Vanderbilt University Policy
for Responding to
Allegations of Research Misconduct
in Research Sponsored by
the U.S. Public Health Service

I. Scope

This policy is intended to carry out Vanderbilt University's responsibilities under the Public Health Service Policies on Research Misconduct codified at 42 CFR Part 93 and applies to allegations of research misconduct involving:

A. Any individual who, at the time of the alleged misconduct, was employed or paid by, was under the control or an agent of, or was otherwise affiliated by contract or agreement with Vanderbilt; and

B. Either (1) PHS support for 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. (This policy does not apply to authorship or collaboration disputes.)

Allegations reviewed under this policy shall also be reviewed in accordance with the PHS regulations at 42 CFR Part 93.

II. Definitions

A. *Allegation* means any written or oral statement or any other indication of possible research misconduct made to or observed by an institutional official through any means of communication.

B. *Complainant* means a person who makes a good faith allegation of research misconduct.

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

D. *Dean* means the dean of the college or school in which Respondent has his or her primary appointment. The Dean makes final determinations on allegations of research misconduct and any responsive institutional actions. The Dean also submits written reports to ORI as provided in this Policy.

E. *Evidence* means any research record, document, tangible item, or testimony offered or obtained in connection with a research misconduct proceeding that tends to prove or disprove the existence of a fact.

F. *Good faith* as applied to a complainant, respondent or witness means having an honest belief in the truth of one's allegation or testimony that a reasonable person in the complainant's, respondent's, or witness' position could have based on the information known to the complainant, respondent, or witness at the time. Any allegation, testimony, 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 the PHS regulation. A committee member does not act in good faith if his or 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.

G. *Inquiry* means preliminary gathering of information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

H. *Investigation* means the 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.

I. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the research misconduct and research integrity activities of the U.S. Public Health Service.

J. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.

K. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 C.F.R. Part 93, entitled "Public Health Service Policies on Research Misconduct."

L. *PHS support* means any relationship between the alleged research misconduct and PHS within the scope of the PHS regulation, including but not limited to, PHS grants, contracts, or cooperative agreements (including research training programs and other research-related activities such as tissue or data banks) or applications therefor, as well as any subgrants or subcontracts or any salary or other payments from PHS under such grants, contracts or cooperative agreements. The scope of the PHS regulation also includes plagiarism of research records produced in the course of PHS research, research training, or related research activities.

M. *Research record* means any data, document, computer file, computer diskette, or any other written or non-written record, 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 research misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded;

grant or contract progress and other reports; any documents or materials provided to DHHS or Vanderbilt in the course of misconduct proceedings; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; patient research files, abstracts, theses, presentations, and publications.

N. *Respondent* means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

O. *Retaliation* means any action that adversely affects the employment or other institutional status of an individual that is taken by Vanderbilt or an employee because the individual has in good faith, made an allegation of research misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

P. *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 Research misconduct does not include honest error or differences of opinion in interpretations or judgments of data.

Q. *Research misconduct proceeding* means any action related to alleged research misconduct encompassed by this policy or the PHS regulation, including but not limited to, preliminary assessments of allegations, inquiries, investigations, grievances, and ORI oversight reviews, hearings and administrative appeals.

III. Rights and Responsibilities

A. Chair of Inquiry Committee/Chair of Investigation Committee

Those chairing inquiry or investigation committees will be appointed by the Dean and will have responsibility for implementation of the procedures set forth in this document. The chairs will be Vanderbilt researchers or faculty members who are qualified to handle the procedural requirements involved and who are sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The chairs will lead the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The chairs will attempt to ensure that confidentiality is maintained. The chairs will assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with

applicable standards imposed by government or external funding sources. The chairs are also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

B. Complainant

The Complainant will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the chairs of the inquiry or investigation committees have determined that the Complainant may be able to provide pertinent information on any portions of the draft report, these portions will be given to the Complainant for comment.

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

C. Respondent

The Respondent will be informed in writing of the allegations before or at the time an inquiry is opened and notified in writing of the final determinations and resulting actions. The Respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, to provide written comments on the draft inquiry and investigation reports, and to have the advice of counsel.

The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the Respondent is not found guilty of research misconduct, he or she has the right to receive all reasonable and practical institutional assistance in restoring his or her reputation, if requested and appropriate.

D. Dean

The Dean will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. The Dean will consult with the Associate Provost for Research and Graduate Education in University Central, or with the Associate Vice Chancellor for Research in the Medical Center, as appropriate, about these reports to obtain feedback and to ensure efficient communication and coordination of support with the appropriate administrative and compliance offices, including the Office of Grants and Contracts Management, the Institutional Review Board, and the Division of Animal Care. Based on these consultations, the Dean will inform the Provost or Vice Chancellor for Health Affairs, as appropriate, whether it will be necessary to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

After informing the Provost or Vice Chancellor, the Dean will provide written notice to ORI of any decision to open an investigation on or before the date it begins and report to ORI as required by regulation. Further, after consultation with the Associate Provost for Research and Graduate Education or the Associate Vice Chancellor for Research, the

Dean will notify ORI of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest. Included in the Dean's responsibilities is submission of the final written Investigation Report to ORI.

If the Dean has any real or apparent personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses with respect to an allegation of research misconduct, then the Dean shall be recused from any research misconduct proceeding involving the allegation and the Associate Provost for Research and Graduate Education or the Associate Vice Chancellor for Research, as the case may be, shall appoint another institutional official with the necessary and appropriate authority and expertise to fulfill the Dean’s duties and responsibilities under this policy.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with Vanderbilt should report observed, suspected, or apparent research misconduct and communicate any reports of research misconduct to the applicable Dean. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may discuss the suspected misconduct informally with the Dean. If the circumstances described by the individual do not meet the definition of research misconduct, the Dean may refer the individual or allegation to other University offices or personnel who may help to resolve the problem.

At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the applicable Dean and will be counseled about appropriate procedures for reporting allegations.

B. Protecting the Complainant and Others

Vanderbilt prohibits retaliation against complainants, witnesses, or committee members. The Dean will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations, including witnesses and inquiry and investigation committee members. The Dean will take steps to ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the applicable Dean.

Vanderbilt will protect the privacy of those who report misconduct in good faith to the maximum extent possible, except for disclosures to ORI required by 42 CFR Part 93 and as necessary to review the allegations or as otherwise required by applicable law. For example, if the Complainant requests anonymity, the institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies

and regulations and state and local laws, if any. The Complainant will be advised that if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity may no longer be guaranteed. Vanderbilt will undertake efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the Respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation. Disclosures will be limited to those individuals who need to know in order to carry out a thorough, competent, objective, and fair research misconduct proceeding except for disclosures to ORI required by 42 CFR Part 93 or as otherwise required by applicable law.

D. Protecting Research Subjects

Any information identified in connection with the review of allegations of research misconduct under this policy that might identify research subjects or contain personally identifiable health information or other private information shall only be obtained and reviewed in compliance with all applicable Federal, state and local law and applicable institutional policies and procedures. Any such information will be maintained securely and confidentially and shall only be disclosed as necessary to review the research misconduct allegations or as required by 42 CFR Part 93 in compliance with applicable law. Any disclosure of personally identifiable health information shall require a written confidentiality agreement restricting further disclosures.

E. Legal Counsel

Respondent and other witnesses may consult with legal counsel at any time, at their own expense, and may rely on legal counsel in the preparation of any documents or the collection of evidence to be presented to the committees. Attorneys may not appear with or on behalf of the Respondent or other witnesses before any committee.

F. Cooperation with Inquiries and Investigations

Vanderbilt employees will cooperate with the Dean and the committee chairs and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees, including respondents, have an obligation to provide relevant evidence to the Dean and committee chairs or other institutional officials on misconduct allegations.

G. Preliminary Assessment of Allegations

Upon receiving an allegation of research misconduct, the Dean will assess the allegation to determine whether there is sufficient identifiable evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of research misconduct. The Dean need not interview the complainant, respondent, or other witnesses or gather data beyond that 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.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the Dean determines that the allegation provides sufficient identifiable information to allow specific follow-up, involves PHS support or applications for PHS support, and falls under the PHS definition of research misconduct, he or she will immediately initiate the inquiry process and appoint an inquiry committee and chair. The Dean must make a good faith effort to notify the respondent in writing of the decision to begin an inquiry at the time of or before beginning an inquiry. The Dean will give written notice of any additional allegations within a reasonable time period after deciding to pursue such additional allegations. Any additional respondents that may be subsequently identified must be notified in writing within a reasonable time period. In initiating the inquiry, the Dean should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, Complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible and does not require a full review of all evidence related to the allegation. The findings of the inquiry must be set forth in an inquiry report.

B. Sequestration of the Research Records

Either before or at the time that the respondent is first notified of the allegations or the inquiry begins, whichever is earlier, the Dean must take all reasonable and practical steps to ensure that all original research records, materials and evidence relevant to the allegation are immediately sequestered and secured and generate an inventory of the records, materials and evidence secured. If data or other research records are on shared scientific instruments, copies of the data or research records are sufficient, so long as the copies are substantially equivalent in evidentiary value to the instruments themselves. All research records will be retained as required in Section XII below.

C. Appointment of the Inquiry Committee

The Dean will appoint an inquiry committee and committee chair within 10 days of the initiation of the inquiry. The inquiry committee should consist of individuals who do not have real or apparent personal, professional, or financial conflicts of interest with the complainant, respondent or witnesses in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons.

The Dean will notify the Respondent of the proposed committee membership within 10 days. If the Respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 days, the Dean

will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

The Dean will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the Respondent, Complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation as required by the PHS regulation. The purpose is not to determine whether research misconduct definitely occurred or who was responsible.

The charge should explain that an investigation is warranted if the allegation falls within the PHS definition of research misconduct, involves PHS supported research or applications for PHS support, and the inquiry indicates that the allegation may have substance.

At the committee's first meeting, the inquiry committee chair 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 within the applicable time limitations, describe the requirements for the inquiry report, and answer any questions raised by the committee. The inquiry committee will be provided with copies of the PHS regulation and this policy.

E. Inquiry Process

The inquiry committee will normally interview the Complainant, the Respondent, and key witnesses as well as examining relevant research records, materials and evidence. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. The committee will decide whether an investigation is warranted based upon the criteria in the charge. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

VI. The Inquiry Report

A. Elements of the Inquiry Report

The inquiry committee must prepare a written inquiry report that states the name and position of the respondent, the name and title of the committee members and experts, if any; the allegations; the PHS support (including grant numbers, grant applications and publications listing PHS support); a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and the committee's determination as to whether an investigation is recommended (including the basis for the determination) and whether any other actions are recommended if an investigation is not recommended.

B. Comments on the Draft Report by the Respondent and the Complainant

The Dean will inform the respondent of whether the inquiry determined an investigation to be warranted and will provide the respondent with a copy of the draft inquiry report for comment and rebuttal. The Dean will provide the complainant, if he or she is identifiable, with at least those portions of the draft inquiry report that address the complainant's role and opinions in the investigation.

1. Confidentiality

The inquiry committee chair may establish reasonable conditions for review to protect the confidentiality of the draft report, including confidentiality agreements.

2. Receipt of Comments

Within 10 calendar days of their receipt of the draft report, the Complainant and Respondent will provide their written comments, if any, to the inquiry committee. Any comments that the Complainant or Respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

1. Decision by Dean

The Inquiry Committee Chair will transmit the final inquiry report (including any comments) to the Dean, who will make the determination in writing of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is completed when the Dean makes this determination, which should be made within 60 days of the first meeting of the inquiry committee. Any extension of this period should be based on good cause and recorded in the inquiry file.

2. Notification

The Dean will notify both the Respondent and the Complainant in writing of his or her decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The notice will include a copy of the final inquiry report and refer to the Public Health Service Policies on Research Misconduct (42 CFR Part 93) and this policy. The Dean is responsible for notifying ORI of the determination that an investigation is warranted and submitting the final inquiry report to ORI as required in Section IX(A) below. The Dean will also notify all appropriate institutional officials of his or her decision.

3. Documentation of Decision Not to Investigate

If the Dean decides that an investigation is not warranted, the Dean shall document that determination in writing in sufficient detail to permit ORI to assess the analysis of that decision. This documentation must be included with the records of the research misconduct proceedings and provided to ORI upon request.

D. Time Limit for Completing the Inquiry Report

The inquiry, including preparation of the final inquiry report and the decision of the Dean as to whether an investigation is warranted, must be completed within 60 days of initiation of the inquiry unless the Dean approves an extension for good cause. If the

Dean approves an extension, the reason for the extension will be documented in writing and entered into the records of the research misconduct proceeding and the final inquiry report. The Respondent also will be notified of the extension.

VII. Conducting the Investigation

A. Purpose of the Investigation

The investigation must begin within 30 days of the Dean's determination that an investigation is warranted. The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Notification of Investigation

The Dean will notify the respondent in writing of the allegations to be investigated before the investigation begins but in no event later than 30 days after the determination that an investigation is warranted. The Dean will give notice of new allegations within a reasonable time after deciding to pursue allegations not in the inquiry or initial notice of investigation.

C. Sequestration of the Research Records

The Dean will take all reasonable and practical steps to sequester in a secure manner any additional pertinent research records and evidence or copies of additional records on shared instruments that are equivalent to the evidentiary value of the original instrument that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records and evidence 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.

D. Appointment of the Investigation Committee

The Dean, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent personal, professional, or financial conflicts of interest with the complainant, respondent, or witnesses in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the respondent, complainant, and key witnesses, and conduct the investigation. These individuals may be

scientists, administrators, subject matter experts, lawyers, or other qualified persons. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The Dean will notify the respondent of the proposed committee membership within 5 days. If the respondent submits a written objection to any appointed member of the investigation committee or expert based upon bias or conflict of interest within 5 days, the Dean will determine whether to replace the challenged member or expert with a qualified substitute.

E. Charge to the Committee and the First Meeting

1. Charge to the Committee

The Dean 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, defines research misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

The charge must explain that a finding of research misconduct requires that the alleged misconduct (a) meets the definition of research misconduct, (b) constitutes a significant departure from accepted practices of the relevant research community, (c) be committed intentionally, knowingly or recklessly, and (d) be proven by a preponderance of the evidence. A preponderance of the evidence means that analysis of the evidence leads to the conclusion that the allegation is more likely true than not. The respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional allegations or respondents, the committee will notify the Dean, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The Dean, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, the requirements for an investigation 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 to complete the investigation within the applicable time limitations. The investigation committee will be provided with a copy of this policy and the PHS regulation.

F. Investigation Process

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

The investigation committee will exercise diligent efforts to ensure that the investigation is thorough and sufficiently documented to enable the investigation committee to reach a decision on the merits for each allegation and take reasonable steps to ensure an impartial and unbiased investigation to the extent practical. The investigation will normally involve examination of all relevant documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the complainant(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations, including witnesses identified by the respondent. Interviews should be recorded or transcribed. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file. The investigation committee will pursue diligently all significant issues discovered that are relevant to the investigation including any evidence of additional instances of research misconduct which will be included in the investigation in accordance with this policy. Vanderbilt will maintain sufficiently thorough documentation of the research misconduct proceedings and provide to ORI upon request all relevant research records and evidence and records of the misconduct proceedings, including the recordings or transcripts of all interviews.

VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation committee must prepare a written report that (i) describes the allegations considered in the investigation, (ii) identifies the respondent, (iii) identifies the PHS support or application for PHS support (including grant numbers, grant applications and publications listing PHS support), (iv) describes the policies and procedures under which the investigation was conducted (including a copy of this policy), (v) describes how and from whom information and evidence relevant to the investigation was obtained, (vi) summarizes the evidence and research records reviewed and identifies evidence not taken into custody or taken into custody but not reviewed, (vii) states the findings for each allegation, (viii) explains the basis for the findings with a summary of the facts and analysis supporting each finding, and (ix) considers the merits of any reasonable explanation of respondent and any evidence that rebuts the respondent's explanation including honest error or difference of opinion. If research misconduct is found, the final report must identify who was responsible for the misconduct, whether the misconduct involved fabrication, falsification or plagiarism and whether it was done intentionally, knowingly or recklessly. The final report shall also identify the specific PHS support involved, any publications that need correction or retraction, and any other current support or applications pending for the respondent with other Federal agencies. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution.

B. Comments on the Draft Report

1. Respondent

The Investigation Committee Chair will provide the respondent with a copy of the draft investigation report and a copy of or supervised access to the evidence on which the report is based for comment and rebuttal. The respondent will be allowed 30 days to review and provide written comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

2. Complainant

The Investigation Committee Chair will provide the complainant, if he or she is identifiable, with those portions of the draft investigation report that address the complainant's role and opinions in the investigation. The complainant will be allowed 30 days to review and provide written comments on the draft investigation report. The report should be modified, as appropriate, based on the complainant's comments.

3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and complainant, the Investigation Committee Chair will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality, including confidentiality agreements.

C. Institutional Review and Decision

After comments have been received and the necessary changes have been made to the draft report, the investigation committee shall transmit the final report with attachments, including the respondent's and complainant's comments, to the Dean, through the investigation committee chair. The Dean will make a final determination in writing whether to accept the findings and recommendations of the investigation committee in the investigation committee report and will also determine the appropriate institutional actions. If this determination varies from that of the investigation committee, the Dean will explain the basis for rendering a decision different from that of the investigation committee in the Dean’s written determination. The Dean's explanation should be consistent with the PHS definition of research misconduct and the evidence reviewed and analyzed by the investigation committee. The Dean may also return the report to the investigation committee with a request for further fact-finding or analysis. The Dean's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review. The Dean is responsible for submitting the final investigation report to ORI as required in Section IX (A) below.

When a final decision on the case has been reached, the Dean will notify both the respondent and the complainant in writing. In addition, the Dean, in consultation with appropriate University officials, will determine whether law enforcement agencies,

professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case and will inform ORI of any such notification. The Dean is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making the draft report available to the respondent for comment, submitting the report to the Dean for approval, and submitting the final investigation report to the ORI as required in Section IX(A) below.

IX. Requirements for Reporting to ORI

A. A Dean's decision to initiate an investigation will be reported in writing to the Director, ORI, on or before the date the investigation begins but in no event later than 30 days of the Dean's determination that an investigation is warranted. The Dean's written determination and a copy of the inquiry report will be provided to ORI with the notification report. At a minimum, the notification will include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of research misconduct, the PHS applications or grant number(s) involved, the basis for recommending that the allegations warrant an investigation and any comments to the inquiry report from the respondent. Upon ORI's request, ORI will be provided with this policy, research records and evidence reviewed (including any relevant documents and transcripts or recordings of interviews), and the charges for the investigation to consider. ORI will also be notified of the final outcome of the investigation and will be provided with a complete copy of the final investigation report. The notification will include (i) the finding of the Investigation Committee as to whether research misconduct was found and if so, who committed it, (ii) a statement as to whether the Dean accepts the findings in the Investigation Committee report (including a copy of the Dean's written determination), and (iii) a description of any pending or final administrative actions against the respondent.

B. Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. If Vanderbilt terminates an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Dean will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination. The Dean, however, is not required to submit a report to ORI if a case is closed after the inquiry stage on the basis that an investigation is not warranted provided that the Dean documents that determination as required in Section VI(C)(3) unless otherwise required by the PHS regulation.

C. If Vanderbilt determines that it will not be able to complete the investigation in 120 days, the Dean will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and

describes other necessary steps to be taken. If the request is granted, the Dean will file periodic progress reports as requested by the ORI.

D. When PHS support or applications for PHS support are involved and an admission of research misconduct or settlement proposal is made, the Dean will contact ORI for consultation and advice. Normally, the individual making the admission or settlement proposal will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS support, the institution cannot accept an admission of research misconduct or settlement proposal as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

E. The Dean, in consultation with the Associate Provost for Research and Graduate Education at University Central or the Associate Vice Chancellor for Research at the Medical Center, will notify ORI immediately at any stage in reviewing or addressing allegations of research misconduct under this policy if:

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

2. HHS resources or interests are threatened;

3.research activities should be suspended;

4. there is a reasonable indication of possible criminal or civil violation;

5. federal action is required to protect the interests of those involved in the research misconduct proceeding;

6. the research misconduct proceeding may be made public prematurely so that DHHS may take appropriate steps to safeguard evidence and protect the rights of those involved; or

7. the research community or public should be informed.

The notification shall also include any facts that may be relevant to protect public health, Federal funds and equipment and the integrity of the PHS supported research process.

X. Institutional Administrative Actions

Vanderbilt will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.

If the Dean determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the investigation committee chair or others as appropriate. The actions may include but are not limited to:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was 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.

Vanderbilt will fully cooperate with and assist DHHS, as needed, in carrying out administrative actions imposed by DHHS as a result of a final finding of research misconduct by DHHS. Vanderbilt shall also cooperate with ORI on a continuing basis during its oversight review process of the research misconduct proceedings pursuant to 42 CFR Part 93 and any subsequent administrative hearings or appeals with DHHS. This includes providing all research records and evidence under Vanderbilt's control, custody or possession and reasonable access to Vanderbilt employees as necessary to develop a complete record of relevant evidence.

XI. Other Considerations

A. Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation

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

If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the preliminary assessment, inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation

Upon request and as appropriate, the Dean will undertake reasonable and practical efforts to restore the respondent's reputation if the Dean (and ORI, when applicable) makes no finding of research misconduct. Depending on the particular circumstances, the Dean may notify those individuals aware of or involved in the investigation of the final outcome, publicize the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunge all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Dean.

C. Protection of the Complainant and Others

Regardless of whether the Dean determines that research misconduct occurred, he or she will undertake all reasonable and practical efforts to protect complainants who made allegations of research misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations from potential and actual retaliation.

Upon receiving any report of retaliation, the Dean will determine, after consulting with the affected individual, what steps, if any, are needed to restore the position or reputation of the complainant, witnesses or inquiry and investigation committee members or to counter potential or actual retaliation. The Dean will also take appropriate steps during the inquiry and investigation to prevent any retaliation.

D. Allegations Not Made in Good Faith

If relevant, the Dean 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 an absence of good faith is determined, the Dean will decide whether any administrative action should be taken against the person not acting in good faith.

E. Interim Administrative Actions

Throughout the research misconduct proceeding, institutional officials will take interim administrative actions, as appropriate, to protect public health, Federal funds and equipment and the integrity of the PHS supported research process. Examples of actions that may be necessary include (i) additional review of research results or delaying their publication, (ii) providing for closer supervision or reassignment of employees who are responsible for the research process or handling federal funds and equipment, (iii) requiring approvals for actions relating to the research that did not previously require approval, (iv) auditing pertinent records, or (v) taking steps to contact other institutions that may be affected by an allegation of research misconduct.

F. Right to File Grievance

Any faculty member who has been disciplined may file a grievance within sixty (60) days after notification of the discipline pursuant to Part IV, Chapter 2, "Faculty Grievances." In the event the respondent files any such grievance, Vanderbilt shall complete the review of the grievance within 120 days. If Vanderbilt determines that it will not be able to complete the grievance process within 120 days, then the Dean will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion, and describes other necessary steps to be taken. If the request is granted, the Dean will file periodic progress reports if requested by ORI.

XII. Record Retention

After completion of a case and all ensuing related actions, the investigation committee chair will prepare a complete file of the records of the research misconduct proceeding and transfer the file to the Dean. Unless custody has been transferred to DHHS or ORI has advised in writing that the records no longer need to be retained, the Dean must maintain the records of the research misconduct proceeding in a secure manner for at least 7 years after completion of the case or any ORI or DHHS proceeding, whichever is later, to permit later assessment of the case and provide the records of the research misconduct proceedings to ORI upon request. The Dean 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.

Records of research misconduct proceedings include, without limitation: (1) the research records and evidence secured for the research misconduct proceeding pursuant to this policy, including any documents or materials provided to the committees in the course of research misconduct proceedings; (2) 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; (3) 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 (4) the complete record of any appeal or grievance submitted to the institution with respect to any finding of research misconduct. Duplicate copies of records of research misconduct proceedings need not be retained provided that the determination that such records are duplicative is documented.