (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. Associate Research Integrity Ombudsperson means the individual, selected in the same manner as the Research Integrity Ombudsperson and similarly qualified, who assumes the Research Integrity Ombudsperson's responsibilities in the event he or she is unavailable or recused.

V. Research misconductmeans fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. *Fabrication* is making up data or results and recording or reporting them. *Falsification* is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.[15] Plagiarism also means the substantial unattributed copying of another's ideas, processes, results, or words. Substantial unattributed copying of another's ideas, processes, results, or words means the unattributed verbatim or nearly verbatim copying of sentences and paragraphs, style or structure which materially mislead the audience regarding the contributions of the author. Plagiarism does not include authorship or credit disputes, including those among former collaborators who have gone their separate ways but may make use of commonly developed concepts, methods, descriptive language, or other products of the former joint effort. Research misconduct does not include honest error or differences of opinion.[15]

W. Research misconduct proceedingmeans any actions related to alleged research misconduct that is within 42 CFR Part 93, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings and administrative appeals.[16]

X. Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals; grant or contract applications, whether funded or not; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory records both physical and electronic; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; patient research files; abstracts, theses, oral presentations, internal reports, and 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.[17] The record of data or results may be any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or

information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct.

Y. Respondent means the person(s) against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.[18]

Z. Retaliation means an adverse action taken against a complainant, witness, or committee member by this institution or one of its institutional members in response to (1) a good faith allegation of research misconduct; or (2) good faith cooperation with a research misconduct proceeding.[19]

AA. Sequestration of records means the location, collection, inventorying, and securing of research records and other relevant documents and materials for the purpose of preventing loss, alteration, or fraudulent creation of records.

III. Rights and Responsibilities

Research Integrity Ombudsperson

The Executive Vice President for Research will appoint the Research Integrity Ombudsperson who will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. The Research Integrity Ombudsperson will be an institutional official who is well qualified to administer the procedures and is sensitive to the varied demands made on those who conduct research, those who are accused of research misconduct, those who make good faith allegations of research misconduct, and those who may serve on inquiry and investigation committees.

All parties participating in an inquiry and / or investigation of research misconduct have a shared responsibility to maintain confidentiality in order to protect the reputations of all parties involved. This responsibility is shared among the complainant, respondent, ombudperson(s), inquiry / investigation committee members, witnesses, advisor(s), institutional officials and support staff involved in

the proceedings.

A detailed listing of the responsibilities of the Research Integrity Ombudsperson is set forth in Appendix A. These responsibilities include the following duties related to research misconduct proceedings:

• Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;

• Receive allegations of research misconduct;

• Assess each allegation of research misconduct in accordance with Section V.A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;

• As necessary, take interim action and notify ORI of special circumstances, in accordance with Section IV.F. of this policy;

• Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;

• Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;

• Notify the respondent and provide opportunities for him/her to review/ comment/respond to allegations, evidence, and committee reports in accordance with Section III.C. of this policy;

• Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;

• Appoint the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;

• Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest

and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;

• In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of all parties to a dispute and counter potential or actual retaliation against them by other parties to the dispute or other institutional members;

• Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;

• Notify and make reports to ORI as required by 42 CFR Part 93;

• Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and

• Maintain records of the research misconduct proceeding and make them available to ORI in accordance with Section VIII.F. of this policy.

Complainant

All parties participating in an inquiry and / or investigation of research misconduct have a shared responsibility to maintain confidentiality in order to protect the reputations of all parties involved in the proceedings. This responsibility is shared among the complainant, respondent, ombudperson(s), inquiry / investigation committee members, witnesses, advisor(s), institutional officials and support staff involved in the proceedings.

The complainant is responsible for making allegations in good faith and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of

the interview for correction. The complainant must be interviewed during an investigation, and be given the transcript or recording of the interview for correction.[20]

Respondent

All parties participating in an inquiry and / or investigation of research misconduct have a shared responsibility to maintain confidentiality in order to protect the reputations of all parties involved in the proceedings. This responsibility is shared among the complainant, respondent, ombudperson(s), inquiry / investigation committee members, witnesses, advisor(s), institutional officials and support staff involved in the proceedings.

The respondent is responsible for cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

• A good faith effort from the Research Integrity Ombudsperson to notify the respondent in writing at the time of or before beginning an inquiry;[21]

• An opportunity to comment on the inquiry report and have his/her comments attached to the report;[22]

• Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 and the institution's policies and procedures on research misconduct;[23]

• Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 business days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;[24]

• Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;[25]

• Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation;[26] and

• Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 business days of the date on which the copy was received and that the comments will be considered by the investigation committee and deciding official and addressed in the final report.[27]

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the Research Integrity Ombudsperson and institutional legal counsel, the Deciding Official may terminate the institution's review of an allegation that has been admitted if the institution's acceptance of the admission and any proposed settlement is approved by ORI.[28]

Deciding Official

The DO will receive the inquiry report and after consulting with the Research Integrity Ombudsperson, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 business days of the finding. If it is found that an investigation is not warranted, the DO and the Research Integrity Ombudsperson will ensure that detailed documentation of the

inquiry is retained for at least 7 years after termination of the inquiry, so that ORI may assess the reasons why the institution decided not to conduct an investigation.[29]

The DO will receive the investigation report and, after consulting with the Research Integrity Ombudsperson and other appropriate officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of the pending or completed administrative action are provided to ORI, as required by 42 CFR § 93.315.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the Research Integrity Ombudsperson. Any official who receives an allegation of research misconduct must report it immediately to the Research Integrity Ombudsperson. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, the individual may meet with or contact the Research Integrity Ombudsperson at:

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 an institutional or HHS official.[3]

B. Business Daymeans a day in which the Institution is operating, regardless of whether classes are in session.[2]

C. Complainant means a person who in good faith makes an allegation of research misconduct.[4]

D. Conflict of interest in the context of research misconduct proceedings means the real or apparent possibility that the interests of one person may compromise or affect the interests of another person due to prior or existing personal, familial, financial, or professional relationships.

E. Deciding Official (DO) means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Executive Vice President for Research and Innovation at the University of Louisville is the Deciding Official for purposes of these "Policies and Procedures For Responding To Allegations of Research Misconduct" and for purposes of satisfying federal PHS (ORI) policy requirements established in 42 CFR Part 93 for the handling of allegations or instances of research misconduct.

F. 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.[5]

G. Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if it is made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the purpose of helping an institution meet its responsibilities under 42 CFR Part 93. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.[6]

H. HHS means the United States Department of Health and Human Services.

I. Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 CFR §§ 93.307-93.309.[7] It is

intended to allow a careful look into a situation without tainting reputations of possibly innocent individuals.

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L. 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.[9] An investigation is a formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct. There are generally three aspects to an investigation: the gathering and reviewing of evidence and testimony (which may include a hearing); the formulation of findings of fact and conclusions regarding the commission of research misconduct; the preparation of a written report.

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P. 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.[11]

Q. Public Health Serviceor *PHS* means the unit within HHS that includes the Office of Public Health and Science and the following Operating Divisions: Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.[12]

R. PHS support means PHS funding, or applications or proposals therefore, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through: PHS grants, cooperative agreements, or contracts or subgrants or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.[13]

S. Records of research misconduct proceedings means: (1) the research records and evidence secured for the research misconduct proceeding pursuant to this policy

and 42 CFR §§ 93.305, 93.307(b), and 93.310(d), except to the extent the Research Integrity Ombudsperson determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that have been retained; (2) the documentation of the determination of irrelevant or duplicate records; (3) 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, as required by 42 CFR § 93.309(c); (4) the investigation report and all records (other than drafts of the report) in support of the report, including the recordings or transcripts of each interview conducted; and (5) the complete record of any appeal within the institution from the finding of research misconduct.[14]

T. Researchmeans a systematic investigation designed to develop or contribute to knowledge, and includes both sponsored research and non-sponsored research, that involves use of University personnel, patients, students, facilities or resources, or the expenditure of University or affiliated corporation funds. The term includes clinical and health-related research, and behavioral and social science research, and encompasses basic and applied research and product development.

U. Research Integrity Ombudsperson means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; and (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. Associate Research Integrity Ombudsperson means the individual, selected in the same manner as the Research Integrity Ombudsperson and similarly qualified, who assumes the Research Integrity Ombudsperson's responsibilities in the event he or she is unavailable or recused.

V. Research misconductmeans fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. *Fabrication* is making up data or results and recording or reporting them. *Falsification* is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. *Plagiarism* is the appropriation of another person's ideas, processes, results,

or words without giving appropriate credit.[15] Plagiarism also means the substantial unattributed copying of another's ideas, processes, results, or words. Substantial unattributed copying of another's ideas, processes, results, or words means the unattributed verbatim or nearly verbatim copying of sentences and paragraphs, style or structure which materially mislead the audience regarding the contributions of the author. Plagiarism does not include authorship or credit disputes, including those among former collaborators who have gone their separate ways but may make use of commonly developed concepts, methods, descriptive language, or other products of the former joint effort. Research misconduct does not include honest error or differences of opinion.[15]

W. Research misconduct proceedingmeans any actions related to alleged research misconduct that is within 42 CFR Part 93, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings and administrative appeals.[16]

X. Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals; grant or contract applications, whether funded or not; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory records both physical and electronic; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; patient research files; abstracts, theses, oral presentations, internal reports, and 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.[17] The record of data or results may be any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct.

Y. Respondent means the person(s) against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.[18]

Z. Retaliation means an adverse action taken against a complainant, witness, or committee member by this institution or one of its institutional members in response to (1) a good faith allegation of research misconduct; or (2) good faith cooperation with a research misconduct proceeding.[19]

AA. Sequestration of records means the location, collection, inventorying, and securing of research records and other relevant documents and materials for the purpose of preventing loss, alteration, or fraudulent creation of records.

The Executive Vice President for Research will appoint the Research Integrity Ombudsperson who will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. The Research Integrity Ombudsperson will be an institutional official who is well qualified to administer the procedures and is sensitive to the varied demands made on those who conduct research, those who are accused of research misconduct, those who make good faith allegations of research misconduct, and those who may serve on inquiry and investigation committees.

All parties participating in an inquiry and / or investigation of research misconduct have a shared responsibility to maintain confidentiality in order to protect the reputations of all parties involved. This responsibility is shared among the complainant, respondent, ombudperson(s), inquiry / investigation committee members, witnesses, advisor(s), institutional officials and support staff involved in the proceedings.

A detailed listing of the responsibilities of the Research Integrity Ombudsperson is set forth in Appendix A. These responsibilities include the following duties related to research misconduct proceedings:

• Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;

• Receive allegations of research misconduct;

• Assess each allegation of research misconduct in accordance with Section V.A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;

• As necessary, take interim action and notify ORI of special circumstances, in accordance with Section IV.F. of this policy;

• Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;

• Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;

• Notify the respondent and provide opportunities for him/her to review/ comment/respond to allegations, evidence, and committee reports in accordance with Section III.C. of this policy;

• Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;

• Appoint the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;

• Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;

• In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of all parties to a dispute and counter potential or actual retaliation against them by other parties to the dispute or other institutional members;

• Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;

• Notify and make reports to ORI as required by 42 CFR Part 93;

• Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and

• Maintain records of the research misconduct proceeding and make them available to ORI in accordance with Section VIII.F. of this policy.

All parties participating in an inquiry and / or investigation of research misconduct have a shared responsibility to maintain confidentiality in order to protect the reputations of all parties involved in the proceedings. This responsibility is shared among the complainant, respondent, ombudperson(s), inquiry / investigation committee members, witnesses, advisor(s), institutional officials and support staff involved in the proceedings.

The complainant is responsible for making allegations in good faith and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation, and be given the transcript or recording of the interview for correction.

All parties participating in an inquiry and / or investigation of research misconduct have a shared responsibility to maintain confidentiality in order to protect the reputations of all parties involved in the proceedings. This responsibility is shared among the complainant, respondent, ombudperson(s), inquiry / investigation committee members, witnesses, advisor(s), institutional officials and support staff involved in the proceedings.

The respondent is responsible for cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

• A good faith effort from the Research Integrity Ombudsperson to notify the respondent in writing at the time of or before beginning an inquiry;[21]

• An opportunity to comment on the inquiry report and have his/her comments attached to the report;[22]

• Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42 CFR Part 93 and the institution's policies and procedures on research misconduct;[23]

• Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 business days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;[24]

• Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;[25]

• Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation;[26] and

• Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 business days of the date on which the copy was received and that the comments will be considered by the investigation committee and deciding official and addressed in the final report.[27]

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the Research Integrity Ombudsperson and institutional legal counsel, the Deciding Official may terminate the institution's review of an allegation that has been admitted if the institution's acceptance of the admission and any proposed settlement is approved by ORI.[28]

The DO will receive the inquiry report and after consulting with the Research Integrity Ombudsperson, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 business days of the finding. If it is found that an investigation is not warranted, the DO and the Research Integrity Ombudsperson will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI may assess the reasons why the institution decided not to conduct an investigation.[29]

The DO will receive the investigation report and, after consulting with the Research Integrity Ombudsperson and other appropriate officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of the pending or completed administrative action are provided to ORI, as required by 42 CFR § 93.315.

A. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the Research Integrity Ombudsperson. Any official who receives an

allegation of research misconduct must report it immediately to the Research Integrity Ombudsperson. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, the individual may meet with or contact the Research Integrity Ombudsperson at:

Belknap Research Integrity Ombudsperson
Michael Perlin, Ph.D.
Biology, 502-852-5944

Health Sciences:
Health Sciences Research Integrity Ombudsperson - Eleanor Lederer, MD
Medicine - Kidney Disease, 502-852-5757

to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the Research Integrity Ombudsperson will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Ombudsperson and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

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

C. Confidentiality

The Research Integrity Ombudsperson shall, as required by 42 CFR § 93.108: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be

identified to those who need to know in order to carry out a research misconduct proceeding. The Research Integrity Ombudsperson should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information. The Research Integrity Ombudsperson should provide confidentiality for witnesses when the circumstances indicate that the witnesses may be harassed or otherwise need protection.

All parties participating in an inquiry and / or investigation of research misconduct have a shared responsibility to maintain confidentiality in order to protect the reputations of all parties involved in the proceedings. This responsibility is shared among the complainant, respondent, ombudperson(s), inquiry / investigation committee members, witnesses, advisor and support staff involved in the proceedings.

D. Protecting complainants, witnesses, and committee members

Institutional members may not retaliate in any way against complainants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the Research Integrity Ombudsperson, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, the Research Integrity Ombudsperson and other institutional officials shall make all reasonable and practical efforts 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.[30]

During the research misconduct proceeding, the Research Integrity Ombudsperson is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the institution. Respondents may consult with legal counsel or non-lawyer personal adviser(s) (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. Respondents are limited to the presence of one adviser or legal representative at convened meetings of the inquiry and / or investigation committee and the presence of the adviser or legal

representative does not negate the requirement for the respondent to be present.

F. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the Research Integrity Ombudsperson will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process. In the event of such a threat, the Research Integrity Ombudsperson will, in consultation with other institutional officials and ORI, take appropriate interim action to protect against any such threat.[31] Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The Research Integrity Ombudsperson shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

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

• HHS resources or interests are threatened;

• Research activities should be suspended;

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

• Federal action is required to protect the interests of those involved in the research misconduct proceeding;

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

• The research community or public should be informed.[32]

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the Research Integrity Ombudsperson will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in this policy and 42 CFR § 93.103.33 An inquiry must be conducted if these criteria are met.

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

B. Initiation and Purpose of the Inquiry

If the Research Integrity Ombudsperson determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.[34]

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the Research Integrity Ombudsperson must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing. On or before the date on which the respondent is notified, or the

inquiry begins, whichever is earlier, the Research Integrity Ombudsperson must 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.[35] The Research Integrity Ombudsperson may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The Research Integrity Ombudsperson, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within 10 business days of the initiation of the inquiry or as soon thereafter as practical. The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry. The committee will be a core committee of three members who are authorized to add or recuse members and use experts when necessary to evaluate specific allegations. Additional committee members should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.[36]

The Research Integrity Ombudsperson or designee will notify the respondent of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The period for submitting objections is limited to no more than 10 business days. The Research Integrity Ombudsperson would make the final determination of whether a conflict exists.

E. Charge to the Committee and First Meeting

The Research Integrity Ombudsperson will prepare a charge for the inquiry committee that:

• Sets forth the time for completion of the inquiry;

• Describes the allegations and any related issues identified during the allegation assessment;

• States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;

• States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and, (2) the allegation may have substance, based on the committee's review during the inquiry;

• Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

At the committee's first meeting, the Research Integrity Ombudsperson 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 Ombudsperson 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, including the testimony obtained during the inquiry. After consultation with the Research Integrity Ombudsperson, the

committee members will decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d). The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI to determine the next steps that should be taken. See Section III.C.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted, must be completed within 60 business days of initiation of the inquiry, unless the Research Integrity Ombudsperson determines that circumstances clearly warrant a longer period. If the Research Integrity Ombudsperson approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-business day period.[37] The respondent will be notified of the extension.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant.[38]

Institutional counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the Research Integrity Ombudsperson and the inquiry committee. The inquiry report should include: the names and titles of the committee members and experts who conducted the inquiry; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; and whether any other actions should be taken if an

investigation is not recommended.

B. Notification to the Respondent and Opportunity to Commit

The Research Integrity Ombudsperson shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 business days, and include a copy of or refer to 42 CFR Part 93 and the institution's policies and procedures on research misconduct.[39]

Any comments that are submitted will be attached to the final inquiry report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the Research Integrity Ombudsperson.

C. Institutional Decision and Notification

The Research Integrity Ombudsperson will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

Within 30 business days of the DO's decision that an investigation is warranted, the Research Integrity Ombudsperson will provide ORI with the DO's written decision and a copy of the inquiry report. The Research Integrity Ombudsperson will also notify those institutional officials who need to know of the DO's decision. The Research Integrity Ombudsperson must provide the following information to ORI upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.[40]

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

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 business days after the determination by the DO that an investigation is warranted.[41] The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. 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. The findings of the investigation will be set forth in an investigation report.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the Research Integrity Ombudsperson must: (1) notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. The Research Integrity Ombudsperson must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.[42]

The Research Integrity Ombudsperson will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. 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. The need for additional sequestration of records for the investigation 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.[43]

C. Appointment of the Investigation Committee

The Research Integrity Ombudsperson, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 business days of the beginning of the investigation or as soon thereafter as practical. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee. When necessary to secure the necessary expertise or to avoid conflicts of interest, the Research Integrity Ombudsperson may select a committee member from outside the institution. When utilizing expertise from outside the institution, the Research Integrity Ombudsperson will secure confidentiality agreements from all external experts. In addition, all external experts consulted will serve in an ex-officio capacity only.

The Research Integrity Ombudsperson or designee will notify the respondent of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The period for submitting objections is limited to no more than 10 business days. The Research Integrity Ombudsperson would make the final determination of whether a conflict exists.

D. Charge to the Committee and the First Meeting

The Research Integrity Ombudsperson 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;

• Identifies the respondent;

• Informs the committee that it must conduct the investigation as prescribed in paragraph E. of this section;

• Defines research misconduct;

• Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;

• Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly; and

• Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313.

The Research Integrity Ombudsperson 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 this policy and 42 CFR Part 93. The Research Integrity Ombudsperson will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee and the Research Integrity Ombudsperson must:

• Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;[44]

• Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;[45]

• 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;[46] and

• Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.[47]

F. Time for Completion

The investigation is to be completed within 120 business days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI. However, if the Research Integrity Ombudsperson determines that the investigation will not be completed within this 120-business day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The Research Integrity Ombudsperson will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.[48]

VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the Research Integrity Ombudsperson are responsible for preparing a written draft report of the investigation that:

• Describes the nature of the allegation of research misconduct, including identification of the respondent;

• Describes and documents the PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;

• Describes the specific allegations of research misconduct considered in the investigation;

• Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;

• Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and

• Includes a statement of findings for each allegation of research misconduct identified during the investigation.[49] Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific PHS support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.[50]

The Research Integrity Ombudsperson must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 business days from the date he/she received the draft report to submit comments to the Research Integrity Ombudsperson. The respondent's comments must be included and considered in the final report.[51]

In distributing the draft report, or portions thereof, to the respondent, the Research Integrity Ombudsperson 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 Ombudsperson may require that the recipient sign a confidentiality agreement.

C. Decision by Deciding Official

The Research Integrity Ombudsperson will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of research

misconduct. If this determination varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the Research Integrity Ombudsperson will normally notify both the respondent and the complainant in writing. After informing ORI, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which reports containing research misconduct 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 Ombudsperson is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Notice to ORI of Institutional Findings and Actions

Unless an extension has been granted, the Research Integrity Ombudsperson must, within the 120-business day period for completing the investigation, submit the following to ORI: (1) a copy of the final investigation report with all attachments; (2) a statement of whether the institution accepts the findings of the investigation report; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.[52]

E. Maintaining Records for Review by ORI

The Research Integrity Ombudsperson must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation.[53] The Research Integrity Ombudsperson is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of

research misconduct or of the institution's handling of such an allegation.[54]

IX. Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The Research Integrity Ombudsperson must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.[55]

X. Institutional Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Ombudsperson. The sanctions and corrective action will be imposed as required by law and in accordance with the Redbook as appropriate. The administrative actions will follow the following guidelines:

·Mitigating factors, such as past disciplinary record, as well as the nature of the offense and injury or harm resulting from it, shall be considered;

·Repeated violations may result in more severe sanctions;

·Attempts to commit acts prohibited by these policies and procedures shall be treated in the same manner as completed violations.

XI. Other Considerations

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 research misconduct proceeding or otherwise limit any of the institution's responsibilities under 42 CFR Part 93.

If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the

assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the Research Integrity Ombudsperson and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the Research Integrity Ombudsperson will, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.[56] Depending on the particular circumstances and the views of the respondent, the Research Integrity Ombudsperson should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the Research Integrity Ombudsperson will undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.[57] The DO will determine, after consulting with the Research Integrity Ombudsperson, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The Research Integrity Ombudsperson is responsible for implementing any steps the DO approves.

D. Allegations Not Made in Good Faith

If relevant, the DO will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith he/she will determine whether any administrative action should be taken against the person who failed to act in good faith in accordance with University policy.

[1] 42 CFR § 93.214

[2] 42 CFR § 93.102

[3] 42 CFR § 93.201

[4] 42 CFR § 93.203

[5] 42 CFR § 93.208

[6] 42 CFR § 93.210

[7] 42 CFR § 93.212

[8] 42 CFR § 93.214

[9] 42 CFR § 93.215

[10] 42 CFR § 93.217

[11] 42 CFR § 93.219

[12] 42 CFR § 93.220

[13] 42 CFR § 93.221

[14] 42 CFR § 93.224

[15] 42 CFR § 93.103

[16] 42 CFR § 93.223

[17] 42 CFR § 93.224

[18] 42 CFR § 93.225

[19] 42 CFR § 93.226

[20] 42 CFR § 93.310(g)

[21] 42 CFR §§ 93.304(c), 93.307(b)

[22] 42 CFR §§ 93.304(e), 93.307(f)

[23] 42 CFR § 308(a)

[24] 42 CFR § 310(c)

[25] 42 CFR § 310(g)

[26] 42 CFR § 310(g)

[27] 42 CFR §§ 93.304(f), 93.312(a)

[28] 42 CFR § 93.316

[29] 42 CFR § 93.309(c)

[30] 42 CFR § 93.304(k)

[31] 42 CFR § 93.304(h)

[32] 42 CFR § 93.318

[33] 42 CFR § 93.307(a)

[34] 42 CFR § 93.307(c)

[35] 42 CFR §§ 93.305, 93.307(b)

[36] 42 CFR § 93.304(b)

[37] 42 CFR § 93.307(g)

[38] 42 CFR § 93.309(a)

[39] 42 CFR § 93.308(a)

[40] 42 CFR § 93.309(a) and (b)

[41] 42 CFR § 93.310(a)

[42] 42 CFR § 93.310(b) and (c)

[43] 42 CFR § 93.310(d)

[44] 42 CFR § 93.310(e)

[45] 42 CFR § 93.310(f)

[46] 42 CFR § 93.310(g)

[47] 42 CFR § 93.310(h)

[48] 42 CFR § 93.311

[49] 42 CFR § 93.313

[50] 42 CFR § 93.313(f)

[51] 42 CFR §§ 93.312(a), 313(g)

[52] 42 CFR § 93.315

[53] 42 CFR § 93.317(b)

[54] 42 CFR §§ 93.300(g), 93.403(b) and (d)

[55] 42 CFR § 93.316(a)

[56] 42 CFR § 93.304(k)

[57] 42 CFR § 93.304(l)

Appendix A: 42 CFR 93

PART 93--PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

The complete regulatory text can be found at:
https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf

Appendix B: Research Integrity Ombudsperson Responsibilities

The Research Integrity Ombudsperson has lead responsibility for ensuring that the institution:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.
- Has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to ORI, as required by 42 CFR Part 93.
- Complies with its written policies and procedures and the requirements of 42 CFR Part 93.
- Informs its institutional members who are subject to 42 CFR Part 93 about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures.
- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process.

II. Notice and Reporting to ORI and Cooperation with ORI

The Research Integrity Ombudsperson has lead responsibility for ensuring that the institution:

- Files an annual report with ORI containing the information prescribed by ORI.
- Sends to ORI with the annual report such other aggregated information as ORI may prescribe on the institution's research misconduct proceedings and the institution's compliance with 42 CFR Part 93.
- Notifies ORI immediately if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, HHS resources or interests are threatened, research activities should be suspended, there is reasonable indication of possible violations of civil or criminal law, federal action is required to protect the interests of those involved in the research misconduct proceeding, the institution believes that the research misconduct proceeding may be made public prematurely, or the

research community or the public should be informed.
- Provides ORI with the written finding by the responsible institutional official that an investigation is warranted and a copy of the inquiry report, within 30 business days of the date on which the finding is made.
- Notifies ORI of the decision to begin an investigation on or before the date the investigation begins.
- Within 120 business days of beginning an investigation, or such additional days as may be granted by ORI, (or upon completion of any appeal made available by the institution) provides ORI with the investigation report, a statement of whether the institution accepts the investigation's findings, a statement of whether the institution found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the respondent.
- Seeks advance ORI approval if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage.
- Cooperates fully with ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.

III. Research Misconduct Proceeding

A. General

The Research Integrity Ombudsperson is responsible for:

- Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.
- Taking 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.
- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR 93.108, other applicable law, and institutional policy.
- Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.
- Keeping the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of research misconduct.
- In cooperation with other institutional officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other institutional members.
- Making 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.
- Assisting the DO in implementing his/her decision to take administrative action against any complainant, witness, or committee member determined by the DO not to have acted in good faith.
- Maintaining records of the research misconduct proceeding, as defined in 42 CFR 93.317, in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.
- Ensuring that administrative actions taken by the institution and ORI are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

B. Allegation Receipt and Assessment

The Research Integrity Ombudsperson is responsible for:

- Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct.
- Receiving allegations of research misconduct.
- Assessing each allegation of research misconduct to determine if an inquiry is warranted because the allegation falls within the definition of research misconduct, is within the jurisdictional criteria of 42 CFR 93.102 (b), and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

C. Inquiry

The Research Integrity Ombudsperson is responsible for:

- Initiating the inquiry process if it is determined that an inquiry is warranted.
- At the time of, or before beginning the inquiry, making a good faith effort to notify the respondent in writing, if the respondent is known.
- On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventorying the records and evidence and sequestering 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 the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
- Appointing an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical.
- Preparing a charge for the inquiry committee in accordance with the institution's policies and procedures.
- Convening the first meeting of the inquiry committee and at that meeting briefing the committee on the allegations, the charge to the committee, and the appropriate procedures for conducting the inquiry, including the need for confidentiality and for developing a plan for the inquiry, and assisting the committee with organizational and other issues that may arise.
- Providing the inquiry committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews.

- Being available or present throughout the inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an investigation is warranted on the basis of the criteria in the institution's policies and procedures and 42 CFR 93.307 (d).
- Determining whether circumstances clearly warrant a period longer than 60 business days to complete the inquiry (including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the 60-business day period in the record of the research misconduct proceeding.
- Assisting the inquiry committee in preparing a draft inquiry report, sending the respondent a copy of the draft report for comment (and the complainant if the institution's policies provide that option) within a time period that permits the inquiry to be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and the complainant if the institution's policies provide that option), and ensuring that the comments are attached to the final inquiry report.
- Receiving the final inquiry report from the inquiry committee and forwarding it, together with any comments the Research Integrity Ombudsperson may wish to make, to the DO who will determine in writing whether an investigation is warranted.
- Within 30 business days of a DO decision that an investigation is warranted, providing ORI with the written finding and a copy of the inquiry report and notifying those institutional officials who need to know of the decision.
- Notifying the respondent (and the complainant if the institution's policies provide that option) whether the inquiry found an investigation to be warranted and including in the notice copies of or a reference to 42 CFR Part 93 and the institution's research misconduct policies and procedures.
- Providing to ORI, upon request, the institutional policies and procedures under which the inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the charges to be considered in the investigation.
- If the DO decides that an investigation is not warranted, securing and maintaining for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted.

D. Investigation

The Research Integrity Ombudsperson is responsible for:

- Initiating the investigation within 30 business days after the determination by the DO that an investigation is warranted.
- On or before the date on which the investigation begins: (1) notifying ORI of the decision to begin the investigation and providing ORI a copy of the inquiry report; and (2) notifying the respondent in writing of the allegations to be investigated.
- Prior to notifying respondent of the allegations, taking all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry.
- In consultation with other institutional officials as appropriate, appointing an investigation committee and committee chair as soon after the initiation of the investigation as is practical.
- Preparing a charge for the investigation committee in accordance with the institution's policies and procedures.
- Convening the first meeting of the investigation committee and at that meeting: (1) briefing the committee on the charge, the inquiry report and the procedures and standards for the conduct of the investigation, including the need for confidentiality and developing a specific plan for the investigation; and (2) providing committee members a copy of the institution's policies and procedures and 42 CFR Part 93.
- Providing the investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews.
- Being available or present throughout the investigation to advise the committee as needed.
- On behalf of the institution, the Research Integrity Ombudsperson is responsible for each of the following steps and for ensuring that the investigation committee: (1) uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented; (2) takes reasonable steps to ensure an

impartial and unbiased investigation to the maximum extent practical; (3) interviews 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 records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the research misconduct proceeding; and (4) pursues diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continues the investigation to completion.

- Upon determining that the investigation cannot be completed within 120 business days of its initiation (including providing the draft report for comment and sending the final report with any comments to ORI), submitting a request to ORI for an extension of the 120-business day period that includes a statement of the reasons for the extension. If the extension is granted, the Research Integrity Ombudsperson will file periodic progress reports with ORI.
- Assisting the investigation committee in preparing a draft investigation report that meets the requirements of 42 CFR Part 93 and the institution's policies and procedures, sending the respondent (and complainant at the institution's option) a copy of the draft report for his/her comment within 30 business days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and complainant at the institution's option) and ensuring that the comments are included and considered in the final investigation report.
- Transmitting the draft investigation report to institutional counsel for a review of its legal sufficiency.
- Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee.
- Transmitting the final investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (2) if the DO determines whether or not to accept the report, its findings and the recommended institutional actions, transmitting to ORI within the time period for completing the investigation, a copy of the final investigation report with all attachments, a statement of whether the institution accepts the findings of the report, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against

the respondent; or (3) if the institution provides for an appeal by the respondent that could result in a modification or reversal of the DO's finding of research misconduct, ensuring that the appeal is completed within 120 business days of its filing, or seeking an extension from ORI in writing (with an explanation of the need for the extension) and, upon completion of the appeal, transmitting to ORI a copy of the investigation report with all attachments, a copy of the appeal proceedings, a statement of whether the institution accepts the findings of the appeal proceeding, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent.

- When a final decision on the case is reached, the Research Integrity Ombudsperson will normally notify both the respondent and the complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.
- Maintaining and providing to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interview.

[1] Sections based on 42 CFR Part 93 have endnotes indicating the applicable section.

[2] This is the case whether an individual is on leave and / or between appointment intervals (e.g. summer term or ten month appointment). An individual's status does not impact whether a day is a treated as a business day.