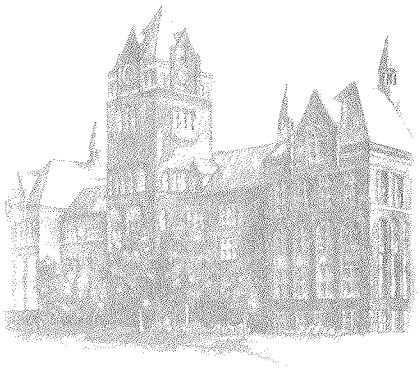

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University Policy 2010-01

Policy-Making by the President

Wayne State University Policy and Procedure Regarding Research Misconduct

1.0 Purpose and Scope

1.1 Regulations of the Public Health Service (PHS) require all universities that receive PHS support to establish policies and procedures for investigating and reporting instances of alleged or apparent research misconduct. The federal requirement for this policy accords with the University's commitment to an institutional culture that values integrity in the conduct of research and scholarship. This policy applies to all research regardless of the source of funding or other support.

Wayne State University therefore adopts this policy and these procedures on research misconduct. The policy and procedures have the purposes of 1) ensuring that the University remains in compliance with the law, 2) establishing uniform and well understood procedures for addressing allegations of research misconduct, 3) protecting those who in good faith bring allegations of misconduct from the possibility of retaliation, and 4) ensuring that unfounded allegations of research misconduct do not work to the detriment of researchers at the University.

1.2 This policy is intended to carry out Wayne State University's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct. This policy applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving:

- Any person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract, agreement, or other arrangement with Wayne State University (this includes all faculty, primary investigators, other staff, students, research assistants, research associates, graduate assistants, postdoctoral fellows, visiting and adjunct faculty, and any other person conducting research at, sponsored by, or under the auspices of Wayne State University). These provisions apply even if the respondent is no longer employed by or otherwise associated with the University; and

- Any of the following:

    - Applications or proposals for PHS or other support for biomedical or behavioral research, research training or activities related to that research or research training; or

- Research records produced in the course of research, research training, or activities related to that research or research training.

This policy includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether or not the research is funded by a grant, contract, cooperative agreement, or other form of support.

This policy and the associated procedures do not apply to authorship 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 authorized by the Code of Federal Regulations. Research misconduct does not include honest error or differences of opinion.

2.0 Definitions

2.1 *Allegation* means a disclosure of possible research misconduct by written, electronic, or oral statement to the Vice President for Research or his/her designee. An allegation must be more than a conclusory statement, and should contain sufficient specificity to allow the Vice President for Research or his/her designee to determine whether, if true, the allegation sets forth a possible basis for a conclusion of scientific misconduct.

2.2 *Complainant* means a person or entity, either known or anonymous, who makes an allegation of research misconduct.

2.3 *Committee* means a group of three or more individuals with the requisite characteristics described in Sections 5.5.1 (Inquiry) or 7.3.1 (Investigation) who are convened by the Vice President for Research or his/her designee for the purpose of an inquiry or investigation.

2.4 *Conflict of Interest* means any commitment or affiliation held by a member of an Inquiry or Investigation committee, or by his/her immediate family member(s), that could potentially or actually affect the member's ability to render an unbiased opinion about an allegation. Examples include significant personal, professional, or financial relationships with the complainant or respondent, or with the Department in which the complainant or respondent has appointments or employment. For the Vice President for Research, the Provost, the President, or other high ranking official of the University, "conflict of interest" means to be a respondent, within the meaning of section 2.22, or to have a commitment of affiliation that could potentially or actually affect significantly the individual's ability to perform a duty under the policy and procedure in an unbiased fashion.

2.5 *Deciding Official (DO)* means the Vice President for Research or designee, who makes determinations about institutional administrative actions concerning allegations of research misconduct. If the Vice President for Research is not able to perform the duties assigned under the Policy and Procedure for any reason, the person replacing the Vice President for Research shall be considered the designee of the Vice President for Research.

2.6 *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.

2.7 *Good faith* as applied to a complainant, means having a reasonable basis for a suspicion that the alleged misconduct had occurred based on the information known to the complainant at the time. As applied to a witness (including a complainant giving testimony as a witness), "good faith" means having a reasonable belief in the truth of one's testimony based on the information known at the time of the testimony. An allegation or testimony in 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 other members of the committee to achieve the purpose of helping an institution meet its responsibilities. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

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

2.9 *Inquiry* means preliminary information-gathering and preliminary fact-finding.

2.10 *Institutional Official* refers to vice presidents, associate vice presidents, assistant vice presidents, deans, deputy deans, associate deans, assistant deans, directors, associate directors, chairs, and associate chairs, but does not include attorneys in the Office of the General Counsel.

2.11 *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.

2.12 *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.

2.13 *Pre-Inquiry* means an initial assessment to determine whether an allegation has been made in good faith, whether it meets the definition of research misconduct provided in this Policy, and whether the support documentation is sufficiently credible to warrant an inquiry.

2.14 *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.

2.15 *Public Health Service or 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, the Substance Abuse and Mental Health Services Administration, and the offices of the Regional Health Administrators.

2.16 *PHS support* means PHS funding, or applications or proposals, 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 sub grants under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.

2.17 *Records of research misconduct proceedings* means: (1) the research records and evidence secured for the research misconduct proceeding pursuant to this policy, except to the extent the Research Integrity Officer 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; (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 findings of research misconduct.

2.18 *Research Integrity Officer* (RIO) means the Associate Vice President for Research or designated substitute who is responsible for: (1) performing the initial assessment of 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 and available supporting documentation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. The Vice President for Research or designee may designate a temporary RIO if the permanent position is vacant, or if the RIO is otherwise unable to conduct the responsibilities designated to him/her in this policy and procedure.

2.19 *Research misconduct* means 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. Plagiarism includes both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work. The theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained by a privileged communication, such as a grant or manuscript review, or a patent application. Substantial unattributed textual copying of another's work means the unattributed verbatim or nearly verbatim copying of sentences and paragraphs which materially mislead the ordinary reader regarding the contributions of the author.

2.20 *Research misconduct proceeding* means any actions related to alleged research misconduct, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings and administrative appeals.

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

2.22 *Respondent* means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

2.23 *Retaliation* means an adverse action taken against a complainant, witness, or committee member by this institution or one of its employees or students in response to (1) a good faith allegation of research misconduct; or (2) a good faith cooperation with a research misconduct proceeding.

2.24 *Undue influence* means the exertion of persuasion that is strong enough to prevent a complainant, witness, or committee member from fulfilling objectively and voluntarily his or her responsibilities under the policy and procedure.

3.0 Rights and Responsibilities

3.1 Research Integrity Officer

3.1.1 The Vice President for Research (VPR) will appoint the RIO who will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. The RIO will be an Associate Vice President (AVPR) 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.

The responsibilities of the RIO 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 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;
- Sequester research data and evidence pertinent to the allegation of research misconduct and maintain and preserve it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding consistent with applicable law and institutional policy;
- Notify the respondent and provide opportunities for him or her to review, comment, or respond to allegations and committee reports;
- 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 good faith complainants, witnesses, and committee members, and counter potential or actual retaliation against them;
- Keep the VPR 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, and licensing boards of those actions; and
- Maintain records of the research misconduct proceeding and make them available to ORI in accordance with Section 8.7 of this policy.

3.2 Complainant

3.2.1 The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. The complainant may, but not necessarily, be interviewed at the inquiry stage. The complainant must be interviewed during an investigation unless extenuating circumstances do not permit this.

3.3 Respondent

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

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report and the institution's policies and procedures on research misconduct;
- An opportunity to comment on the inquiry report. Comment must be submitted to RIO within 30 days of the date on which the respondent received the inquiry report in order to have his/her comments attached to the report;
- 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 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;
- Be interviewed during the investigation;
- Request to have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation-and to have the recording or transcript of the interview with the witness included in the record of investigation;
- Received 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 days of the date on which the copy was received and that the

comments will be considered by the institution and addressed in the final report; and

- Request an institutional appeal (see section 8.4).

3.3.2 If the respondent in an allegation is also the VPR, then a different University official who does not report to the VPR will be appointed by the President to serve as the RIO with respect to that specific case. If the respondent is also the AVPR, or Research Integrity Officer, then the VPR in consultation with the Provost will designate a different University Official to act as the RIO in that specific case. In addition, if the VPR or the Provost cannot fulfill the duties assigned to them under this policy and procedure because of a conflict of interest, as defined in section 2.4, or for any other reason, the President shall appoint a member of the University community to serve in place of the VPR or Provost. If the President is unable to fulfill his or her obligations under this policy and procedure, the Board of Governors shall appoint some member or group of members of the University community to serve as a substitute for the President.

3.3.3 The respondent should be afforded the opportunity to admit that the alleged research misconduct occurred and that he/she committed the research misconduct, provided that there is no inference as to whether misconduct occurred should the respondent decline to make an admission. The admission must be in writing, signed by the respondent. With the advice of the RIO and institutional legal counsel, the VPR may accept the admission and terminate the institution's review of an allegation that has been admitted. The admission must be accompanied by a report, prepared by the RIO, of the procedures leading up to the admission and a description of the evidence that has been assessed up to that point. Upon accepting the report and the admission, the VPR may recommend remedial activities or sanctions against the respondent. The admission, the report, and the recommendations, if any, will be submitted to the Provost and/or other University officials for a final settlement and implementation of sanctions, if any. If the research in question has PHS support, ORI must approve the institution's acceptance of the admission and any proposed settlement. If the VPR decides not to accept the admission and any proposed settlement. If the VPR decides not to accept the admission in settlement of all or part of the allegation(s) of misconduct, he/she shall remand the case for further inquiry or investigation in accordance with the procedures in this Policy.

3.4 Vice President for Research (VPR, or Deciding Official)

3.4.1 The VPR or Deciding Official will receive the inquiry report and after consulting with the RIO, decide whether an investigation is warranted. Any finding that an investigation is warranted must be in writing by the VPR, and must be provided to ORI when the investigation involves PHS-funded research, together with a copy of the inquiry report, within 30 days of the finding. If it is found that an investigation is not warranted, the VPR and the RIO 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 of PHS funded research.

3.4.2 The VPR will receive the investigation report and, after consulting with the RIO and other appropriate officials, decide the extent to which Wayne State University accepts the findings of the investigation and, if research misconduct if found, decide what, if any, institutional administrative actions are appropriate. The VPR shall ensure that the final investigation report, the findings of the VPR and a description of any pending or completed administrative action are provided to ORI, when the investigation report involves PHS funded research.

4.0 General Policies and Principles

4.1 Responsibility to Report Misconduct

4.1.1 Anyone who has observed or has other reason to suspect that research misconduct has occurred is encouraged to report it to the RIO. Any institutional official who receives an allegation of research misconduct must report it immediately to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct he or she may meet with or contact the RIO 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 RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

4.1.2 At any time, a person or entity may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

4.2 Cooperation with Research Misconduct Proceedings

4.2.1 All WSU employees must cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees and other members of the University community, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

4.2.2 Any attempt by WSU employees or students to exert undue influence over the research misconduct proceedings, including the activities of the RIO or DO, could result in disciplinary actions.

4.3 Confidentiality

4.3.1 The RIO will (1) to the extent permitted by law, limit disclosure of the identity of respondents and complainants, and other sensitive information, 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 RIO should make a reasonable effort to ensure that recipients of confidential information do not make any further disclosure of such

information. The RIO may take reasonable steps to protect the confidentiality of witnesses when the circumstances indicate that the witnesses may be harassed, retaliated against, or otherwise need protection.

4.4 Protecting complainants, witnesses, and committee members

4.4.1 WSU employees and students may not unduly influence or retaliate in any way against complainants, witnesses, or committee members. Individuals who become aware of violations shall immediately report to the RIO, who shall review the matter and, as necessary, make reasonable and practical efforts to counter any potential or actual undue influence or retaliation. WSU employees who make an allegation of misconduct, provide testimony as a witness, serve on a committee, or otherwise participate in a proceeding under this policy and procedure shall be treated as having acted in the ordinary course of their duties as an employee as long as they have acted in good faith.

4.5 Protecting the Respondent

4.5.1 As requested or as appropriate, the RIO 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.

4.5.2 During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the information provided for in this policy. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case. The role of the attorney or advisor shall be limited to counseling and assisting the respondent.

4.6 Interim Administrative Actions and Notifying ORI of Special Circumstances

4.6.1 Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the research process. In the event of such a threat, the RIO shall, in consultation with other institutional officials, and ORI when applicable, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results, or delaying publication. The RIO shall, at any time during a research misconduct proceeding related to PHS funded research, 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 related to the research misconduct proceeding;
- 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.

4.7 Time Limitations

4.7.1 An allegation of research misconduct must be made by a complainant within six (6) years of the occurrence of the alleged misconduct.

4.7.2 Exceptions to the six-year limitation include the following:

- Subsequent use exception. The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit or the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.
- Health or safety of the public exception. If ORI or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

5.0 Conducting the Assessment and Inquiry

5.1 Assessment of Allegations

5.1.1 Upon receiving an allegation of research misconduct, the RIO will assess the allegation and supporting documentation to determine whether they are sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdiction of ORI, and whether the allegation falls within the definition of research misconduct in this policy. An inquiry must be conducted if all these criteria are met; otherwise, an inquiry may be conducted at the RIO's discretion.

5.1.2 A complainant may request, or the RIO may decide, that the University will conduct a pre-inquiry review of the research misconduct. The pre-inquiry shall be completed within 90 days of receipt of the allegation.

5.1.3 The pre-inquiry shall be undertaken by the RIO and VPR, or his or her designee, and shall take into account the following considerations:

- Whether the allegation is accomplished by supporting evidence sufficient to demonstrate a reasonable possibility that research misconduct has occurred;
- Whether the complainant has reviewed and considered all the evidence known to the complainant related to purported research misconduct, and has provided or, if such evidence is unavailable to the complainant, called all such evidence to the attention of the RIO at the time the allegation was filed;

- Whether the complainant has agreed to cooperate in the inquiry and investigation, and to testify before the Investigation Committee if requested to do so:

5.1.4 In conducting the pre-inquiry, the RIO 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 RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, sequester, and preserve all research records and evidence needed to conduct the research misconduct proceeding, as provided in 5.3.1 of this section. The complainant shall cooperate with the RIO in obtaining, gathering, or organizing relevant research records and evidence.

5.2 Invitation and Purpose of the Inquiry

5.2.1 If the RIO 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.

5.3 Notice to Respondent; Sequestration of Research Records

5.3.1 At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing. 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 RIO 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. The RIO may consult with ORI for advice and assistance in this regard.

5.4 Appointment of the Inquiry Committee

5.4.1 The RIO, in consultation with other institutional officials as appropriate, will appoint an Inquiry Committee 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, including the respondent. The respondent shall be made aware of this provision. The Committee should include individuals with appropriate expertise to evaluate the evidence and issues related to the allegation, to interview the principals and key witnesses, and to conduct the inquiry.

5.5 Charge to the Committee and First Meeting

5.5.1 At the Committee's first meeting, the RIO will review the charge (described below) 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 RIO will be available throughout the inquiry to advise the Committee as needed.

5.5.2 The RIO will prepare a charge for the Inquiry Committee that:

a. Describes the allegations and any related issues identified during the allegation assessment or pre-inquiry (if conducted);
b. States that the purpose of the inquiry is to conduct an initial review of the evidence, which may include the testimony of the respondent, complainant and key witnesses, and to determine whether an investigation is warranted. The inquiry's purpose is not to determine whether research misconduct definitely occurred or who was responsible for any such misconduct;
c. Sets forth the deadline for completing the inquiry;
d. States that an investigation is warranted if the committee determines;

- There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct described in this policy; and
- The allegation is supported by sufficient evidence to be credible and warrants an investigation, based on the Committee's review during the inquiry

e. 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.

5.7 Inquiry Process

5.7.1 The Inquiry Committee may interview the complainant, the respondent, and key witnesses, and must examine available relevant research records and materials. Then the Inquiry Committee must evaluate this evidence. After consultation with the RIO, the Committee members will decide whether an investigation is warranted based on the criteria in this policy.

5.8 Time for Completion

5.8.1 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 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry report must document the reasons for extending the 60-day period.

6.0 The Inquiry Report

6.1 Elements of the Inquiry Report

6.1.1 The Inquiry Committee must prepare a written report that includes:

a. The name and position of the respondent;
b. A description of the allegations of research misconduct;
c. The PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS support;
d. A summary of the inquiry process used;
e. A list of the research records reviewed;
f. Summaries of any interviews;
g. The basis for recommending or not recommending that the allegations warrant an investigation; and
h. Any other actions that should be taken if an investigation is not recommended.

6.1.2 The Inquiry Committee must transmit a copy of the report to the RIO with confirmation that all Committee members have reviewed and agreed to its contents.

6.2 Notification and Opportunity to Comment

6.2.1 If the Inquiry Committee finds an investigation is warranted, the RIO shall so notify the respondent. The RIO shall provide the respondent with the inquiry report for comment within 10 business days of when the Committee issues the report to the RIO, and shall include a copy of Wayne State University's policies and procedures on research misconduct.

6.2.2 The RIO may notify the complainant whether the inquiry found an investigation to be warranted and may provide relevant portions of the inquiry report to the complainant for comment within 10 business days of when the Committee issues the report to the RIO. The complainant must agree in writing to maintain confidentiality before receiving access to the report.

6.2.3 Any comments that are submitted will be attached to the inquiry report.

6.3 Institutional Decision and Notification

6.3.1 Decision by Deciding Official

6.3.1.1 The RIO will transmit the inquiry report and any comments to the DO, who must determine in writing whether an investigation is warranted. The DO must make this determination within 10 business days of receiving the inquiry report. The inquiry is complete when the DO makes this determination.

6.3.2 Notification to ORI

6.3.2.1 If notification to ORI is required under the Code of Federal Regulations, the RIO must provide ORI with the DO's written decision and a copy of the inquiry report within 30 calendar days of the DO's decision that an investigation is warranted. The RIO must provide the following information to ORI upon request:

a. The institutional policies and procedures under which the inquiry was conducted;
b. The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
c. The charges to be considered in the investigation.

6.3.3 Documentation of Decision Not to Investigate

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

7.0 Conducting the Investigation

7.1 Initiation and Purpose

7.1.1 The investigation must begin within 30 calendar days after the DO's determination that an investigation is warranted. 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.

7.2 Notifying ORI and Respondent; Sequestration of Research Records

7.2.1 Before the investigation begins, the RIO must:

a. Notify the ORI Director of the decision to begin the investigation;
b. Provide ORI a copy of the inquiry report; and
c. Notify the respondent in writing of the allegations to be investigated.

7.2.2 If the Investigation Committee pursues new allegations of research misconduct not addressed in the inquiry report or in the notice of investigation, the RIO must give the respondent written notice within 10 business days of the Committee's decision to pursue these allegations.

7.2.3 To conduct the investigation, the RIO must take all reasonable and practical steps to obtain custody of and sequester in a secure manner all relevant research records and evidence. 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 sufficient to evaluate the

evidence. The need for additional sequestration of records for the investigation may occur for any number of reasons, including Wayne State University's decision to investigate additional allegations or respondents. Sequestration procedures for the investigation are the same as those for the inquiry.

7.3 Appointment of the Investigation Committee

7.3.1 The RIO will appoint an Investigation Committee. The Investigation Committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest who those parties involved with the investigation. The Investigation Committee should include individuals with the appropriate expertise to evaluate the evidence and issues related to the allegation, to interview the respondent and complainant, and to conduct the investigation. The Committee must include at least three members. Two members must be Wayne State University faculty. No member may be affiliated with either the complainant's or the respondent's departments or equivalent units. The RIO may appoint individuals to the Investigation Committee who served on the Inquiry Committee. The RIO may select Committee members from outside Wayne State University.

7.3.2 The VPR will make the final determination on whether such a conflict exists. If it is decided that such a conflict exists, the member must be removed from the Investigation Committee. If a replacement member is needed for any reason, the RIO shall follow the procedures described above to appoint the replacement member.

7.4 Charge to the Committee and the First Meeting

7.4.1 Charge to the Committee

7.4.1.1 The RIO will define the subject matter of the investigation in a written charge to the Committee that:

a. Describes the allegations and related issues identified during the inquiry;
b. Identifies the respondent;
c. Informs the Committee that it must conduct the investigation as prescribed in 7.5 of this section;
d. Defines Research Misconduct;
e. Informs the Committee that it must;
    1. Evaluate the evidence and testimony;
    2. Determine whether, based on a preponderance of the evidence research misconduct occurred; and if so,
    3. Determine the type and extent of research misconduct and who was responsible for the research misconduct.
f. Informs the Committee that to determine that the respondent committed research misconduct it must find, by a preponderance of the evidence, that:
    1. Research misconduct occurred, and
    2. Respondent committed the research misconduct intentionally, knowingly, or recklessly.

g. Informs the committee that it must prepare or direct the preparation of a written Investigation Report that meets the requirements of this policy.

7.4.2 The First Meeting

7.4.2.1 The RIO 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. The RIO will emphasize the necessity for the confidentiality and for a specific investigation plan. The RIO will provide a copy of this policy to the Investigation Committee. The RIO will be available throughout the investigation to advise the Committee.

7.5 Investigation Process

7.5.1 The Investigation Committee and the RIO must:

a. Use diligent efforts to ensure that the investigation is thorough, sufficiently documented, and includes examination of all research records and evidence relevant to reaching a decision on each allegation;
b. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
c. Interview each respondent, complainant, and other individuals who are likely to have information regarding relevant aspects of the investigation. The Committee must ensure there is a record or transcription of each interview, and include the recording or transcript in the record of the investigation; and

d. Pursue diligently any evidence of any additional instances of possible research misconduct and any additional respondents, and continue the investigation to completion.

7.6 Time for Completion

7.6.1 The investigation is to be completed within 120 days. If the research is governed by 42 CFR Part 93, and the RIO determines that the investigation will not be completed within 120 days, the RIO will submit to ORI a written request for an extension. If ORI grants the extension, and directs Wayne State University to file periodic progress reports, the RIO will ensure that the reports are filed with ORI.

8.0 The Investigation Report

8.1 Elements of the Investigation Report

8.1.1 The Investigation Committee and the RIO are responsible for preparing a written draft report of the investigation that:

a. Describes the nature of the allegation of research misconduct, including identification of the respondent;
b. 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;

c. Describes the specific allegations of research misconduct considered in the investigation;

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

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

f. Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must: (1) identify whether the alleged research misconduct was or was not falsification, fabrication, or plagiarism, and if research misconduct occurred, 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, known applications, or proposals for support that the respondent has pending with non-PHS federal agencies.

8.2 Comments on the Draft Report and Access to Evidence

8.2.1 Respondent

8.2.1.1 The RIO 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 has 30 days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

8.2.2 Complainant

8.2.2.1 The RIO may give the complainant a copy of the draft investigation report or relevant portions of the report for comment and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The complainant has 30 days from the date he/she received the draft report to submit comments to the RIO. The complainant's comments must be included and considered in the final report.

8.2.3 Confidentiality

8.2.3.1 In distributing the draft report, or portions thereof, to the respondent or complainant, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

8.3 Decision by Deciding Official

8.3.1 The RIO will assist the Investigation Committee in finalizing the draft investigation report, including ensuring that the respondent's and complainant's comments are included and considered, and transmit the final investigation report to the DO. The DO 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.

8.3.2 When a final decision on the case has been reached, the RIO will notify both the respondent and the complainant in writing. The notification must include the DO's written decision. After informing ORI, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports have been published or submitted, collaborators of the respondent in the work, or other relevant parties should be notified of outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

8.4 Appeals

8.4.1 The respondent may appeal the final decision of a finding of research misconduct and the recommendations for appropriate disciplinary action to the Provost. If the respondent desires to appeal, the respondent must file a written Notice of Appeal with the Provost and the Vice President for Research within 30 days of the date when the RIO transmits notification of the final decision of the DO to the respondent.

8.4.2 The Notice of Appeal shall be in the form of a written submission to the Provost. Respondent shall have 30 days from the date of the Notice of Appeal in which to submit written argument in support of his/her appeal. Upon a showing of good cause by the respondent, this period may be extended by the Provost. The submission shall identify specific elements or portions of the final report which the respondent believes to be in error. Factual materials not previously made available to the Committee of Inquiry or the Investigating Committee will not be considered except under the conditions set forth in Section 8.4.3.

8.4.3 If new evidence with significant probative value, which it was not possible to provide earlier, becomes available to the complainant or respondent after the DO's decision, the Provost may consider the new evidence during the appeal.

8.4.4 The Provost may affirm, reverse, or modify the final report and may increase or decrease the recommended sanctions. The Provost shall notify the respondent, the Vice President for Research, and the complainant of his/her decision within 90 days of receiving the respondent's written argument in support of his/her appeal. The Vice President for Research shall provide the results of the appeal to the Office

of Research Integrity and to any agencies, organizations, and individuals which may have received prior notice of the finding of research misconduct.

8.5 Notice to ORI of Institutional Findings and Actions

8.5.1 Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation or the 90-day period for completion of any appeal, submit the following to ORI: (1) a copy of the final investigation report with all attachments and any appeal; (2) a statement of whether the institution accepts the findings of the investigation report or a statement of the outcome of the appeal; (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.

8.6 Time for Completion

8.6.1 The Appeal is to be completed within 90 days of the respondent's filing the Notice of Appeal. If the research is governed by the Code of Federal Regulations (42 CFR Part 93), and the RIO determines that the Appeal will not be completed within 90 days, the RIO will submit to ORI a written request for an extension. If ORI grants the extension, and directs Wayne State University to file periodic progress reports, the RIO will ensure that the reports are filed with ORI.

8.7 Maintaining Records for Review by ORI

8.7.1 The RIO must maintain and provide to ORI upon request *Records of research misconduct proceedings*. Unless custody has been transferred to HHS or ORI has advised in writing 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. The RIO 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.

9.0 Institutional Administrative Actions

9.1 After a finding of research misconduct has been made and the appeals process is completed, the Vice President for Research in consultation with the Provost will decide on the appropriate actions to be taken. The administrative actions may include:

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

- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the misconduct.

10.0 Reporting to Sponsors and Federal Agencies

10.1 The RIO will ensure that the reporting requirements of sponsors of the research, and federal agencies if applicable, are met regarding research misconduct proceedings and/or findings.

10.2 Premature Closures

10.2.1 The RIO must notify ORI in advance if there are 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: (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.

11.0 Other Considerations

11.1 Termination or Resignation Prior to Completing Inquiry or Investigation

11.1.1 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 refuses to participate in the process after termination or resignation, the RIO and any Inquiry or Investigation Committee will note in the report the respondent's failure to cooperate in its effect on the evidence.

11.2 Restoration of the Respondent's Reputation

11.2.1 Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the RIO will, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and the views of the respondent, the RIO 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/or
- Expunging all reference to the research misconduct allegation from the respondent's personnel file

11.3 Protection of the Complainant, Witnesses and Committee Members

11.3.1 During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO 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. The DO will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves.

11.4 Institutional Administrative Actions

11.4.1 Any institutional administrative actions taken in accordance with section 3.4.2 do not prohibit the institution from taking appropriate administrative actions that are not specifically covered under this policy.

12.0 Notification

12.1 The Vice President for Research shall notify faculty and staff, including both scientific and administrative staff, of the existence of these policies and procedures, and of the importance of compliance with them.

13.0 Revocation

13.1 This University Policy is revocable by the President at any time and without notice. That revocation shall not affect a proceeding that has already been initiated.

14.0 Effective Date

14.1 This University Policy is effective upon issuance.

14.2 Executive Order 89-4 is hereby revoked, effectively immediately.

Jay Noren
President

7/13/10
Date