1.0 PURPOSE

1.1 Safeguarding the integrity of research is fundamental to the mission of Van Andel Research Institute, Van Andel Graduate School, and Van Andel Education Institute (collectively referred to as Van Andel Institute or VAI). We owe no less to the public that sustains institutions like ours and to the government agencies and other agencies that sponsor our research enterprise. All members (employees and non- employees) of VAI share in the responsibility to assure that Research Misconduct or fraud in research does not occur and that VAI's high standards for scholarly integrity are preserved. In compliance with federal regulation 42 CFR Part 93, the following policies and procedures are established for reporting, investigating, and evaluating alleged or apparent Research Misconduct. These policies and procedures shall be widely disseminated at VAI and all members of VAI are expected to read and be knowledgeable about the policies and procedures described herein.

2.0 APPLICABILITY

2.1 Compliance with 42 CFR Part 93 is required of individuals and institutions that have submitted a grant application to or are involved in a project sponsored by the U.S. Public Health Service (PHS). These policies and procedures therefore apply to members of VAI who engage in research, regardless of funding source, and other sponsored activities.

2.2 This policy applies to Allegations of Research Misconduct and Research Misconduct involving but not limited to:

2.2.1 Applications or proposals for support of research, research training or activities related to that research or research training, such as the operation of biorepositories and data banks and the dissemination of research information;

2.2.2 Any research, whether funded or not;

2.2.3 Any research training program, whether funded or not;

2.2.4 Any research proposed, performed, reviewed or reported, or any research record generated from that research; regardless of whether an application or proposal for extramural funds resulted in a grant, contract, cooperative agreement, or other form of extramural support.

2.3 This policy does not apply to authorship/collaboration disputes, honest errors, differences of opinion, or research that was not conducted at VAI. In the latter case, allegations may be referred to the institution with which the Respondent was affiliated at the time the Research Misconduct is alleged to have occurred.

2.4 In the event of alleged Research Misconduct, the time limitations and criteria for applicability set forth by any Federal agency regulations, e.g., 42 CFR 93.104, shall determine whether this policy is applicable.

2.4.1 With respect to PHS funded research, this policy applies to Research Misconduct occurring within six (6) years of the date HHS or VAI receives an Allegation of Research Misconduct, which time frame may be extended for the following reasons (i.e., subsequent use exception):

2.4.1.1 The Respondent continues or renews any incident of alleged Research Misconduct that occurred before the six-year limitation through the use of, republication of, or citation to the portion(s) of the Research Record alleged to have been Fabricated, Falsified, or Plagiarized, for the potential benefit of the Respondent.

2.4.1.2 The Respondent uses, republishes, or cites to the portion(s) of the Research Record that is alleged to have been Fabricated, Falsified, or Plagiarized, in submitted or published manuscripts, submitted PHS grant applications, progress reports submitted to PHS funding components, posters, presentations, or other research records within six years of when the Allegations were received by HHS or VAI.

2.4.1.3 If the Office of Research Integrity (ORI) or VAI, following consultation with ORI, determines that the alleged Research Misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

2.4.2 For Research Misconduct that appears subject to the subsequent use exception, VAI will document its determination whenever it deems that the subsequent use exception does not apply. Such documentation shall be retained in accordance with § 93.318.

2.4.3 In cases involving close questions regarding the applicability of the six (6) year time limitation or the subsequent use exception under 42 CFR § 93.105, VAI shall consult with the Office of Research Integrity (ORI) prior to making a final determination that an Allegation is time-barred. Documentation of such consultation shall be retained as part of the Institutional Record.

3.0 POLICY STATEMENT

3.1 It is the policy of VAI to comply with 42 CFR Part 93, Public Health Service Policies on Research Misconduct and all other federal Research Misconduct policies. To that end, VAI will:

3.1.1 Respond to each Allegation of Research Misconduct for which it is responsible in a thorough, competent, objective, and fair manner, which includes taking precautions to ensure that individuals responsible for carrying out any part of a Research Misconduct Proceeding do not have unresolved personal, professional, or financial conflicts of interest with the Complainant, Respondent, or Witnesses;

3.1.2 Foster a research environment that promotes research integrity and the responsible conduct of research, discourages Research Misconduct, and deals promptly with Allegations or Evidence of possible Research Misconduct;

3.1.3 Inform VAI Members about this policy and VAI's commitment to compliance with the policy;

3.1.4 Make this policy publicly available.

3.1.5 Cooperate with HHS during any Research Misconduct Proceeding or compliance review, including addressing deficiencies or additional allegations in the Institutional Record if directed by ORI;

3.1.6 Assist in administering and enforcing any HHS administrative actions imposed on VAI members; and

3.1.7 Have an active research integrity assurance.

3.2 VAI recognizes the authority of the Office of Research Integrity (ORI) to oversee institutional compliance with 42 CFR Part 93 and to review Research Misconduct Proceedings at any stage. Upon request, VAI shall provide ORI access to documentation, records, and evidence related to Preliminary Assessments, Inquiries, Investigations, and institutional determinations, including materials not relied upon in final findings, to the extent required by federal regulation.

3.3 In the event of any conflict between this policy and applicable federal research misconduct regulations, including 42 CFR Part 93, the federal regulations shall control. This policy shall be interpreted and applied in a manner consistent with federal requirements and ORI guidance in effect at the time of the Research Misconduct Proceeding

3.4 Insofar as this policy is written to ensure VAI complies with the Public Health Service's regulations at 42 CFR Part 93, VAI recognizes that other sponsors may have Research Misconduct policies that differ (e.g., the National Science Foundation). To the maximum extent possible, therefore, this policy and any references to PHS or PHS Awarding Components should be flexibly interpreted and implemented in such a way as to enable VAI's compliance with all other Federal Research Misconduct policies.

3.5 VAI adopts the following definition of Research Misconduct: Fabrication, Falsification, or Plagiarism in proposing, performing or reviewing research, or in reporting research results.

3.6 In order for a finding of Research Misconduct to be made, the following three criteria must be met:

3.6.1 There must be a Significant Departure from Accepted Practices of the Relevant Research Community;

3.6.2 The Research Misconduct must be committed Intentionally, Knowingly or Recklessly, and;

3.6.3 The Allegation must be proven by a Preponderance of the Evidence.

3.6.3.1 VAI has the burden of proof for making a finding of Research Misconduct.

3.6.3.2 A Respondent's destruction of Research Records documenting the questioned research is evidence of Research Misconduct where VAI establishes by a Preponderance of the Evidence that the Respondent Intentionally or Knowingly destroyed Research Records after being informed of the Research Misconduct Allegation.

3.6.3.3 A Respondent's failure to provide Research Records documenting the questioned research is evidence of Research Misconduct where the Respondent claims to possess the Research Records but refuses to provide them upon request.

3.7 Each Member of VAI has a responsibility to report any conduct that they believe in Good Faith to be Research Misconduct at VAI.

3.7.1 If an individual is unsure whether a suspected incident falls within the definition of research misconduct, they may meet with or contact the Research Integrity Officer (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.

3.7.2 At any time, a VAI Member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting Allegations.

3.7.3 All Allegations of Research Misconduct, wherever initially received, must be conveyed promptly to VAI. A supervisor who becomes aware of possible Research Misconduct, either from their own observations or because of reports, has a responsibility to bring Allegations of Research Misconduct directly to the RIO to ensure that proper procedures are followed. If a supervisor feels that the RIO is not the appropriate official to whom to report Allegations in a particular case, the Allegations may be reported to the General Counsel (GC).

3.8 VAI Members will cooperate with the RIO, other VAI Officials, and funding agencies in the review of Allegations and the conduct of Inquiries and Investigations. VAI Members, including Respondents, have an obligation to provide Evidence relevant to Research Misconduct Allegations to the RIO, other VAI Officials, and funding agencies.

3.9 The RIO and VAI Officials shall, as required by 42 CFR § 93.106:

3.9.1 Limit to the extent possible disclosure of the identity of Respondents, Complainants, and Witnesses to those who need to know in order to carry out a thorough, competent, objective and fair Research Misconduct Proceeding. Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. This limitation on disclosure of the identity of Respondents, Complainants, and Witnesses no longer applies once VAI has made a final determination of Research Misconduct findings.

3.9.2 Disclose the identity of Respondents, Complainants, or other relevant persons to ORI pursuant to an ORI review of Research Misconduct proceedings under this part.

3.9.3 Except as otherwise prescribed by law or this policy, confidentiality must be maintained to limit the disclosure of either proprietary information, or 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.

3.9.4 This section does not prohibit VAI Officials from managing published data or acknowledging that data may be unreliable.

3.10 VAI's institutional roles under this policy are:

3.10.1 Institutional Deciding Official (DO). VAI's Chief Scientific Officer (CSO) or their designee is the Institutional Deciding Official. Any individual designated by the CSO to carry out their responsibilities as DO shall be identified in writing, noting however that VAI's Research Integrity Officer (RIO) may not be designated as the DO. In the event the CSO has a potential Conflict of Interest with respect to a particular Allegation of Research Misconduct, the GC or their designee shall determine who shall be responsible as DO for review of the particular Allegation. This appointment shall be identified in writing.

3.10.2 Institutional Certifying Official (CO). VAI's Vice President for Research Protections and Support (VP-RPS) or their designee is the CO. Any individual designated by the VP-RPS to carry out their responsibilities as CO shall be identified in writing.

3.10.3 Research Integrity Officer (RIO). VAI's Vice President for Research Protections and Support is the RIO. The role and responsibilities of RIO may not be delegated to another person.

3.11 VAI's Institutional Deciding Official (DO) will immediately notify a federal agency if at any time during a Research Misconduct Proceeding a VAI Member has a reasonable basis to believe that any of the following conditions exist:

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

3.11.2 Federal resources or interests are threatened.

3.11.3 Research activities should be suspended.

3.11.4 There is reasonable indication of possible violations of civil or criminal law.

3.11.5 Federal action is required to protect the interests of those involved in the Research Misconduct Proceeding.

3.11.6 There is reason to believe the Research Misconduct Proceeding may be made public prematurely so that the federal agency may take appropriate steps to safeguard Evidence and protect the rights of those involved. In this event, the DO will, in consultation with other VAI Officials and ORI, take appropriate interim action to protect against any such conditions.

3.12 Triage and Precedence of Procedures

3.12.1 Determination of the Precedence of Proceedings. Review of an Allegation of Research Misconduct shall precede all other internal institutional proceedings that relate to or arise out of the alleged Research Misconduct. However, the RIO in consultation with the GC may stay any proceeding if it is determined that other institutional procedures mandated by law must be completed prior to the institution's further review of the Allegation. The ordered principles guiding the RIO's determination are:

3.12.1.1 Protect public health and safety and the safety and well-being of research subjects.

3.12.1.2 Protect Evidence necessary to review an Allegation of Research Misconduct or alleged violations under other regulated areas of research.

3.12.1.3 Protect the public interest.

3.12.1.4 Review the Allegation of Research Misconduct under institutional procedures.

3.12.1.5 When an Allegation of Research Misconduct is also the subject of a criminal investigation or proceeding, the pertinent governmental authority may advise VAI that its review of the Allegation may prejudice or interfere with the criminal investigation or proceeding. In such instances, the DO in consultation with the GC may stay the Research Misconduct Proceeding provided they ensure that the Evidence necessary for its review of the Allegation is protected and the chain of custody is preserved.

3.12.1.6 When an allegation involves a Respondent at VAI and a collaborator at another institution, the RIO may consult the RIO of the other institution, share evidence, and conduct a joint review of the Allegation when appropriate.

3.12.1.7 Certain governmental agencies may have the option of initiating their own investigation of an Allegation of misconduct involving research supported by that agency. In the event an agency initiates its own investigation, the RIO will consult that agency and, in concert with the DO, determine whether to suspend VAI's review of the Allegation.

3.12.1.8 Administrative Referrals. Regardless of the outcome of a Research Misconduct Proceeding, the RIO shall determine whether any other compliance matters are implicated and inform the appropriate regulatory oversight office (e.g., IRB, IACUC, COI, IBC, OSR, etc.).

3.12.2 Multiple Respondents. If additional Respondents are identified during an Inquiry or Investigation, VAI is not required to conduct a separate Inquiry for each new Respondent. However, each additional Respondent must be provided notice of and an opportunity to respond to the Allegations.

3.12.3 Multiple Institutions. When allegations involve research conducted at multiple institutions, either VAI or another institution will be designated as the lead institution if a joint Research Misconduct Proceeding is conducted. In a joint Research Misconduct Proceeding, the lead institution will obtain Research Records and Evidence pertinent to the proceeding, including Witness testimony, from the other relevant institutions. By mutual agreement, the joint Research Misconduct Proceeding may include committee members from the institutions involved. The determination of whether further Inquiry and/or Investigation is warranted, whether Research Misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.

3.13 Allegations

3.13.1 Any Member of VAI or other Person who reports an Allegation should promptly contact their supervisor, contact the RIO, make a report through Ethics Point at www.vai.ethicspoint.com, or use any other reasonable means for ensuring a VAI Official is made aware of the Allegation.

3.13.2 Allegations should be supported by Evidence.

3.13.3 Concerns expressed as part of an Allegation may not rise to the level of Research Misconduct and therefore should be handled outside of a formal Research Misconduct Proceeding.

3.13.4 Allegations must be made in Good Faith.

3.14 Preliminary Assessment

3.14.1 The RIO shall notify the DO and the GC upon receipt of the Allegations.

3.14.2 In the event of an Allegation, the RIO shall promptly conduct a Preliminary Assessment to determine whether an Inquiry is warranted. In general, Preliminary Assessments will be finalized within twenty one (21) Days.

3.14.3 The Preliminary Assessment is a screening process with the purpose of culling out a clearly erroneous, unsubstantiated, or Bad Faith Allegation before the Respondent is subjected to an Inquiry or an Investigation. Hence, in conducting the Preliminary Assessment, the RIO is not obligated to conduct any interviews on the Allegation or to engage in an exhaustive review of the Evidence relevant to such Allegation. However, should testimony be obtained during a Preliminary Assessment, it shall be obtained from Complainants, Respondents, Witnesses or other involved parties through private interviews rather than through a formal Inquiry process.

3.14.4 Any Evidence brought forward by Complainants, Respondents, Witnesses or others during the Preliminary Assessment will be appropriately sequestered, as provided in Section 3.13.4.

3.14.5 The RIO shall determine that an Inquiry is warranted if, in their judgment the Allegation:

3.14.5.1 Falls within the definition of Research Misconduct in this policy;

3.14.5.2 Is within the applicability criteria of Section 2.0; and

3.14.5.3 Is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

3.14.6 The RIO shall prepare a written Preliminary Assessment documenting their assessment and the basis for their determination of whether an Inquiry is warranted, and shall transmit copies of the written Preliminary Assessment to the DO.

3.14.7 If the RIO determines that an Inquiry is not warranted, the RIO shall keep sufficiently detailed documentation of the Preliminary Assessment to permit a later review by ORI of the reasons why VAI did not conduct an Inquiry. The RIO may also, as deemed appropriate by the DO, share a summary of the Preliminary Assessment with the Complainant. The determination that an Inquiry is not warranted shall conclude VAI's review of that Allegation.

3.14.8 If the RIO determines that an Inquiry is warranted, the procedures in Section 3.13 shall be followed.

3.14.9 If the RIO concludes that the Complainant acted in Bad Faith in making the Allegation, or that the Complainant or any Witness acted in Bad Faith during the Preliminary Assessment, the RIO shall refer the matter for administrative review and appropriate action as set forth in Section 3.17 of this policy.

3.15 Inquiry

3.15.1 Unless circumstances prevent otherwise (e.g., an unresolvable conflict), the Inquiry shall be conducted by the RIO with the caveat that if needed, the RIO may shall secure for the Inquiry such special scientific or technical assistance (including subject matter experts) as they may require to evaluate an Allegation, provided any individuals providing such assistance do not have any unresolved personal, professional, or financial conflicts of interest with the Complainant, Respondent, or Witnesses.

3.15.2 Before the Inquiry begins, the RIO and the GC shall brief any other persons assisting in the conduct of the Inquiry on (a) this policy, (b) other relevant VAI requirements, and (c) legal and procedural issues that may likely be encountered in conducting the Inquiry.

3.15.3 Where multiple institutions have agreed to conduct a joint Research Misconduct Proceeding, it shall be conducted consistent with Section 3.10.3.

3.15.4 Either before or when the Respondent is notified of the Allegation, all reasonable and practical steps will be taken to obtain, inventory, and securely sequester any Research Records and Evidence needed to conduct the proceeding.

3.15.4.1 Where the Research Records or Evidence are located on or encompass scientific instruments shared by multiple users, copies of the data or Evidence from such instruments may be obtained instead, so long as those copies are substantially equivalent in evidentiary value.

3.15.4.2 The RIO has the right and institutional authority to sequester any Research Record or Evidence they deem may be pertinent to a Research Misconduct Proceeding.

3.15.4.3 The RIO shall assemble a team of relevant VAI personnel to sequester the Evidence.

3.15.4.4 Any Evidence brought forward by Complainants, Respondents, Witnesses or others during the Inquiry or later will be appropriately sequestered.

3.15.5 At the time of an Inquiry, but no sooner than after the Sequestration of Evidence, the RIO will make a Good Faith effort to notify in writing the Respondent of the Allegation that an Inquiry is proceeding. If the Inquiry subsequently identifies additional Respondents, they must be notified in writing. Only Allegations specific to a particular Respondent are to be included in the notification to that Respondent. If additional Allegations are raised, the Respondent(s) must be notified in writing of the additional Allegations raised against them.

3.15.6 If it is determined that an Inquiry is warranted, the DO, with the assistance of the RIO, shall draft a charge that:

3.15.6.1 Sets forth the timeline for completion of the Inquiry.

3.15.6.2 Briefly describes the Allegations and any related issues identified during the Preliminary Assessment.

3.15.6.3 States that the purpose of the Inquiry is to conduct an initial review of the Evidence, including any testimony of the Respondent, Complainant and key Witnesses, to determine whether an Investigation is warranted.

3.15.6.4 States that the Respondent, Complainant and key Witnesses may be interviewed during the Inquiry, but such interviews are not required, nor are transcripts of any interviews conducted during the Inquiry.

3.15.6.5 States that an Inquiry does not require a full review of the Evidence related to the Allegation, nor is it intended to determine whether Research Misconduct occurred or who was responsible.

3.15.6.6 States that an Investigation is warranted if the Inquiry reveals: (a) there is a reasonable basis for concluding that the Allegation falls within the definition of Research Misconduct; and (b) the Allegation may have substance.

3.15.6.7 States that the RIO is responsible for preparing or directing the preparation of a written report of the Inquiry that meets the requirements of this policy.

3.15.7 Like the Preliminary Assessment, the Inquiry is a preliminary process. Its purpose is to cull out an insufficiently substantiated, erroneous, or Bad Faith Allegation before the Respondent is subjected to an Investigation. Although it is expected that the Inquiry will be more comprehensive than the Preliminary Assessment, the RIO is not obligated to conduct any interview on the Allegation or to engage in an exhaustive review of all Evidence relevant to the Allegation.

3.15.8 The scope of the Inquiry shall not include deciding whether Research Misconduct occurred or who committed the Research Misconduct or conducting exhaustive interviews and analyses.

3.15.9 The RIO may at their discretion interview the Complainant, the Respondent, and Witnesses.

3.15.10 The RIO will examine relevant Research Records and Evidence and based on such examination recommend whether an Investigation is warranted. An Investigation shall be recommended if there is (a) a reasonable basis for concluding the Allegation falls within the definition of Research Misconduct, and (b) preliminary information-gathering and fact-finding from the Inquiry indicates that the Allegation has substance.

3.15.11 The Inquiry shall be completed within ninety (90) Days of its inception unless circumstances warrant a longer period, in which case the RIO shall notify the DO of the reason for the delay and the date on which the Inquiry is expected to be completed. The DO shall decide whether the delay is warranted. If warranted, the RIO shall notify the Respondent. If the DO finds the delay unwarranted, the RIO shall work to expedite completion of the Inquiry, but the Inquiry shall continue until its completion if, despite their diligent efforts, it cannot be finished in ninety (90) Days. The RIO shall make the report about the delay as part of the Research Misconduct Proceeding Records.

3.15.12 Inquiry Report Content. At the conclusion of the Inquiry, the RIO shall prepare an Inquiry Report containing the following information:

3.15.12.1 The names, professional aliases, and positions of the Respondent and Complainant;

3.15.12.2 A description of the Allegation of Research Misconduct;

3.15.12.3 Any involved sponsored funding (e.g., grant numbers, grant applications, contracts) and/or publications;

3.15.12.4 The composition of the Inquiry committee, if used, and the name(s), position(s), and subject matter expertise of individuals who assisted the RIO with the Inquiry;

3.15.12.5 An inventory of sequestered Research Records and other Evidence and a description of how sequestration was conducted;

3.15.12.6 Transcripts of any transcribed interviews;

3.15.12.7 The timeline and procedural history, including any delays and the reasons for such delays;

3.15.12.8 Any scientific or forensic analyses conducted;

3.15.12.9 The basis for recommending that the Allegation(s) warrants an Investigation;

3.15.12.10 The basis on which any Allegation(s) do not merit an Investigation;

3.15.12.11 Any potential evidence of honest error or difference of opinion;

3.15.12.12 If the alleged Research Misconduct involves a Detrimental Research Practice, Evidence of such practice and an analysis of the Allegation, in light of such practice; and

3.15.12.13 Any comments on the Inquiry report by the Respondent, as described in Section 3.13.13.

3.15.13 The RIO shall send the Respondent a copy of the draft Inquiry Report (excluding any content identifying the Complainant or Witnesses) along with a copy of 42 CFR Part 93 and this policy. The Respondent may return comments on the draft Inquiry Report to the RIO within seven (7) Days of receipt. If the Respondent comments on the draft Inquiry Report, the RIO shall consider such comments and make any changes in the Inquiry Report they deem appropriate, in light of such comments. The Respondent's comments shall be included as an appendix to the final Inquiry Report.

3.15.14 After making any changes they deem appropriate in the draft Inquiry Report in light of the Respondent's comments, the RIO shall prepare a final draft of the Inquiry Report. The RIO shall send the DO a copy of the final draft of the Inquiry Report, attaching any RIO comments regarding procedural questions and concerns. If the DO, with advice from the GC, finds that the final draft Inquiry Report reflects procedural error by the RIO, the DO will submit an opinion to the RIO within fourteen (14) Days after receiving the final draft report identifying and explaining the RIO's procedural error. The RIO shall either correct the error before completing the Inquiry Report or notify the DO in the final Inquiry Report that they do not believe a procedural error occurred. If issued, the opinion by the DO, shall be included as an appendix to the final Inquiry Report.

3.15.15 Following receipt of the final Inquiry Report, the DO shall prepare a written determination as to whether an Investigation is warranted. The DO may request the assistance of the RIO in the preparation of the determination but shall independently determine whether an Investigation is warranted. The Inquiry is complete when the DO makes this determination.

3.15.16 If the DO determines that an Investigation is not warranted, the written determination shall include a detailed statement of (a) why the Respondent's alleged conduct does not fall within the definition of Research Misconduct, and/or (b) how preliminary information-gathering and fact-finding from the Inquiry indicate that the Allegation does not have substance. The Inquiry report and the DO's written determination must be sufficiently detailed to permit a later assessment by ORI of the reasons why VAI decided not to conduct an Investigation. Such documentation must be retained in accordance with Section 3.19.1.

If the DO determines that an Investigation is not warranted, the distribution of the final Inquiry report and the DO's determination will conclude VAI's review of the Allegation, except as provided in Section 3.16.7.

3.15.17 If the DO determines that an Investigation is warranted, the written determination may be summary in nature, provided that the DO sets forth the Evidence that supports their determination in sufficient detail for the Respondent to understand the basis for the DO's decision.

3.15.18 Distribution of Final Inquiry Report and DO Determination. Within a reasonable amount of time from deciding to conduct an Investigation, the RIO shall send the Respondent a copy of the final Inquiry Report, the determination of the DO, and any new Allegations of Research Misconduct not addressed during the Preliminary Assessment or Inquiry or in the initial notice of Investigation. If an Investigation is warranted, these materials will be distributed prior to the initiation of the Investigation.

3.15.19 After completion of the Inquiry, the RIO may at their discretion notify the Complainant of the outcome of the Inquiry and provide the Complainant with a summary of the Inquiry Report and the determination of the DO. If one Complainant in a case receives such notice, the RIO must provide notice, to the extent possible, to all Complainants in the case.

3.15.20 If the DO concludes that the Complainant acted in Bad Faith in making the Allegation, or that the Complainant or any Witness acted in Bad Faith during the Inquiry, the DO shall refer the matter for administrative review and appropriate action, as set forth in Section 3.17.

3.16 Investigation

3.16.1 If the DO decides that an Allegation warrants an Investigation, the DO shall initiate the Investigation within thirty (30) Days of the decision to do so. If the Allegations involve federally funded research such as that subject to 42 CFR 93 (PHS), 45 CFR 689 (NSF), 14 CFR 1275 (NASA), and 2 CFR 422 (USDA), the DO must notify the federal agency or agencies (e.g., ORI ***and*** NIH) on or before the date the Investigation begins and provide a copy of the Inquiry Report and any other information required by the agency (e.g., the existence of exigent/special circumstances described in Section 3.9 and institutional actions implemented, including communications with journals or funding agencies).

3.16.2 If additional respondents are identified during the Investigation, VAI may but is not required to conduct a separate Inquiry for each new Respondent. If any additional Respondent(s) are identified during the Investigation, VAI must notify them of the Allegation(s) and provide them an opportunity to respond consistent with this policy.

3.16.3 While an Investigation into multiple Respondents can convene with the same Investigation committee members, separate Investigation reports and Research Misconduct determinations are required for each Respondent.

3.16.4 A Research Misconduct Proceeding involving multiple institutions must be conducted consistent with Section 3.10.3.

3.16.5 The DO shall appoint a Research Misconduct Committee comprised of VAI faculty and others, as described below, with consideration of potential personal, professional or financial Conflicts of Interest. The DO will confer with the RIO and others, as appropriate, to ensure that those serving on the Research Misconduct Committee can be impartial, unbiased and capable of dealing with the Allegation. The

Research Misconduct Committee may also include entities or individuals not affiliated with VAI (e.g., consortia, non-VAI scientists) when the DO determines that such entities or individuals have experience or expertise useful to the Research Misconduct Proceeding and the RIO confirms there are no potential, perceived, or actual personal, professional, or financial conflicts of interest between members of the committee or consortium, or other person, and the Complainant, Respondent, or Witnesses. The DO shall select one of the members to act as the Research Misconduct Committee Chair.

3.16.5.1 In the event that the DO is a Respondent, the GC will appoint the members of the Research Misconduct Committee comprised of suitable and qualified members, internal or external to VAI, who have no Conflicts of Interest.

3.16.5.2 The RIO shall secure for the Investigation such special scientific or technical assistance as the Research Misconduct Committee may request to evaluate an Allegation, provided any individuals who provide assistance to the committee do not have any unresolved personal, professional, or financial conflicts of interest with the Complainant, Respondent, or Witnesses.

3.16.6 In the course of the Investigation, the Research Misconduct Committee will:

3.16.6.1 Use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all Research Records and Evidence relevant to reaching a decision on the merits of each Allegation.

3.16.6.2 Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical.

3.16.6.3 Interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including Witnesses identified by the Respondent, and record and transcribe each interview.

3.16.6.4 Ensure the Respondent is not present during Complainant or Witness interviews but receives a transcript of the interviews.

3.16.6.5 Number any exhibits shown to an interviewee during an interview and referred the exhibits by their number in the interview.

3.16.6.6 Make the transcript of any interview available to the relevant interviewee for correction.

3.16.6.7 Include interview transcript(s) with any corrections and numbered exhibits in the institutional record of the Investigation.

3.16.6.8 Pursue diligently all significant issues and leads that are determined relevant to the Investigation, including any Evidence of any additional instances of possible Research Misconduct, and continue the Investigation to completion.

3.16.6.9 Consider the prospect of additional researchers being responsible for the alleged Research Misconduct.

3.16.6.10 If additional Allegations are raised, inform the RIO so that the Respondent(s) may be informed in writing of the additional Allegations raised against them.

3.16.7 The RIO or DO shall issue notifications to the following prior to initiation of the Investigation:

3.16.7.1 The GC.

3.16.7.2 The Respondent, as required in Section 3.13.18.

3.16.7.3 Any relevant federal agencies, as stipulated in Section 3.14.1

3.16.7.4 Any relevant non-federal sponsor

3.16.8 The DO, with the assistance of the RIO, shall draft a charge to the Research Misconduct Committee based on the Inquiry Report and the determination of the DO. The RIO shall submit the charge, the Preliminary Assessment referral, the Inquiry Report, and the determination of the DO to the Research Misconduct Committee and the Respondent at the beginning of the Investigation. The charge shall:

3.16.8.1 Describe the Allegations and related issues identified during the Inquiry.

3.16.8.2 Identify the Respondent.

3.16.8.3 Inform the committee that it must conduct the investigation as prescribed in Section 3.14.6.

3.16.8.4 Define research misconduct.

3.16.8.5 Clarify that the purpose of the Investigation is to develop a factual record by exploring the Allegations in detail and examining the Evidence and testimony in depth, leading to recommended findings on whether Research Misconduct has been committed, and if so, what kind, by whom, where, and to what extent.

3.16.8.6 Task the Research Misconduct Committee with determining whether there are additional instances of possible Research Misconduct that would justify broadening the scope beyond the initial Allegations.

3.16.8.7 State the Standards for a finding of Research Misconduct, i.e., in order to determine that the Respondent committed Research Misconduct the Research Misconduct Committee must find that a Preponderance of the Evidence establishes: (a) Research Misconduct, as defined in this policy, occurred (noting however that 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, evidence to which VAI shall give due consideration if Respondent's evidence is admissible and credible); (b) the Research Misconduct is a Significant Departure from Accepted Practices of the Relevant Research Community; and (c) the Respondent committed the Research Misconduct Intentionally, Knowingly, or Recklessly.

3.16.8.8 Inform the Research Misconduct Committee that it must prepare or direct the preparation of a written Investigation report that meets the requirements of this policy.

3.16.9 Before the Investigation begins, the GC and the RIO shall brief the Research Misconduct Committee on the charge, the Inquiry Report, the prescribed procedures and standards for the conduct of the Investigation (including the necessity for confidentiality and for developing a specific investigation plan), this policy, other relevant VAI regulations, and legal and procedural issues that the Research Misconduct Committee is likely to encounter in conducting the Investigation.

3.16.10 While the RIO may not participate in the deliberations of the Research Misconduct Committee, the Research Misconduct Committee may request the assistance of the RIO and seek counsel from the GC during its deliberations and in the preparation of the Investigation Report.

3.16.11 Any Research Records or Evidence brought forward by Complainants, Respondents, Witnesses or others during the Investigation will be appropriately sequestered, consistent with Section 3.13.4. The need for additional sequestration may occur for any number of reasons, including VAI's decision to investigate additional Allegations not considered during the Inquiry 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.

3.16.12 The Research Misconduct Committee shall examine the Evidence that it deems pertinent to the Allegation. Research Misconduct Committee requests to review Evidence shall be made to and managed by the RIO. At its discretion, the Research Misconduct Committee may also inspect laboratories and examine laboratory specimens, materials, procedures, and methods. The Respondent will be provided copies of, or supervised access to, Evidence made available to the Research Misconduct Committee.

3.16.13 Communication with Involved Parties. Research Misconduct Committee communication with Complainants, Respondents, Witnesses and other involved Persons will be made through and managed by the RIO.

3.16.14 The Research Misconduct Committee shall interview the Complainant, the Respondent, and other Persons, if any, who have material information regarding the Allegation.

3.16.14.1 Each interview shall be recorded and transcribed following the requirements of Section 3.14.6.

3.16.14.2 Each transcript shall be sent to the interviewee for comment or correction.

3.16.14.3 The interviewee shall have seven (7) Days after receipt of the transcript to submit comments on and correction of any errors in the transcript to the RIO.

3.16.14.4 Both the transcript and any such comments and corrections shall be made part of the Research Misconduct Proceeding Records.

3.16.14.5 The RIO shall give the Respondent a copy of the corrected transcript of all interviews.

3.16.15 The work of the Research Misconduct Committee (including conducting the investigation, preparing the draft Investigation report for each respondent, providing the draft report to each respondent for comment, and transmitting the institutional record including the final Investigation report and decision by the DO to ORI) shall be completed within one hundred eighty (180) Days of the initiation of the Investigation, or a request for an extension shall be made.

3.16.16 If the work of the Research Misconduct Committee cannot be completed within 180 Days of the initiation of the Investigation, the Research Misconduct Committee Chair or the RIO may request an extension from the DO, in which event the RIO shall notify the Respondent of the reason for the delay and the date on which the Investigation is expected to be completed. The report about the delay shall be included in the Research Misconduct Proceeding Records. If the alleged Research Misconduct involves research supported by a federal funding source, the RIO shall:

3.16.16.1 Notify the appropriate agency of the delay;

3.16.16.2 Request an extension; and

3.16.16.3 Explain the circumstances or issues warranting additional time.

3.16.17 The Research Misconduct Committee shall prepare a written Investigation Report that reflects the perspectives of all members of the Committee. It shall include:

3.16.17.1 A description of the nature of the Allegations of Research Misconduct, including any additional Allegations addressed during the Research Misconduct Proceeding.

3.16.17.2 The name, degree(s) and position(s) of the Respondent.

3.16.17.3 The Respondent's relevant sources of research support, including applications, grant number, contracts, and publications listing the support.

3.16.17.4 A description of the specific Allegations of Research Misconduct for consideration in the Investigation.

3.16.17.5 The composition of the Investigation committee, including name(s), position(s), and subject matter expertise.

3.16.17.6 The name of the Complainant, if known and not held in confidence.

3.16.17.7 An inventory of sequestered Research Records and Evidence, including manuscripts and funding proposals, except for Research Records not considered or relied on.

3.16.17.8 A description of how any sequestration was conducted during the Investigation.

3.16.17.9 A transcript of each interview conducted during the Investigation.

3.16.17.10 Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), funding applications, progress reports, presentations, posters, or other Research Records that allegedly contained Falsified, Fabricated, or Plagiarized material.

3.16.17.11 Any scientific or forensic analyses conducted.

3.16.17.12 Any comments made by the Respondent and Complainant on the draft Investigation report (as provided for in Section 3.14.21 and 3.14.22) and the Investigation committee's consideration of those comments.

3.16.17.13 A statement for each separate Allegation of whether the Investigation committee recommends a finding of Research Misconduct.

3.16.17.14 If applicable, the reasons for exceeding the 180-Day period for completing the Investigation.

3.16.17.15 A copy of the charge to the Research Misconduct Committee, this policy and any other VAI policies and procedures relevant to the Investigation.

3.16.18 For each Allegation the Investigation committee recommends a finding of Research Misconduct, the report shall:

3.16.18.1 Identify the individual(s) who committed the Research Misconduct.

3.16.18.2 Indicate whether the Research Misconduct was Falsification, Fabrication, and/or Plagiarism.

3.16.18.3 Indicate whether the Research Misconduct was committed Intentionally, Knowingly, or Recklessly.

3.16.18.4 State whether the Research Misconduct was a significant departure from Accepted Practices of the Relevant Research Community.

3.16.18.5 State whether the Research Misconduct was proven by a Preponderance of the Evidence.

3.16.18.6 Summarize the facts and the analysis which support the conclusion and consider the merits of any explanation by the Respondent.

3.16.18.7 Identify the relevant sources of the Respondent’s research support, including, for example, grant numbers, grant applications, and contracts.

3.16.18.8 Identify any publications or other parts of the public research record (e.g., protein structures or gene sequences in public repositories) needing correction or retraction.

3.16.18.9 List any current support or known applications or proposals for support that the Respondent has pending.

3.16.19 For each Allegation the Investigation committee does not recommend a finding of Research Misconduct, the report shall provide a detailed rationale.

3.16.20 If an Investigation determines that an Allegation was of a Detrimental Research Practice, the Investigation Report shall include a description of the Evidence regarding the Detrimental Research Practice and an analysis of the Allegation in light of such practices.

3.16.21 The RIO shall send the Respondent a copy of the draft Investigation Report and, concurrently, a copy of, or supervised access to the Research Record and Evidence that the Investigation committee considered or relied on. The Respondent may return comments on the draft Investigation Report to the RIO within thirty (30) Days of receiving the draft Investigation report. If the Respondent comments on the draft Investigation Report, the Research Misconduct Committee shall consider such comments and make any changes in the Investigation Report it deems appropriate in light of such comments. The Respondent's comments shall be included as an appendix to the final Investigation Report.

3.16.22 The RIO may at their discretion provide the Complainant a copy of the draft Investigation report or relevant portions of that report. The comments of the Complainant, if any, must be submitted to the RIO within thirty (30) Days of the date on which the Complainant received the draft investigation report or relevant portions of it.

3.16.23 In distributing the draft report, the RIO will inform the Respondent and the Complainant (if applicable) of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality.

3.16.24 In light of the Respondent's and/or Complainant's comments made to the draft Investigation Report, the Research Misconduct Committee will make changes they deem appropriate and include the written comments as part of a final draft Investigation Report. The RIO shall send the DO a copy of the final draft of the Investigation Report, attaching any RIO comments regarding procedural questions and concerns. If the DO, with advice from the GC, finds that the final draft Investigation Report reflects procedural error by the Research Misconduct Committee, within fourteen (14) Days after receiving the final draft report, the DO will inform the RIO and submit an opinion to the RIO and the Research Misconduct

Committee. This opinion will identify and explain the Research Misconduct Committee's procedural error. The Research Misconduct Committee shall either correct the error before completing the Investigation Report or notify the DO in the final Investigation Report that it does not believe a procedural error occurred. If issued, the opinion by the DO, shall be included as an appendix to the final Investigation Report.

3.16.25 Following delivery of the final Investigation Report to the DO, the DO shall prepare a written determination as to (a) whether Research Misconduct was found and, if so, who committed the Research Misconduct, and (b) the relevant institutional actions taken or to be taken. The DO may request the assistance of the RIO in the preparation of the determination, but shall not seek the RIO's opinion as to whether Research Misconduct occurred.

3.16.25.1 If the DO's determination varies from the findings of the Investigation Committee, the DO will, as part of their written determination, explain in detail the basis for rendering a decision different from the findings of the Investigation Committee.

3.16.25.2 If the DO finds that Research Misconduct occurred, the written determination by the DO must include statements that: (a) there was a Significant Departure from Accepted Practices of the Relevant Research Community; (b) the Research Misconduct was committed Intentionally, Knowingly, or Recklessly; and (c) the Allegation was proven by a Preponderance of the Evidence.

3.16.25.3 If the DO does not find that Research Misconduct occurred, the DO shall explain the reasons for their decision in the written determination, with specific reference to the pertinent criteria set forth in Sections 3.3 and 3.4.

3.16.25.4 If the DO concludes that the Complainant acted in Bad Faith in making the Allegation, or that the Complainant or any Witness acted in Bad Faith during the Research Misconduct Proceeding, the DO shall refer the matter for administrative review and appropriate action as set forth in Section 3.17.

3.16.26 The following notifications will be issued after completion of the Investigation:

3.16.26.1 The DO shall promptly notify the Respondent of its outcome and provide the Respondent with a copy of the Institutional Record.

3.16.26.2 The RIO shall notify the Complainant of its outcome and provide the Complainant with a brief summary of the Investigation Report and the DO's determination regarding Research Misconduct, including those portions of the Investigation Report and the DO's determination that address the Complainant's role and testimony, if any, in the Investigation.

3.16.26.3 When the alleged Research Misconduct involves research supported by a federal funding source, the RIO shall submit the Institutional Record, including the Investigation Report and all attachments, the DO's written determination regarding Research Misconduct to the federal funding source (e.g., NIH) and any other federal regulatory body (e.g., ORI). The notification shall state whether VAI accepts the Investigation’s findings and describe any pending or completed administrative actions against the Respondent.

3.16.26.4 When the alleged Research Misconduct involves research supported by a non-federal funding source, the RIO shall notify the non-federal sponsor of the outcome of the Investigation promptly after the completion of the Investigation and as well as a brief summary of the Investigation Report, the DO's determination regarding Research Misconduct, and other information, if any, as it may request in response to the RIO's notification. VAI will honor the requirements of the funding agency.

3.16.27 The DO will determine in consultation with the GC 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.

3.17 External Appeal

3.17.1 A Respondent who has applied for or received support from a federal funding source for the research to which the Research Misconduct occurred may have the right under federal agency regulations to appeal the DO’s Research Misconduct finding, as part of an Investigation to that federal funding source.

3.17.2 If the Respondent appeals a finding of Research Misconduct by the DO as part of an Investigation to/by a federal funding source, the RIO shall attempt to obtain copies of any document filed in that appeal to keep informed of the situation/case.

3.17.3 If the RIO learns of previously unavailable Evidence relevant to the finding of Research Misconduct during the external appeal, the RIO shall inform the federal agency, DO and the Respondent of the new Evidence.

3.18 Final Resolution and Outcome

3.18.1 If the Preliminary Assessment results in a determination that an Inquiry is not warranted, or if the DO decides, as part of an Inquiry, that an Investigation is not warranted, or if the DO does not find, as part of an Investigation, that Research Misconduct has occurred, or if a finding of Research Misconduct is reversed on external appeal, the DO and other relevant VAI Officials shall, if requested and as appropriate, endeavor to protect and restore the Respondent's reputation to the extent these efforts:

3.18.1.1 Are reasonable and practicable under the circumstances;

3.18.1.2 Are consistent with applicable federal funding source expectations, if the research that was the subject of the Allegation was supported by that federal funding source; and,

3.18.1.3 Do not affect VAI's ability to take action against the Respondent for Detrimental Research Practices which come to VAI's attention as a result of the review of the Allegation under this policy.

Depending on the particular circumstances and the views of the Respondent, the DO may choose to notify those individuals aware of or involved in the Investigation of the final outcome, publicize the final outcome in any forum in which the Allegation of Research Misconduct was previously publicized, and expunge references to the Research Misconduct Allegation from the Respondent's personnel file.

3.18.2 When there is a final decision that Research Misconduct has occurred, the DO shall take appropriate actions in response to the finding of Research Misconduct. Such actions may include:

3.18.2.1 Imposing sanctions within the authority of the DO and initiating VAI disciplinary proceedings appropriate to the finding of Research Misconduct pursuant to applicable VAI policies, procedures, and contracts, or

3.18.2.2 Referring the finding of Research Misconduct to another supervisor or administrator who has authority to impose sanctions and initiate disciplinary proceedings.

3.18.2.3 Correcting and/or seeking retraction of any part of the research record affected by the Research Misconduct based on the findings of the Investigation. This includes the responsibility to notify and follow-up with publishers to ensure that necessary steps were taken to correct or retract any results of the research that were affected by the Research Misconduct. The Respondent will not interfere with the RIO's efforts in this regard.

3.18.2.4 Imposing disciplinary action pursuant to applicable VAI policies, procedures, and contracts.

3.18.2.5 Revoking a VAI Graduate School degree.

3.18.3 If the DO terminates the review of any Allegation, an explanation for such termination shall be included in the Research Misconduct Proceeding Records.

3.18.4 During an Inquiry, the DO may find that, while a Respondent's conduct does not warrant an Investigation, it nevertheless constitutes a Detrimental Research Practice. Similarly, during an Investigation, the DO may find that, while a Respondent's conduct does not constitute Research Misconduct, it constitutes a Detrimental Research Practice. Any such finding shall be referred to the appropriate supervisor or VAI Official for review. The supervisor or official may deem further action appropriate, including disciplinary action pursuant to applicable VAI policies, procedures, and contracts.

Detrimental Research Practices may also be discovered in circumstances other than a review of an Allegation under this policy. When that happens, the alleged Detrimental Research Practice should be referred to the appropriate supervisor or VAI Official for review and further action, if any, as the supervisor or official may deem appropriate, including, disciplinary action pursuant to applicable VAI policies, procedures, and contracts.

A determination that conduct constitutes a Detrimental Research Practice does not preclude, replace, or substitute for a finding of Research Misconduct where the criteria for Research Misconduct under 42 CFR Part 93 are met. Where an Allegation involves research supported by the Public Health Service, VAI shall ensure that conduct meeting the definition and evidentiary standards for Research Misconduct is addressed and reported as such, regardless of whether additional institutional findings or corrective actions related to Detrimental Research Practices are also pursued.

3.18.5 Generally, all Inquiries and Investigations will be carried through to completion and all significant issues and credible Allegations will be pursued diligently. The RIO must notify federal sponsors or regulatory bodies in advance if there are plans to close a case at the Inquiry, Investigation, or external appeal stage on the basis that the Respondent has admitted guilt or a settlement with the Respondent has been reached.

A Respondent's admission of Research Misconduct must be made in writing and signed by the Respondent. An admission must specify the Falsification, Fabrication, and/or Plagiarism that occurred and which Research Records were affected. The admission statement must meet all elements required for a research misconduct finding under § 93.103 and must be provided to ORI before VAI closes its Research Misconduct Proceeding. The DO must also provide a statement to ORI describing how they determined that the scope of the Research Misconduct was fully addressed by the admission and confirmed the Respondent's culpability.

Restrictions on Early Closure of PHS-Related Cases

For Allegations involving research supported by the Public Health Service, VAI shall not close a Research Misconduct Proceeding at the Preliminary Assessment, Inquiry, Investigation, or settlement stage based solely on an admission, resignation, or other resolution without first satisfying all applicable reporting and documentation requirements under 42 CFR Part 93 and, where required, obtaining ORI concurrence

3.18.6 The termination of the Respondent's employment with VAI, 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 federal policy.

If the Respondent, without admitting to Research Misconduct, elects to resign their position after VAI receives an allegation of Research Misconduct, the assessment of the Allegation will proceed, as well as the Inquiry and Investigation, as appropriate based on the outcome of the preceding steps. If the Respondent refuses to participate in the process after resignation, the RIO and Research Misconduct Committee will use their best efforts to reach a conclusion concerning the Allegations, noting in the report the Respondent's failure to cooperate and its effect on the proceeding.

3.18.7 If, following the conclusion of a Research Misconduct Proceeding, any participant in the proceeding discovers or learns of previously unavailable Evidence relevant to the findings of the original proceeding, said Evidence shall be forwarded to the RIO with an explanation of its origin and importance. The RIO shall submit the new Evidence to the DO. The DO shall promptly consider the new Evidence and notify the GC of its impact, if any, on the findings of the Research Misconduct Proceedings. The DO may consult with the Research Misconduct Committee as needed. Based on the new Evidence and the information from the DO, the GC may affirm the previous finding of Research Misconduct or remand the matter to the DO to conduct a new Investigation in light of the new Evidence. The GC shall issue that decision with stated rationale within thirty (30) Days of receiving the notice from the DO but may extend this period for good cause by notice to the Respondent and the RIO.

3.19 Bad Faith

3.19.1 If the RIO or the DO concludes that a Complainant or Witness who is a VAI Member acted in Bad Faith in a Research Misconduct Proceeding, the matter shall be referred to the Vice President for Human Resources and the appropriate supervisor for review. Upon review, they may deem appropriate action, including disciplinary action pursuant to applicable VAI policies, procedures, and contracts.

3.19.2 If the DO receives a complaint or report that a Research Misconduct Committee member or the RIO did not act in Good Faith in carrying out their duties under these procedures, the DO will investigate the complaint or report, with advice from the GC, and in cooperation with the RIO, if the complaint or report is not against or about the RIO.

If the DO concludes that the individual about whom the complaint is made did not act in Good Faith in carrying out their duties under this policy, and that the failure to act in Good Faith had an adverse impact on any Research Misconduct Proceeding, the DO shall:

3.19.2.1 Take such action as may be necessary to preserve the integrity of the review of the Allegation, including, but not limited to, replacing the implicated individual and initiating new Research Misconduct Proceedings, and,

3.19.2.2 In the case of a VAI Member, refer the matter to the Vice President for Human Resources and the appropriate supervisor for review and such action, if any, as they may deem appropriate, including disciplinary action.

3.19.3 If any VAI Official receives a complaint or report that the DO did not act in Good Faith in carrying out their duties under these procedures, the GC will investigate the complaint or report. If the GC concludes that the DO did not act in Good Faith in carrying out their duties under this policy, the GC shall:

3.19.3.1 Take such action as may be necessary to preserve the integrity of the review of the Allegation, and

3.19.3.2 Refer the matter to VARI's Board of Trustees to appoint a special review committee and to take such action, if any, as the committee may deem appropriate, including disciplinary action.

3.20 Protecting Participants in Research Misconduct Proceedings

3.20.1 VAI shall make diligent efforts to protect the position and reputation of each individual who has, in Good Faith, participated in a Research Misconduct Proceeding as a Complainant, Witness, Research Misconduct Committee member, GC, sequestration team member, or RIO, or who has otherwise cooperated in the review of an Allegation under these Procedures. These efforts shall be:

3.20.1.1 Reasonable and practical under the circumstances;

3.20.1.2 Proportionate to the risk to the individual's position and reputation; and

3.20.1.3 Consistent with applicable funder expectations, if the research that was the subject of the Allegation was supported by a federal funding source.

3.20.2 VAI Members shall not engage in or threaten Retaliation. The RIO shall inform/remind all Complainants, Respondents and Witnesses of VAI's policy against Retaliation.

3.20.3 If the RIO receives a complaint or report of Retaliation or threatened Retaliation by a VAI Member, the RIO shall refer the matter to the Vice President of Human Resources for investigation and any potential action as may be deemed appropriate, including disciplinary action.

3.20.4 VAI shall make diligent efforts to provide protection against Retaliation for all individuals involved in a Research Misconduct Proceeding. These efforts shall be reasonable and practical under the circumstances. If the research that was the subject of the Allegation and that led to the Retaliation was supported by a federal funding source, efforts shall be consistent with the applicable funding source's expectations and requirements.

3.21 Other Responsibilities

3.21.1 Unless custody has been transferred to a federal agency or a federal agency has advised VAI in writing that it no longer needs to retain the records, the Institutional Record and all sequestered Evidence (including physical objects, regardless of whether the Evidence is part of the institutional record) in a secure manner for seven (7) years after completion of the proceeding or the completion of any federal proceeding involving the Allegation of Research Misconduct, whichever is later.

3.21.2 On request, VAI will transfer custody, or provide copies, to a Federal agency of the Institutional Record or any component of the Institutional Record and any sequestered Evidence (regardless of whether the Evidence is included in the institutional record) for the Federal agency to conduct its oversight review, develop its administrative record, or present its administrative record in any proceeding.

3.21.3 The CO will file an annual report with ORI, which contains information specified by ORI, on the VAI's compliance with this part. The CO is responsible for certifying the content of this report and for ensuring the report is submitted as required. The CO and all other VAI Officials shall send ORI such other information as ORI may request on VAI's Research Misconduct Proceedings and/or compliance with the requirements of Federal regulations.

4.0 DEFINITIONS

4.1 ACCEPTED PRACTICES OF THE RELEVANT RESEARCH COMMUNITY: Those practices established by 42 CFR part 93 and by PHS funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS awards. [42 CFR 93.200]

4.2 ALLEGATION: A disclosure of possible Research Misconduct through any means of communication and brought directly to the attention of a VAI Official. [42 CFR 93.203]

4.3 BAD FAITH: A material and demonstrable failure to meet the standards for Good Faith set forth herein as a Complainant, a Witness, a Research Misconduct Committee member, or Research Integrity Officer (RIO). The context in which actions have occurred is a relevant and important factor to be taken into account in determining whether an individual has acted in Bad Faith.

4.4 COMPLAINANT: A Person, who in Good Faith, makes an Allegation of Research Misconduct. A Complainant need not be a member of the VAI community. [42 CFR 93.206]

4.5 CONFLICT OF INTEREST: Any personal, professional, or financial relationship of an individual involved in a Research Misconduct Proceeding that influences, or reasonably could be perceived to influence, the impartial execution of the proceeding or the resolution of an Allegation.

4.6 DAY: A calendar day unless otherwise specified. If a deadline falls on a Saturday, Sunday, or Federal holiday, the deadline will be extended to the next day that is not a Saturday, Sunday, or Federal holiday. [42 CFR 93.208]

4.7 DETRIMENTAL RESEARCH PRACTICES: Practices that do not constitute Research Misconduct but require attention because they (a) violate applicable laws, regulations, or other governmental requirements, or VAI rules or policies, of which the Respondent had received notice or of which the Respondent reasonably should have been aware, for proposing, performing or reviewing research, or reporting research results, or (b) could erode confidence in the integrity of research.

4.8 EVIDENCE: Anything offered or obtained during a Research Misconduct Proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony. [42 CFR 93.210]

4.9 FABRICATION: Making up research data or results and recording or reporting them. [42 CFR 93.211]

4.10 FALSIFICATION: Manipulating research materials, equipment, or processes, or changing or omitting research data or results, such that research is not accurately represented in the research record. [42 CFR 93.212]

4.11 GOOD FAITH: As applied to a Complainant or Witness, a reasonable belief in the truth of one's Allegation or testimony based on the information known to the Complainant or Witness at the time. An Allegation or cooperation with a Research Misconduct Proceeding is not in Good Faith if made with knowledge of or reckless disregard for information that would negate the Allegation or testimony. Good Faith as applied to a Research Misconduct Committee member or the RIO, cooperating with the Research Misconduct Proceeding by impartially carrying out the duties assigned under these policies and procedures for the purpose of helping VAI meet its responsibilities under 42 CFR Part 93. A Research Misconduct Committee member or the RIO does not act in Good Faith if their acts or omissions during the Research Misconduct Proceeding are dishonest or influenced by personal, professional, or financial Conflict of Interests with those involved in the Research Misconduct Proceeding. [42 CFR 93.214]

4.12 INQUIRY: Preliminary information-gathering and preliminary fact-finding to determine whether an Allegation has sufficient substance to warrant an Investigation. [42 CFR 93.215]

4.13 INQUIRY REPORT: A report prepared by the Research Misconduct Committee that reflects the perspectives of all members of the committee.

4.14 INSTITUTIONAL CERTIFYING OFFICIAL (CO): The VAI Official responsible for assuring on behalf of VAI that it has written policies and procedures for addressing Allegations of Research Misconduct in compliance with Federal regulations; and that VAI complies with its own policies and procedures and the requirements of Federal regulations. The CO is responsible for certifying the content of VAI's annual report, which contains information specified by ORI on VAI's compliance with Federal regulations, and ensuring the report is submitted to ORI, as required. [42 CFR 93.217]

4.15 INSTITUTIONAL DECIDING OFFICIAL (DO): The VAI Official who makes final determinations on Allegations of Research Misconduct and any institutional administrative actions. The Deciding Official may not be the same individual as VAI's Research Integrity Officer. [42 CFR 93.218]

4.16 INSTITUTIONAL RECORD: (a) The records VAI compiled or generated during the Research Misconduct Proceeding, except records VAI did not consider or rely on, including, but are not limited to: (i) Documentation of the Preliminary Assessment; (ii) If an Inquiry is conducted, the Inquiry Report and all records (other than drafts of the report) considered or relied on during the Inquiry, including, but not limited to, Research Records and the transcripts of any transcribed interviews conducted during the Inquiry, information the respondent provided to VAI, and the documentation of any decision not to investigate; (iii) If an Investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the Investigation, including, but not limited to, Research Records, the transcripts of each interview conducted, and information the Respondent provided to VAI; (iv) Decision(s) by the Institutional Deciding Official. (b) A single index listing all the Research Records and Evidence VAI compiled during the Research Misconduct Proceeding, except records VAI did not consider or rely on. (c) A general description of the records that were sequestered but not considered or relied on. [42 CFR 93.220]

4.17 INTENTIONALLY: To act with the aim of carrying out the act. [42 CFR 93.221]

4.18 INVESTIGATION: 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. [42 CFR 93.222]

4.19 KNOWINGLY: To act with awareness of the act. [42 CFR 93.223]

4.20 MEMBER OF VAI (OR VAI MEMBER): Any Person who is employed by, is an agent of, or is affiliated by contract or agreement with Van Andel Research Institute and Van Andel Education Institute, collectively referred to as a "Member of VAI" (Van Andel Institute). VAI Members may include, but are not limited to, officials, faculty, joint faculty, adjunct faculty, teaching and support staff, researchers, research coordinators, technicians, postdoctoral and other fellows, students, guest workers, volunteers, subject matter experts, consultants, and attorneys/employees/agents of contractors, subcontractors, and subawardees. [42 CFR 93.219]

4.21 PERSON: Any individual, corporation, partnership, institution, association, unit of government, or legal entity, however organized. [42 CFR 93.226]

4.22 PLAGIARISM: The appropriation of another Person's ideas, processes, results, or words without giving appropriate credit. (a) Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology. (b) Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct. [42 CFR 93.227]

4.23 PRELIMINARY ASSESSMENT: A consideration of whether an Allegation of Research Misconduct appears to fall within the definition of Research Misconduct and is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified. The Preliminary Assessment only involves the review of readily accessible information relevant to the Allegation. [42 CFR 93.204]

4.24 PREPONDERANCE OF THE EVIDENCE: Proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more probably true than not. [42 CFR 93.228]

4.25 RECKLESSLY: To propose, perform, or review research, or report research results with indifference to a known risk of Fabrication, Falsification, or Plagiarism. [42 CFR 93.231]

4.26 RESEARCH: Systematic experimentation, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) by establishing, discovering, developing, elucidating, or confirming information or underlying mechanisms related to biological causes, functions, or effects; diseases; treatments; or related matters to be studied. [42 CFR 93.232]

4.27 RESEARCH INTEGRITY OFFICER (RIO): The VAI Member responsible for administering VAI's written policies and procedures for addressing Allegations of Research Misconduct in compliance with Federal regulations. [42 CFR 93.233]

4.28 RESEARCH MISCONDUCT: Fabrication, Falsification, or Plagiarism in proposing, performing or reviewing research, or in reporting research results. Research Misconduct does not include honest error or differences of opinion. [42 CFR 92.234]

4.29 RESEARCH MISCONDUCT PROCEEDING: Any actions related to alleged Research Misconduct, including but not limited to Preliminary Assessments, Inquiries, Investigations, and external appeals. [42 CFR 93.235]

4.30 RESEARCH RECORD: The record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles. [42 CFR 93.236]

4.31 RESPONDENT: The individual against whom an Allegation of Research Misconduct is directed or who is the subject of a Research Misconduct Proceeding. [42 CFR 93.237]

4.32 RETALIATION: An adverse action taken against a Complainant, Witness, or Research Misconduct Committee member by VAI or a Member of VAI in response to (a) a Good Faith Allegation of Research Misconduct, or (b) Good Faith Cooperation with a Research Misconduct Proceeding. [42 CFR 93.238]

4.33 SEQUESTRATION: The process of securing Evidence.

4.34 SIGNIFICANT DEPARTURE: A marked divergence from standard practices.

4.35 VAI OFFICIAL: An individual designated by VAI to perform functions under this policy.

4.36 WITNESS: A Person who sees or observes an event/events.

5.0 PERFORMANCE MATERIALS *(available on Research Protections and Support SharePoint site)*

5.1 Allegations and Preliminary Assessments

- 5.1.2 Allegation Intake Standard Operating Procedure ("SOP")
- 5.1.3 Allegation Intake Form
- 5.1.4 Authorship Disputes SOP
- 5.1.5 Preliminary Assessment Form
- 5.1.6 Six-Year Time Limitation and Subsequent Use Exception SOP

5.2 Inquiry

- 5.2.1 Referral of Allegations SOP
- 5.2.2 Conflict of Interest SOP
- 5.2.3 Conflict of Interest Form

5.3 Sequestration

- 5.3.1 Sequestration and Record Retention SOP
- 5.3.2 Evidence Sequestration Kit (see 6342 conference room storage)
- 5.3.3 Consent to Image or Access Research Records Form
- 5.3.4 Custody Data Transfer Form
- 5.3.5 Evidence Receipt Form
- 5.3.6 FERPA Release Form
- 5.3.7 Records Inventory Log
- 5.3.8 Sequestered Records Data Access Log

5.4 Resolution

- 5.4.1 Settlements and Admissions SOP
- 5.4.2 Retractions and Corrections SOP
- 5.4.3 Sanctions and Other Findings SOP

5.5 Sample letters, reports, training materials

6.0 HIGH LEVEL PROCEDURES

N/A

7.0 REFERENCES

7.1 42 FR Part 93, Public Health Services Policies on Research Misconduct, Final Rule, Sept. 17, 2024

8.0 HISTORY / REVISIONS FROM PREVIOUS VERSIONS

8.1	Original	January 29, 2003
8.2	Revision 1	July 29, 2007
8.3	Revision 2	December 22, 2010
8.4	Revision 3	July 20, 2016
8.5	Revision 4	August 17, 2016
8.6	Revision 5	February 1, 2023
8.7	Revision 6	December 4, 2023
8.8	Revision 7	April 29, 2025
8.9	Revision 8	December 31, 2025