SCIENTIFIC INTEGRITY

- 1. **REASON FOR ISSUE:** To establish Veterans Affairs (VA) policy to ensure the highest level of integrity in all aspects of VA's generation, communication and use of scientific findings and products and to instill confidence among Veterans and the broader public in VA research and other scientific endeavors and the policy-making decisions that are informed by such endeavors.
- 2. **SUMMARY OF CONTENTS:** This Directive sets forth policies and responsibilities for the preservation and promotion of scientific integrity in VA.
- 3. **RESPONSIBLE OFFICE:** The Veterans Health Administration (VHA) (10), Office of Discovery, Education and Affiliate Networks (DEAN) (14).
- 4. **RELATED HANDBOOK:** Not applicable.
- 5. **RESCISSION:** Not applicable.

CERTIFIED BY:

BY DIRECTION OF THE SECRETARY OF VETERANS AFFAIRS:

/s/ Guy T. Kiyokawa Assistant Secretary for Enterprise Integration

/s/ Dr. Carolyn M. Clancy Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks and VA Chief Science Officer

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SCIENTIFIC INTEGRITY

1. PURPOSE / AUTHORITY.

- a. This Department of Veterans Affairs (VA) Directive establishes policy to ensure the highest level of integrity in all aspects of VA's generation, communication and use of scientific findings and products. This Directive is intended to instill confidence among Veterans and the broader public in VA research and other scientific endeavors and the policy-making decisions that are informed by such endeavors, by articulating the values, principles and conduct necessary to uphold scientific integrity and the expectation that all VA employees, including career staff and political appointees, contractors, subcontractors, partners, and grantees, will adhere to these values and principles and conduct themselves accordingly.
- b. Scientific integrity extends well beyond the conduct of research and other scientific activities and applies to the communication of findings from scientific activities and the reliance on scientific findings and products to inform policy- and decision-making. As such, this Directive applies to all VA employees and appointees who engage in, supervise, manage and/or communicate on scientific activities and/or utilize information derived from such activities in policy- and decision-making. Further, this Directive applies to a broad spectrum of scientific endeavors including basic science, applied science, evaluation science, engineering, technology, economics, social sciences and statistics, and in the context of such endeavors, a broad range of activities including data collection, inventorying, monitoring, statistical analysis, surveying, research, economic analysis, forecasting, predictive analytics, modeling and technology development. (See Paragraphs 5.f and 5.g for the definitions of "science" and "scientific activities," respectively.)
- c. This Directive is issued in accordance and consistent with the Federal Policy on Research Misconduct, dated December 6, 2000, the Presidential Memorandum on Scientific Integrity, dated March 9, 2009, the Office of Science and Technology Policy (OSTP) Memorandum on Scientific Integrity, dated December 17, 2010, the Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, dated January 27, 2021, and the National Science and Technology Council Framework for Federal Scientific Integrity Policy and Practice, dated January 2023.
- 2. POLICY. VA's Core Values Integrity, Commitment, Advocacy, Respect and Excellence ("I CARE") serve as the foundation for VA employees' conduct when carrying out VA's mission. The adherence to VA's I CARE values and the principles of trustworthiness, objectivity and transparency derived therefrom when generating, communicating and/or using scientific findings and products, are essential for upholding scientific integrity. Consistent with the aforementioned application of these values and principles, it is the policy of the Department to:
 - a. Promote a culture of scientific integrity. Science and the public's trust in science thrives in an environment that shields scientific data and analyses and their use in

policymaking from political interference or inappropriate influence. Scientific findings and products must not be suppressed; delayed from release or altered for political purposes; and must not be subjected to inappropriate influence. (See Paragraphs 5.b and 5.c for the definitions of "inappropriate influence" and "political interference," respectively). Science and the public's trust in science also thrive when issues of diversity, equity, inclusion and accessibility are an integral component of the entire scientific process, including providing for more equitable participation in science by diverse communities.

NOTE: Information on efforts within VA to broaden science participation is publicly available at <u>The Office of Research and Development</u>.

- b. Select and retain candidates for scientific and technical positions at VA based on candidates' scientific and technical knowledge, credentials, experience and integrity, with appropriate consideration of diversity, equity and inclusion practices, and hold them and their supervisors to the highest standards of professional and scientific ethics.
- c. Require that VA scientists and others engaged in designing, conducting or otherwise engaging in scientific activities:
 - (1) Ensure the accuracy of scientific findings and products in accordance with established professional standards and practices and make reasonable efforts to correct identified inaccuracies that pertain to their contribution to a scientific product.
 - (2) Disclose any conflicts of interest to their supervisor or other appropriate agency official(s) for determination as to whether a recusal, disclaimer or other appropriate notification would be appropriate.
 - (3) Represent their contributions to scientific activities fairly and accurately and neither accept nor assume unauthorized and/or unwarranted credit for another's accomplishments.
 - (4) Disclose any invention made while employed at VA pursuant to <u>37 C.F.R. Part</u> <u>501</u>.

NOTE: Failure to make the aforementioned required disclosure in a timely manner may result in administrative action as described in applicable VA policy including, but not limited to, the applicable collective bargaining agreement, <u>VA</u> <u>Directive 5021</u>, <u>Employee/Management Relations and</u> its associated <u>Handbook and VA Handbook 5027</u>, <u>Senior Executive Service</u>. If development of the invention or research was conducted on Government time, or utilized government facilities, equipment, material, funds, information, or personnel, VA retains ownership rights to the invention. Additional VA-specific requirements and processes pertaining to inventions are outlined under <u>38 C.F.R. Part 1.650-1.663</u> and <u>VHA Directive 1200.18</u>, Determination of Rights for Inventions and <u>Discoveries</u>.

- d. Ensure the quality, accuracy and transparency of scientific information used to support policy- and decision-making, including to:
 - (1) Use scientific information that is derived from well-established and sound scientific processes.
 - (2) Ensure that scientific data and research used to support policy decisions undergo independent peer review by qualified experts, where feasible and appropriate and consistent with law and Federal governmentwide requirements and guidance, including the <u>Office of Management and Budget (OMB) Final</u> <u>Information Quality Bulletin for Peer Review, dated December 16, 2004.</u>

NOTE: VA policy and processes pertaining to peer review are addressed in <u>VA</u> <u>Directive 0009, Ensuring Quality of Information Disseminated by VA, dated</u> <u>June 3, 2019</u>.

(3) Reflect scientific information appropriately and accurately, consistent with <u>OMB</u> <u>Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and</u> <u>Integrity of Information Disseminated by Federal Agencies, dated February 22,</u> <u>2002, and OMB Memorandum M-19-15, Improving Implementation of the</u> <u>Information Quality Act, dated April 24, 2019.</u>

NOTE: VA policy and processes pertaining to the quality of information disseminated by VA and the correction of that information are addressed in \underline{VA} <u>Directive 0009</u>.

- (4) Make scientific findings and conclusions considered or relied upon in VA policy decisions publicly available online and in open formats, to the extent practicable, consistent with <u>U.S. Open Government Initiatives</u>, the Freedom of Information Act, the Administrative Procedure Act and other applicable statutes, regulations or document-handling procedures and policies. Where feasible and appropriate, the following will also be provided: information on the specific approach, data and models used to develop such scientific conclusions, including a clear explanation of underlying assumptions and uncertainties; and, where appropriate, probabilities associated with a range of projections or scenarios.
- e. Ensure that Federal Advisory Committees (FAC) tasked with providing scientific advice to VA are appointed and convened by VA in accordance with the <u>Federal Advisory Committee Act (FACA)</u> and implementing regulations (<u>41 C.F.R. Part 102-3</u>) from the General Services Administration, and the following:
 - (1) The recruitment process for new FAC members should be as transparent as practicable. When practicable and appropriate, and to the extent otherwise consistent with VA policies and applicable law, FAC member vacancies will be announced widely, including notification in the Federal Register with an invitation for the public to recommend individuals for consideration and for selfnominations.

- (2) Professional biographical information of FAC appointees (including current and past affiliations) will be made widely available to the public (e.g., via a Web site or other appropriate process) subject to the <u>Privacy Act (5 U.S.C. § 552a)</u> and other statutory/regulatory considerations. The information should clearly illustrate the appointees' qualifications for serving on the committee.
- (3) To the extent otherwise consistent with VA policies, the selection of individuals to serve as members on a scientific or technical FAC will be based on expertise, knowledge and contribution to the relevant subject area, with additional consideration given to availability of individuals to serve, balance of the points of view represented on the advisory committee with respect to the functions to be performed, the ability to work effectively on advisory committees and diversity, equity and inclusion practices.
- (4) Except when prohibited by law, VA will make all Conflict-of-Interest waivers granted to committee members publicly available.
- (5) Except when prohibited by law, all reports, recommendations and products produced by FACs will be treated as solely the findings of such committees rather than of the U.S. Government, and thus, will not be subject to revision by VA.

NOTE: FAC reports, recommendations and other products are strictly advisory. VA is not obligated to implement committee scientific recommendations. Additional VA-specific requirements and implementing guidance for FACs is available at <u>The Advisory Committee Management Office.</u>

- f. Facilitate the free flow of scientific information, consistent with privacy and classification standards and the <u>VA Ethics Principles for Access to and Use of</u> <u>Veteran Data</u> and support scientific integrity in the communication of scientific findings and products.
 - (1) Accordingly, it is VA policy to:
 - (a) Encourage VA scientists to participate in communications with the media regarding their scientific findings (data and results) and, when appropriate, to utilize social media for wider dissemination of scientific findings to the extent allowed by law and in accordance with VA social media policy and any other applicable VA policy. VA scientists must coordinate media queries or opportunities (e.g., requests for interviews or requests for submissions of written commentary, etc.) with their immediate supervisors and public affairs offices in accordance with the applicable policies of the Department and their respective Administrations/Staff Offices.

NOTE: Administrations and Staff Offices must coordinate with the VA Office of Public and Intergovernmental Affairs (OPIA), which provides centralized operational direction for communications about VA activities.

OPIA's and other VA public affairs officials' role in communications regarding research and analysis done by VA scientists is to assist with presentation, style and logistics of the communications and to advise on potential media requests or media outreach strategies. VA Directive 8500, Public Affairs and VA Handbook 8500, VA Public Affairs Program, both dated October 28, 2019, provide further information on the role and responsibilities of OPIA and expectations for VA employees when communicating with the media and external audiences. VA Directive 6515, Use of Web-Based Collaboration Technologies, dated June 28, 2011, provides further information on the use of web-based resources and tools by VA employees to facilitate collaboration, outreach, communication and information sharing. Of particular note, VA Directive 6515 sets forth the expectation that to increase accountability, promote informed participation by the public and create economic opportunity, the presumption shall be in favor of openness with regard to information sharing.

- (b) Ensure that the work and views of VA scientists are accurately represented in official VA communications, including media communications and social media posts. This includes providing VA scientists with the opportunity to review proposed communications about their work and provide clarifications in advance of release if they request such an opportunity, or proactively seeking their review and comment if necessary to ensure accurate representation.
- (c) Ensure that VA scientists may communicate their scientific findings (data and results) objectively without political interference or inappropriate influence, while at the same time complying with VA policies and procedures for planning and conducting scientific activities, reporting scientific findings and reviewing and releasing scientific products. Scientific communications for non-VA media (e.g., manuscripts and presentations for scientific journals, workshops, conferences and symposia) should adhere to agency technical review procedures and applicable privacy policies. **NOTE:** The provisions in this Directive are neither intended to limit the ability of OPIA or other VA public affairs officials from making decisions about whether the Department issues press releases or other external communications about its scientific activities and findings nor limit OPIA or other VA public affairs officials selection of a VA employee subject matter expert to respond to a media inquiry in an objective, non-partisan and articulate manner.
 - <u>i</u> Public and media queries received by VA scientists about the policy implications of VA scientific findings should be addressed by designated VA officials responsible for conveying information about VA policy matters. When reporting scientific findings or communicating with the media or the public in their official capacities as VA employees, VA scientists must refrain from making or publishing

statements that could be construed as being judgments about, or recommendations on, VA or any other Federal Government policy, unless they have secured the appropriate prior approval to do so. VA scientists' communications with the media or the public in their official capacities should remain within the bounds of their scientific findings, unless otherwise authorized.

- ii When communicating with the media or the public in their personal capacities, VA scientists may express their personal views and opinions. Under such circumstances, VA scientists have an obligation to make clear that the views and opinions that they are expressing are their own and do not necessarily represent those of VA; must not claim to officially represent the Department or its policies; and must not use official VA seals or logos or other visual representations that could be misconstrued as the individual officially representing VA.
- (d) Ensure that the scientific information provided by VA in response to Congressional inquiries and other Congressional requests for information, including testimony by VA employees, is accurately represented.
- (2) Further, it is VA policy that:
 - (a) VA officials, including public affairs officers, may not direct VA scientists to alter their communications of their scientific findings for political purposes.
 - (b) VA officials, including public affairs officers, may neither ask nor require that VA scientists alter their communications of their scientific findings in a manner that may compromise the objectivity or accurate representation of those findings. **NOTE:** Recommendations to improve the clarity and effectiveness of communications may be made; however, such recommendations, if adopted, must not result in scientific findings be mischaracterized, distorted, or inaccurately portrayed.
- g. Encourage VA scientists and other VA employees involved in VA scientific activities to interact with the broader scientific community, in a manner that is consistent with Federal statutes and regulations, Federal rules of ethics, the <u>VA Ethics Principles</u> for Access to and Use of Veteran Data, job responsibilities and existing VA policies (including <u>VA Directive 5015</u>, Employee Development, dated April 15, 2002) and to the extent that is practicable given the availability of funding to support such interactions and any budgetary restraints. This includes the following:

- (1) Encouraging publication of research findings and, where applicable, other scientific findings in peer-reviewed, professional, or scholarly journals. Encouraging presentation of research findings and, where applicable, other scientific findings at professional meetings.
- (2) Allowing service on editorial boards or as editors of professional or scholarly journals.
- (3) Allowing participation in professional societies, committees, task forces and other specialized bodies of professional societies, including serving as officers or on governing boards of such societies, to the extent allowed by law.
- (4) Allowing honors and awards to be received for contributions to scientific activities, discoveries and products with the goal of minimizing, to the extent practicable, disparities between private-sector and public-sector scientists' potential to accrue the professional recognition of such honors or awards, to the extent allowed by law.
- h. Provide for a process for resolving disputes involving differences of opinion about the validity and appropriateness of the underlying methodologies used in scientific activities and conclusions that can be drawn from resulting scientific findings and scientific products.

NOTE: Appendix A of this Directive provides for a process to resolve disputes involving differences of opinion.

- i. Define actions and practices that compromise scientific integrity and to expressly prohibit such actions and practices. Accordingly, the following actions and practices are deemed to compromise scientific integrity and are explicitly prohibited:
 - (1) Engaging in research misconduct (i.e., fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results).
 - (2) Altering, distorting, mischaracterizing, changing, or omitting select portions of scientific findings or products such that the findings or products are no longer accurately represented.
 - (3) Using methods or processes when conducting scientific activities that significantly deviate from accepted professional standards and practices and that compromise the validity of resulting findings.
 - (4) Inappropriately influencing or politically interfering with scientific activities.
 - (5) Placing undue influence on, or otherwise attempting to compromise, the objectivity and/or independence of, peer review processes and/or Federal Advisory Committees charged with evaluating or making recommendations on scientific activities and products.

- (6) Selecting or appointing scientific staff based on non-science qualifications with the intent of inappropriately influencing policy and/or undermining the credibility of research.
- (7) Preventing or delaying the release of scientific findings and products without scientific justification if there are no other legal, regulatory or established policy restrictions on such release.
- (8) Preventing VA scientists from speaking with the media and public about the findings from their VA scientific activities if they have appropriately coordinated with their immediate supervisor and relevant VA public affairs office in advance.
- (9) Directing others to engage in the prohibited actions or practices delineated in Paragraphs 2.i(1) though (8).

NOTE: This paragraph is <u>not</u> intended to cover other alleged improprieties that may occur in the conduct of scientific activities and for which other processes for responding are provided for through applicable law, regulation or Federal policy (e.g., breaches of human research subject protections or noncompliance with laboratory animal welfare requirements, etc.). See <u>VHA</u> <u>Directive 1058.01</u>, <u>Research Compliance Reporting Requirements</u>, <u>dated</u> <u>October 22</u>, 2020, for additional information.

NOTE: Individuals found to have committed any of the expressly prohibited actions and/or practices articulated in Paragraph 2.i of this Directive may be subject to adverse or disciplinary actions as described in the applicable collective bargaining agreement, <u>VA Directive 5021</u>, <u>Employee/Management</u> <u>Relations</u> and its associated <u>Handbook</u> and <u>VA Handbook 5027</u>, <u>Senior</u> <u>Executive Service</u>.

- j. Protect VA employees who uncover or report allegations of compromised scientific integrity, including allegations of research misconduct in good faith, from prohibited personnel practices (as defined in <u>5 U.S.C. § 2302(b)</u>).
- k. Comply with the requirements of <u>Public Law (P.L.) 101-12</u>, the Whistleblower <u>Protection Act of 1989</u> and its expanded protections enacted by <u>P.L. 112-199</u>, the <u>Whistleblower Protection Enhancement Act of 2012</u>, which extends protection to employees who disclose information about censorship related to research, analysis or technical information.
- Ensure that there are processes for responding to alleged actions or practices that compromise scientific integrity as delineated in Paragraph 2.i. NOTE: Appendix B of this Directive delineates VA processes for responding to allegations of compromised scientific integrity.
- m. Be transparent regarding formal actions taken by VA to respond to allegations pertaining to actions or practices that compromise scientific integrity as delineated

in Paragraph 2.i. Accordingly, on an annual basis, VA will publish, except and to the extent prohibited by national security, privacy and other legal requirements, on a publicly facing VA website, the following information:

- (1) Number of new administrative investigations, initiated across VA during the most recently completed calendar year, into the alleged occurrence of actions or practices prohibited under Paragraph 2.i.
- (2) Additional number of ongoing administrative investigations (i.e., initiated prior to the start of and continuing into, the reporting period), across VA during the most recently completed calendar year, into the alleged occurrence of actions or practices prohibited under Paragraph 2.i.
- (3) Number and general description of the nature (e.g., "inappropriate delay in the release of a scientific product") of any final findings, made across VA during the most recently completed calendar year, that the alleged actions or practices prohibited under Paragraph 2.i occurred.
- (4) Number of new appeals, filed across VA during the most recently completed calendar year, of any findings that the alleged actions or practices prohibited under Paragraph 2.i occurred.
- (5) Additional number of ongoing appeals (i.e., filed prior to and still pending in, the reporting year), across VA during the most recently completed calendar year, of any findings that the alleged actions or practices prohibited under Paragraph 2.i occurred.
- n. Ensure that VA employees have awareness of this Directive and any applicable responsibilities set forth by this Directive. Accordingly:
 - (1) Within 1 year of issuance of this Directive, all VA employees and appointees must receive information providing awareness of the issuance of this Directive and its purpose.
 - (2) Within 1 year of issuance of this Directive, a process must be implemented for providing all new VA employees and appointees with information about the existence of this Directive and its purpose within 6 months of their hire or appointment.
 - (3) Within 1 year of issuance of this Directive, comprehensive training (beyond just information on the awareness of the existence and purpose of the Directive as required for all VA employees per Paragraphs 2.n(1) and (2)) must be developed. All VA employees and appointees who engage in, supervise, manage and/or communicate on scientific activities and/or utilize information derived from such activities in policy and decision-making, must complete such training within 6 months of deployment of the training.

NOTE: New VA employees and appointees who are both hired after deployment of the comprehensive training and engage in, supervise, manage and/or communicate on scientific activities and/or utilize information derived from such activities in policy and decision-making, must complete such training within 6 months of their hire or appointment.

- (4) Refresher training must be completed by employees covered by Paragraph 2.n(3) every 2 years.
- (5) Training required under Paragraphs 2.n(3) and (4) must be tracked to ensure compliance.

3. RESPONSIBILITIES.

- a. Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks shall:
 - (1) Serve as the senior Department official responsible for ensuring that scientific integrity is upheld across VA, including ensuring that scientific integrity is upheld in VA's generation, communication, and use of scientific findings and products.
 - (2) Serve as the VA Chief Science Officer (CSO) and fulfill the responsibilities of the position as described in Paragraph 3.d.
 - (3) Provide, in collaboration with the VA Scientific Integrity Official (SIO), leadership for the Department on scientific integrity.
 - (4) Ensure Department-wide awareness of the contents of this Directive.
 - (5) Ensure that this Directive is posted on one or more VA public-facing accessible webpages, including a webpage dedicated to VA scientific integrity activities and communications.
 - (6) Appoint within the VHA Office of Discovery, Education and Affiliate Networks a senior career individual, who has formal educational training in a scientific discipline, experience conducting scientific activities and holds a permanent position (i.e., not a probationary, temporary, term, or excepted appointment), to serve in a full-time capacity as the VA SIO and report directly to the Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks.
 - (7) Establish, in collaboration with the VA SIO, Department-wide policies, processes and guidance to supplement this Directive, if and as needed.
 - (8) Ensure that an evaluation plan to regularly monitor and evaluate ongoing scientific integrity activities and outcomes is developed and implemented.

- (9) Ensure that a review of this Directive is undertaken at least every 3 years in accordance with Paragraph 3.e(4) and the Directive is updated in response to the outcome of this review if and as warranted.
- (10) Ensure that any substantive changes made to this Directive are communicated to the Director of OSTP within 30 days of adoption.
- (11) Ensure, in collaboration with the VA SIO and Chief Acquisition Officer, the development and implementation of an education program on the requirements and responsibilities delineated in this Directive for all VA employees, as well as for contractors who engage in, supervise, manage and/or communicate on scientific activities, develop scientific products and/or support VA's utilization of information derived from such activities in policyand decision-making.
- (12) Ensure that VA annually publishes on a public facing VA website the information specified in Paragraph 2.m pertaining to investigations into alleged compromise of scientific integrity, resulting determinations and appeals of any findings that scientific integrity has been compromised.

b. Under Secretaries, Assistant Secretaries and Other Key Officials shall:

- (1) Ensure broad awareness of the contents of this Directive in their respective Administrations and Staff Offices.
- (2) Ensure that scientific integrity is upheld and the requirements in this Directive are adhered to, in the generation, communication and use of scientific findings and products in their respective Administrations and Staff Offices.
- (3) Ensure that Administration and Staff Office policies and processes pertaining to the generation, communication and use of scientific findings and products are consistent with the values, principles and requirements set forth in this Directive.
- (4) Ensure that the VA SIO and the appropriate VA Administration Scientific Integrity Liaison (see Paragraph 3.f), if applicable, are made aware of and provided the opportunity to offer feedback on efforts to develop or revise policies that support or otherwise intersect with scientific integrity to facilitate consistency with the requirements of this Directive and prevent the creation of conditions that could undermine scientific integrity.
- (5) Establish and maintain a mechanism for collecting information across their Administrations and Staff Offices pertaining to formal investigations into alleged compromise of scientific integrity, resulting determinations and appeals of any findings that scientific integrity has been compromised and providing that information to the VA SIO for purposes of publishing VA's annual report pursuant to Paragraph 2.m.

c. **Under Secretaries**, in addition the carrying out the responsibilities in Paragraph 3.b, shall each designate a senior career individual, who has formal educational training in a scientific discipline, experience conducting scientific activities and holds a permanent position (i.e., not a probationary, temporary, term, or excepted appointment) within an office within their respective Administrations, to serve as a VA Administration Scientific Integrity Liaison (ASIL) for purposes of liaising with the VA SIO on Administration-related matters pertaining to scientific integrity and leading efforts to instill scientific integrity across their respective administrations.

NOTE: The VA SIO, who per Paragraph 3.a(6) reports directly to the Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks, will serve as the ASIL for VHA.

- d. VA Chief Science Officer shall:
 - (1) Serve as the principal advisor to the Secretary on scientific issues and ensure that VA's research programs are scientifically well-founded and conducted with integrity.
 - (2) Oversee the implementation and iterative improvement of policies and processes affecting the integrity of research funded, conducted, or overseen by VA, as well as policies affecting Federal and non-Federal scientists who support VA research activities.

e. VA Scientific Integrity Official shall:

- (1) Lead and oversee the implementation of this Directive.
- (2) Develop and implement an evaluation plan to regularly monitor and evaluate ongoing scientific integrity activities and outcomes.
- (3) Serve as the Department's primary subject matter expert on scientific integrity and contact for questions regarding this Directive, including serving as a consultant, if and as requested, to VA entities conducting investigations into alleged actions or practices that compromise scientific integrity as described in Appendix B.
- (4) Advise the Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks and VA senior leadership on scientific integrity matters, including the updating and revising of this Directive and the development of supplemental implementing guidance, as necessary. This will include conducting at least every 3 years a review of this Directive with respect to:
 - (a) Scientific integrity issues encountered and the extent to which this Directive adequately addressed and/or provided for an effective process for resolving, such issues.

- (b) Laws, regulations, or policies promulgated that may necessitate revision of one or more provisions in this Directive.
- (c) Updated scientific integrity guidance provided by OSTP.
- (d) Results from the evaluation specified in Paragraph 3.e(2).
- (e) Other issues or evidence indicative that revision of this Directive would strengthen scientific integrity.
- (5) Ensure that any substantive changes made to this Directive are communicated to the Director of OSTP within 30 days of adoption.
- (6) Ensure the Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks has general awareness of specific concerns about scientific integrity being compromised.
- (7) Serve as an ombudsman about scientific integrity concerns that are raised, including:
 - (a) Serving as a consultant and/or mediator to resolve disputes about differences of opinion involving the validity of the underlying methodologies used to develop scientific products or the conclusions drawn in or from such products (*see* Appendix A of this Directive).
 - (b) Serving as a neutral point of contact to whom allegations of compromised scientific integrity may be submitted (see Appendix B of this Directive).
- (8) Develop and keep up-to-date a VA public-facing accessible web page for reporting out on scientific integrity activities and information. At a minimum, the web page will include the following (or links to the following):
 - (a) The VA Scientific Integrity Policy.
 - (b) The name and contact information for the VA SIO and each VA ASIL.
 - (c) A description of the mechanisms available for reporting allegations of compromised scientific integrity.
 - (d) An annual accounting of investigations into allegations of compromised scientific integrity, resulting findings that scientific integrity was compromised and appeals, if any, of said findings (*see* Paragraphs 2.m and 3.e(9)).
- (9) Annually account for and publish on a public-facing VA website, the number of formal investigations into allegations of compromised scientific integrity conducted across VA during the year, resulting findings that scientific integrity

was compromised and appeals of findings that scientific integrity was compromised, in accordance with Paragraph 2.m.

(10) Develop and implement, in collaboration with the VA Chief Learning Officer, an education program on the requirements and responsibilities delineated in this Directive for all VA employees, as well as for contractors who engage in, supervise, manage and/or communicate on scientific activities, develop scientific products and/or support VA's utilization of information derived from such activities in policy- and decision-making.

f. VA Administration Scientific Integrity Liaisons shall:

- (1) Support VA SIO efforts to implement this Directive within their respective Administrations.
- (2) Serve within their respective Administrations as primary subject matter experts on scientific integrity and as contacts for questions regarding this Directive, including serving as consultants, if and as requested, to VA entities conducting investigations into alleged actions or practices that compromise scientific integrity as described in Appendix B.
- (3) Advise the VA SIO on scientific integrity matters within their Administrations, including providing awareness of:
 - (a) Scientific integrity issues encountered and the extent to which this Directive adequately addressed and/or provided for an effective process for resolving, such issues.
 - (b) Other issues or evidence indicative that revision of this Directive would strengthen scientific integrity.
- (4) Serve as a neutral point of contact to whom allegations of compromised scientific integrity may be submitted (see Appendix B of this Directive).
- (5) Collect information from within their assigned Administration pertaining to formal investigations into alleged compromise of scientific integrity, resulting determinations and appeals of any findings that scientific integrity has been compromised and provide that information to the VA SIO for purposes of publishing VA's annual report pursuant to Paragraph 2.m.
- (6) Develop and implement, if and as necessary, an Administration-specific education program on the requirements and responsibilities delineated in this Directive for employees of that Administration, in collaboration with the VA SIO and Administration-level entities that administer educational programs within their respective Administrations.
- g. Principal Executive Director, Office of Acquisition, Logistics and Construction and VA Chief Acquisition Officer shall:

- (1) Set forth policy and processes to ensure that VA contractors who engage in and/or communicate on scientific activities, develop scientific products and/or support VA's utilization of information derived from such activities in policyand decision-making:
 - (a) Are aware of and required to conduct themselves in accordance with, the values and principles articulated in this Directive for upholding scientific integrity.
 - (b) Are required to report to their respective Contractor Officer or Contracting Officer's Representative any allegations of, or determinations that, VA contractors engaged in the actions and practices deemed to compromise scientific integrity articulated in Paragraph 2.i.
 - (c) Notify the VA SIO and, if applicable, the appropriate VA ASIL, of receipt of any reports of allegations or determinations of scientific integrity being compromised pursuant to Paragraph 3.g(1)(b).
- (2) Examples of acquisitions covered by this paragraph include purchase orders, delivery orders, task orders, blanket purchase or ordering agreements/calls, and contracts that must adhere to the Federal Acquisition Regulation (FAR) Part 35 - Research and Development Contracting Part 35 and VA Acquisition Regulation Part 835 - Research and Development Contracting.

h. VA employees and appointees shall:

- (1) Uphold the values and adhere to the principles articulated in this Directive and comply with its specified requirements.
- (2) Fulfill VA training requirements on scientific integrity, as applicable.
- (3) Report any knowledge of the actions or practices delineated in Paragraph 2.i that compromise scientific integrity and are explicitly prohibited by this Directive.

NOTE: Appendix B provides guidance as to individuals or entities to whom allegations of compromised scientific integrity can be reported.

NOTE: All VA contractors and grantees engaged in or who communicate on VA scientific activities or support VA efforts to utilize information derived from such activities in policy- and decision-making, are expected to conduct themselves in accordance with the values and principles articulated in this Directive for upholding scientific integrity; however, any express requirements for VA contractors and grantees will be set forth in agreements, contracts, statements of work, etc. and/or established via a separate rule or policy.

4. REFERENCES.

- a. Information Quality Act (P.L. 106-554)
- b. Federal Advisory Committee Act of 1972 (P.L. 92-463)
- c. Privacy Act of 1974 (5 U.S.C. Sec 552a)
- d. Prohibited Personnel Practices (5 U.S.C. Sec. 2302)
- e. <u>Whistleblower Protection Act of 1989 (P.L. 101-12)</u>
- f. Whistleblower Protection Enhancement Act of 2012 (P.L. 112-199)
- g. <u>Uniform Patent Policy for Rights in Inventions Made by Government Employees (37</u> <u>C.F.R. Part 501)</u>
- h. <u>Inventions by Employees of Department of Veterans Affairs (38 C.F.R. Part 1.650-1.663)</u>
- i. Federal Advisory Committee Act Final Rule 2001 (41 C.F.R. Part 102–3)
- j. Federal Policy on Research Misconduct, December 6, 2000
- k. <u>Presidential Memorandum for the Heads of Executive Departments and Agencies,</u> <u>Scientific Integrity, March 9, 2009</u>
- I. <u>OSTP Memorandum for the Heads of Executive Departments and Agencies</u>, <u>Scientific Integrity, December 17, 2010</u>
- m. <u>Presidential Memorandum for the Heads of Executive Departments and Agencies,</u> <u>Restoring Trust in Government Through Scientific Integrity and Evidence-Based</u> <u>Policymaking, January 27, 2021</u>
- n. <u>National Science and Technology Council Framework for Federal Scientific Integrity</u> <u>Policy and Practice, dated January 2023</u>
- o. <u>OMB Memorandum M-05-03, Final Information Quality Bulletin for Peer Review,</u> <u>December 16, 2004</u>
- p. <u>OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and</u> <u>Integrity of Information Disseminated by Federal Agencies, February 22, 2002</u>
- q. <u>OMB Memorandum M-19-15, Improving Implementation of the Information Quality</u> <u>Act, April 24, 2019</u>
- r. <u>National Science and Technology Council's Scientific Integrity Fast-Track Action</u> <u>Committee Report on Protecting the Integrity of Government Science, January 2022</u>

- s. Federal Acquisition Regulation Part 35 Research and Development Contracting
- t. VA Acquisition Regulation Part 835 Research and Development Contracting
- u. <u>VA Directive 0009, Ensuring Quality of Information Disseminated by VA, June 3, 2019</u>
- v. VA Directive 8500, Public Affairs, October 28, 2019
- w. VA Handbook 8500, VA Public Affairs Program, October 28, 2019
- x. VA Directive 6515, Use of Web-Based Collaboration Technologies, June 28, 2011
- y. VA Directive 5015, Employee Development, April 15, 2002
- z. VA Directive 5021, Employee/Management Relations
- aa. VA Handbook 5021, Employee/Management Relations
- bb. VA Handbook 5027, Senior Executive Service
- cc. <u>VA Directive 0700, Administrative Investigation Boards and Fact findings, August</u> <u>10, 2021</u>
- dd. <u>VA Handbook 0700, Administrative Investigation Boards and Fact findings, August</u> <u>17, 2021</u>
- ee. <u>VA Directive 0500</u>, Office of Accountability and Whistleblower Protection: <u>Investigation of Whistleblower Disclosures and Allegations Involving Senior Leaders</u> <u>or Whistleblower Retaliation, September 10, 2019</u>
- ff. <u>VHA Directive 1200.18</u>, Determination of Rights for Inventions and Discoveries, <u>January 11, 2017</u>
- gg. <u>VHA Directive 1058.01</u>, Research Compliance Reporting Requirements, October 22, 2020
- hh. VHA Directive 1058.02, Research Misconduct, July 10, 2020
- ii. VA Federal Advisory Committee Management Guide, September 2023
- jj. VA [Federal Advisory] Committee Member Handbook, September 2023
- kk. Ethics Principles for Access to and Use of Veteran Data

5. **DEFINITIONS**.

a. **Allegation.** An allegation is a written or oral statement that a prohibited action or practice delineated in Paragraph 2.i of this Directive has occurred.

NOTE: An informal conversation with the VA SIO or others to discuss the potential scope and/or applicability of this Directive to a particular situation does not, in and of itself, constitute an allegation.

- b. **Inappropriate Influence.** Inappropriate influence is the attempt to compromise the integrity (including objectivity and validity) of scientific and technical activities; suppress the communication of scientific findings and products without scientific justification; distort or mischaracterize scientific findings and products; and/or interfere with the independence of peer-review and FAC processes involving the assessment of scientific activities and products. **NOTE:** The provisions in this Directive are not meant to limit the obligations of political appointees and senior leaders in setting research priorities or the priorities of other scientific activities.
- c. Political Interference. Political interference is the politically motivated and scientifically unjustified attempt to inappropriately influence the conduct of scientific activities; the communication of scientific findings and products; and the conduct of peer-review and FAC processes involving the assessment of scientific activities and products. NOTE: The provisions in this Directive are not meant to limit the obligations of political appointees and senior leaders in setting research priorities or the priorities of other scientific activities.
- d. **Research.** Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. **NOTE:** Activities that meet this definition constitute research for purposes of this Directive, whether or not they are conducted or supported under a program that is considered research for other purposes.
- e. **Research Misconduct.** Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. **NOTE:** Research misconduct does not include honest error or differences of opinion.
- f. **Science.** Science refers to the full spectrum of scientific endeavors, including basic science, applied science, evaluation science, engineering, technology, economics, social sciences and statistics, as well as the scientific and technical information derived from these endeavors.
- g. **Scientific Activities.** Scientific activities are activities that are part of a scientific endeavor involving the utilization of a systematic approach and application of well-accepted scientific methodologies to generate new knowledge, confirm or disprove existing knowledge, or facilitate the translation of knowledge into practical applications. Such activities as part of a scientific endeavor include, but are not limited to: data collection, inventorying, monitoring, statistical analysis, surveying,

research, economic analysis, forecasting, predictive analytics, modeling and technology development.

NOTE: The reference to scientific endeavors in the definition of "scientific activities" in this Directive encompasses a broad spectrum of such endeavors including basic science, applied science, evaluation science, engineering, technology, economics, social sciences and statistics. Scientific endeavors typically do <u>not</u> include endeavors such as individual-patient level clinical care or routine business/administrative operations.

- h. **Scientific Findings.** Scientific findings are findings, including data, results and analyses, that are derived from scientific activities.
- i. **Scientific Integrity.** Scientific integrity is the adherence to professional practices, ethical behavior and the principles of honesty and objectivity when conducting, managing, using the results of and communicating about science and scientific activities. Inclusivity, transparency and protection from inappropriate influence are hallmarks of scientific integrity.

NOTE: This is a Federal-wide definition.

j. **Scientific Product.** A scientific product refers to the primary vehicle used to directly communicate scientific findings for use by VA and/or the public and may be in written (e.g., research manuscript intended for publication in a peer-reviewed journal article) or oral format (e.g., research presentation intended for a professional conference).

NOTE: For purposes of this Directive, policy, budget and management documents are not considered scientific products; however, the use and representation of scientific findings in those documents are covered by this Directive.

- k. Senior Executive. Senior executive refers to an individual who is:
 - (1) A career appointee in the Senior Executive Service (SES), including those serving a probationary period, except for those individuals employed by the Office of Inspector General (OIG).
 - (2) Appointed in an administrative or executive position under 38 U.S.C. §§ 7306(a), 7401(1), or 7401(4). These appointments include:
 - (a) Title 38 SES-equivalent employees.
 - (b) Veterans Integrated Service Network (VISN) and VA Medical Center (VAMC) directors and deputy directors.
 - (c) VISN and VAMC chiefs of staff or equivalent positions (e.g., chief medical officers).

- (d) VISN and VAMC associate directors for patient care services or equivalent positions (e.g., nurse executives).
- I. Senior Leader. Senior Leader refers to an individual who is:
 - (1) A senior executive (as defined in Paragraph 5.k).
 - (2) Employed in a confidential, policymaking, policy-determining, or policyadvocating position (e.g., political appointees and those appointed under Schedule C (5 CFR part 213, subpart C)).
 - (3) Employed in a position the Secretary of Veterans Affairs considers similar to those identified in Paragraphs 5.k(1) and (2) pursuant to VA Directive 0500. These are:
 - (a) Senior-level (SL) positions described in 5 CFR § 319.102.
 - (b) Scientific and Professional (ST) positions described in 5 CFR § 319.103.
 - (c) Veterans law judges (including chief veterans law judges).
 - (d) Veterans Health Administration (VHA) and Veterans Benefits Administration (VBA) directors, associate directors and assistant directors at General Schedule grade 14 or above.
 - (e) National Cemetery Administration (NCA) cemetery directors and district chiefs of operation at General Schedule grade 14 or above.
 - (f) Other SES appointees (e.g., noncareer SES appointees and limited term SES appointees).
- m. **VA Scientist.** For purposes of this Directive, a VA scientist is a VA employee who has specialized scientific training and whose responsibilities include conducting research and/or engaging in other scientific endeavors that involve the application of scientific methodologies in a systematic matter.

NOTE: For purposes of this Directive, the term does not refer to individuals, regardless of whether they have scientific and technical training, whose primary job functions are in non-scientific roles (e.g., policymaking, communications, administration, oversight, etc.).

APPENDIX A — Process for Resolving Disputes Involving Differences of Opinion about Scientific Findings and Products.

- Scientific products and, correspondingly, the decisions informed by such (1)products are strengthened when relevant evidence and varying viewpoints about the validity and appropriateness of the underlying methodologies used in the scientific activities described in such products are taken into consideration. Similarly, scientific products and, correspondingly, the decisions informed by such products are strengthened when relevant evidence and varying viewpoints about the validity and appropriateness of the conclusions that can be drawn from the scientific findings are taken into consideration. As such, VA encourages vigorous internal discussion and critical analysis of the methodologies used to generate such products and the conclusions drawn in and from such products. When a VA employee, who has been substantively engaged in a specific scientific activity disagrees with the resulting scientific data, interpretations, or conclusions that are included in a scientific product or relied upon to inform an agency policy decision, the employee is encouraged to express that opinion along with the rationale for disagreement in those internal discussions and/or through internal vetting processes.
- (2) In cases where good-faith and reasonable differences of opinion about the validity of the underlying methodologies used to develop scientific products or the conclusions drawn in or from such products exist, it is VA policy (per Paragraph 2.h of the Directive) that efforts will be made to resolve disputes among VA employees that arise from such differences.

NOTE: This Appendix is <u>not</u> intended to cover personal differences of opinion about policy options or decisions; rather, this Appendix applies to differences of opinion regarding the validity and appropriateness of the methodologies used in scientific activities and the conclusions drawn in or from scientific products.

(a) In many instances, disputes involving differences of opinion with regard to the validity of scientific methods, or the conclusions drawn in or from scientific products can be readily resolved by open communication and transparency. As such, VA employees are encouraged to initially bring their differences of opinion directly to the individual or team responsible for conducting the scientific activities and/or generating the resulting scientific product. If such action does not result in appropriate resolution or a VA employee does not wish to engage directly with the individual or team that conducted the scientific activities and/or generated the resulting scientific product, the VA employee is encouraged to bring her/his differing opinion to the first-level management official(s) that supervised or otherwise directed the work of the individual or team that conducted the activities or generated the resulting product. If the dispute cannot be readily resolved, the first-level management official(s) should consider the viability of resolving the dispute through consultation with internal VA subject-matter experts (SMEs) who were not involved with the development of the product; informal consultation with external SMEs; or utilization of a more formal peer-review process. **NOTE:** In some cases, based on the nature of the issue or time constraints, one or more of these options may not be practicable. Further, although a good faith exploration of these options for resolving disputes involving a difference of opinion is encouraged, this paragraph does not establish a right to exercise such options.

- (b) If the dispute is not able to be resolved through the foregoing mechanisms, the first-level management official must notify and engage with the VA Scientific Integrity Official (SIO) and, if applicable, the appropriate VA Administration Scientific Integrity Liaison (ASIL), to explore additional options for reconciliation. Such options to consider may include but are not limited to the following: consulting with SMEs or, if SMEs were already consulted, consulting with additional SMEs; utilization of a formal peer-review process if one was not already utilized for purposes of resolving the difference; and/or engagement in mediation in which the VA SIO serves as the mediator or other established VA processes for mediation are utilized.
- (c) If after first-level management official and VA SIO engagement the dispute is still unable to be resolved, the VA SIO will refer the dispute to the VA Chief Science Officer (CSO) for a determination as to whether there remains a reasonable concern regarding the validity of scientific methods used in scientific activities or the conclusions drawn in or from scientific products. The parties involved in the dispute must be provided the opportunity to submit succinct written arguments for consideration by the CSO. The CSO may request additional information from the parties involved, consult with others who have relevant knowledge or expertise and/or direct that the matter be referred for formal peer-review.
 - i If the CSO determines that there is not a reasonable basis for the scientific disagreement (e.g., based on the outcome of peer review or SME consultation processes), the matter will be considered resolved.
 - <u>ii</u> If the CSO determines that there is a reasonable basis for the scientific disagreement and the dispute pertains to a scientific product intended for use in VA decision-making, the first-level management official and VA SIO will be responsible for ensuring that an objective summary of the differing scientific opinion and the actions taken to resolve the differing opinion is included in deliberative documents provided to VA policy- and decision-makers whose decisions are expected to be informed by the scientific activities or scientific product in question.

iii If the CSO determines that there is a reasonable basis for the scientific disagreement and the dispute pertains to a scientific product intended for purposes other than that described in Paragraph (2)(c)ii of this Appendix, the CSO, in consultation with the VA SIO and, if and as applicable, the appropriate VA ASIL, will determine whether appropriate practicable actions should be taken to facilitate transparency regarding the difference of opinion. Such actions, if determined to be appropriate, could include, but are not limited to the following: revising the scientific product to make audiences more readily aware of limitations, uncertainties, or plausible alternative interpretations; and submission of an expression of concern or comment for already published scientific products (utilizing publisher venues for such expressions).

APPENDIX B — Processes for Responding to Alleged Actions or Practices that Compromise Scientific Integrity

- (1) Individuals with concerns that scientific integrity could be (but has not yet been) compromised or who are unsure about whether certain actions or practices may violate this Directive are encouraged to informally consult as early as possible with the VA Scientific Integrity Official (SIO) and/or the applicable VA Administration Scientific Integrity Liaisons (ASIL). Such early consultations may enable violations of this policy to be prevented (through VA SIO and/or ASIL engagement with appropriate parties); misunderstandings to be readily resolved; and/or the concerns to be directed to more appropriate entities for follow up.
- (2) Allegations of the occurrence of the actions or practices in Paragraph 2.i of this Directive, all of which have been deemed to compromise scientific integrity and are expressly prohibited, must be reported, investigated and adjudicated in accordance with existing applicable VA policies and processes for investigating and resolving alleged VA policy violations. Similarly, appeals of resulting determinations that scientific integrity has been compromised shall be processed in accordance with existing applicable VA policies and processes.

NOTE: <u>VA Directive 0700, Administrative Investigation Boards and Fact</u> <u>findings</u> and its associated <u>Handbook</u> describe fact-finding processes that may be used for the conduct, reporting and review of administrative investigations into alleged violations of VA policies. <u>VA Directive 5021</u>, <u>Employee/Management Relations</u> and its associated <u>Handbook</u>, and/or the appropriate collective bargaining unit agreement delineate procedures to be followed when proposing a disciplinary, adverse, or major adverse action against a VA employee for violating VA policies and other misconduct.

- (a) Individuals with good-faith and reasonable concerns that scientific integrity has been compromised may avail themselves of various mechanisms for reporting such concerns including, as applicable, reporting such concerns to the supervisors of those who have allegedly compromised scientific integrity, the VA SIO, a VA ASIL, the VA Office of Accountability and Whistleblower Protections (OAWP) and/or the VA Office of Inspector General (OIG).
- (b) To the extent allowed by law, the VA SIO and appropriate VA ASIL, if applicable, must be notified as soon as possible of the receipt of an allegation pertaining to the actions or practices prohibited under Paragraph 2.i of this Directive; the opening of a formal investigation into such allegations; the general nature of any findings that the alleged actions or practices occurred (e.g., "inappropriate delay in the release of a scientific product"); any appeals of said findings, including the outcome

of said appeals; and any actions taken to restore scientific integrity in instances where it has been determined to have been compromised.

- (c) Allegations of the prohibited actions or practices in Paragraph 2.i of this Directive made against a VA senior leader, including but not limited to a VA Senior Executive Service (SES) or equivalent employee, or a political appointee, must be referred to the VA Office of Accountability and Whistleblower Protection (OAWP) pursuant to <u>VA Directive 0500</u>, Office of Accountability and Whistleblower Protection: Investigation of Whistleblower Disclosures and Allegations Involving Senior Leaders or Whistleblower Retaliation. In the event that OAWP cannot objectively investigate the allegation or provide objective oversight of an investigation conducted by another entity to which OAWP has referred the allegation for investigation, the Assistant Secretary for OAWP must refer the allegation to the VA Office of Inspector General (OIG) for consideration for investigation.
- (d) Allegations of research misconduct involving VHA research must be processed and investigated, if applicable, in accordance with the processes stipulated in <u>VHA Directive 1058.02</u>, <u>Research Misconduct</u>.