

SCIENTIFIC INTEGRITY

- 1. REASON FOR ISSUE:** In accordance with the Presidential Memorandum on Scientific Integrity dated March 9, 2009, and the related Office of Science and Technology Policy Memorandum dated December 17, 2010, this Department of Veterans Affairs (VA) Directive establishes policy to ensure the highest level of integrity in all aspects of VA involvement with scientific and technological processes by (a) fostering a culture of transparency, integrity, and ethical behavior in the development and application of scientific and technological findings in VA, and (b) protecting the development, application, and dissemination of scientific and technological information by VA from inappropriate political or commercial influence.
- 2. SUMMARY OF MAJOR CHANGES:** This Directive summarizes current policy and establishes new policy for the preservation and promotion of scientific integrity in VA.
- 3. RELATED DIRECTIVES AND HANDBOOKS:** VA Directives and Handbooks related to human resources management and employee development (VA Directives 5001 and 5015, and VA 5015-series Handbooks); information management and dissemination (VA Directives 6300 and 6360, and VA 6300-series Handbooks); information security and privacy (VA Directives 6500, 6502, 6509, 6511, and 6600 and VA 6500-series Handbooks); and Veterans Health Administration (VHA) Directives and Handbooks related to ethics in health care (VHA Directive 1004 and VHA 1004-series Handbooks); research oversight (VHA Directive 1058 and VHA 1058-series Handbooks); research and development (VHA Directive 1200 and VHA 1200-series Handbooks); academic affiliations (VHA Directive 1400 and VHA 1400-series Handbooks); conflict of interest aspects for contracting certain services (VHA Handbook 1660.03); privacy and information release (VHA Directive 1605 and VHA 1605-series Handbooks); VA Public Affairs Guidelines; VHA Communications Guidelines; and VA Advisory Committee Management Guide and memorandums.
- 4. RESPONSIBLE OFFICE:** The Office of Policy and Planning (008) is responsible for contents of this Directive.
- 5. RECISSIONS:** None.

CERTIFIED BY:

**BY DIRECTION OF THE SECRETARY
OF VETERANS AFFAIRS**

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SCIENTIFIC INTEGRITY

1. PURPOSE

In accordance with the Presidential Memorandum on Scientific Integrity dated March 9, 2009, and the related Office of Science and Technology Policy (OSTP) Memorandum dated December 17, 2010, this Department of Veterans Affairs (VA) Directive establishes policy to ensure the highest level of integrity in all aspects of VA research and in VA's application and use of scientific and technological findings (including their application and use in operations activities, quality assessment and quality improvement activities, evidence-based practice, the development of VA policies and standards, and the presentation of VA research to the public) by:

- a. Fostering a culture of transparency, integrity, and ethical behavior in the development and application of scientific and technological findings in VA, and
- b. Protecting from inappropriate political and other influence the development, application, and dissemination of scientific and technological information by VA.

NOTE: This policy is organized around the following four themes described in the 2010 OSTP Memorandum: Foundations of Scientific Integrity (paragraph 5), Public Communications (paragraph 6), Federal Advisory Committees (paragraph 7), and Professional Development (paragraph 8).

2. RESPONSIBILITIES

Under Secretaries, Assistant Secretaries, Inspector General, General Counsel, Program Office Directors, Network Directors, Regional Directors, and Facility Directors are responsible for ensuring implementation of this Directive.

3. DEFINITIONS

a. Research. Research means a systematic investigation including research, development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy whether or not they are conducted or supported under a program which is considered research for other purposes. *NOTE: Research is further discussed in VHA 1200 series Handbooks.*

b. Scientific and Technological Findings. For the purposes of this policy, scientific and technological findings are any findings, results, analyses, or data sets that derive from the application of well-accepted scientific methodologies by professional staff trained in such methodologies. This includes any of the following:

- (1) VA research findings (see subparagraph 3.d.).

(2) VA quality assessment, quality improvement, quality control, and similar findings.

(3) Consensus statements, practice guidelines, or reports of a group of scientific or technological experts that are developed through systematic analysis and receive widespread acceptance within the relevant professional discipline(s).

(4) Systematic analyses, reports, data sets, findings, etc. that have been endorsed through a rigorous peer review process involving scientific and technological experts.

(5) Systematic analysis, reports, data sets, findings, etc. that have been published in the scientific or technological peer reviewed literature or are intended for such publication. Note: scientific and technological findings do not include pre-decisional data, information or documents including data from research that has not been completed.

c. VA Research Investigator (VA Researcher). A VA research investigator (VA researcher) is any individual who conducts research approved by a VA Research and Development Committee (R&DC) while acting on VA time under a VA appointment, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970. *NOTE: VA investigators/researchers are further discussed in VHA 1200 series Handbooks.*

d. VA Research. VA research is research that is approved by a VA R&DC and conducted by a VA research investigator on VA time, utilizing VA resources (e.g., equipment), or on VA property including space leased to, and used by VA. The research may be funded by VA, by other sponsors, or be unfunded. *NOTE: Research is further discussed in VHA 1200 series Handbooks.*

e. VA Science and Technology Experts. For the purpose of this policy, VA science and technology experts are any VA employees, including VA research investigators, who have specialized scientific or technological training and who contribute to the production of scientific and technological findings as defined under this policy.

4. CORE PRINCIPLES

a. Culture of Scientific Integrity. A culture that promotes, preserves, and implements the principles of scientific integrity is essential to the successful achievement of VA's missions. VA recognizes that scientific and technological findings are important contributors to the development of sound policies in support of the Nation's Veterans. For example, biomedical and behavioral research findings not only provide clinicians in VA medical centers with the information needed for evidence-based practice decisions but also inform policy determinations related to VA coverage and benefits. Successful integration of science and technology into VA policy decisions

depends on the integrity of the scientific process to ensure the validity of information, to engender public trust in VA programs, and to protect the Nation's Veterans.

b. Principles of Scientific Integrity. VA policies related to scientific integrity reflect the following core principles evident in the President's 2009 memorandum:

(1) Selection and Retention for Science and Technology Positions. In addition to consideration of Federal hiring principles, the selection and retention of candidates for science and technology positions in VA will be based primarily on the candidate's demonstrated scientific and technology knowledge and potential, credentials, experience, and integrity. VA's Research Career Development Programs (see subparagraph 8b) support this core principle.

(2) Rules and Procedures to Ensure Scientific Integrity. The policies and procedures described in this Directive are established to ensure the integrity of the scientific process throughout all components of the Department. As a matter of policy, VA will implement specific requirements, as needed, to ensure the continued integrity of the scientific process in emerging areas of concern. VA will supplement the policies described in this Directive as the Secretary deems necessary to ensure the integrity of scientific and technological information and processes upon which the Department relies in fulfilling its missions.

(3) Policy Informed by Science. The development and implementation of VA science and technology policies will be informed by sound scientific data and rigorous analyses that have been protected from inappropriate influences including political influence. In particular, where feasible and relevant the development of policies, information, guidelines, processes, and procedures related to the provision of health care to the Nation's Veterans will be based on the application of the best available clinical and public health standards and sound scientific and technological findings, and will be protected from inappropriate influences including political and commercial influence.

(4) Expert Involvement in Policy Development. Where feasible and relevant, VA will involve science and technology experts in developing and implementing VA policies. Where appropriate, information used in developing and implementing VA policies or other operational standards (e.g. clinical practice guidelines, patient education material, performance metrics) will be subjected to well-established scientific processes, including peer review by qualified internal and/or external experts.

(5) Transparency and Public Availability. Except where information is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, VA will make available to the public the scientific and technological findings or conclusions considered or relied upon in making VA policy or related operational decisions (e.g. clinical practice guidelines, patient education material, performance metrics). Scientific and technological findings may not be suppressed or altered for political purposes.

(6) Oversight. It is VA policy to maintain regulations, policies, and procedures for identifying, investigating, adjudicating, and imposing sanctions related to deviations from accepted standards of scientific integrity in accordance with the Federal Policy on Research Misconduct, Office of Management and Budget Guidelines on Governmentwide Nonprocurement Debarment and Suspension, and the Standards of Ethical Conduct for Employees of the Executive Branch.

5. FOUNDATIONS OF SCIENTIFIC INTEGRITY

a. Culture of Scientific Integrity in VA Research. VA research is founded on principles of integrity that have evolved over the history of scientific inquiry and have been embraced in the United States by national institutions including the National Science Foundation and the Department of Health and Human Services National Institutes of Health.

(1) A culture of scientific integrity is essential for the VA research mission. VA recognizes that scientific progress depends on honest investigation, open discussion, refined understanding, and a firm commitment to evidence.

(2) Scientific and technological findings resulting from VA research may not be suppressed or altered for political purposes.

(3) To ensure the credibility of VA research, VA is developing revised formal disclosure processes specifically addressing research investigator financial conflicts of interest. *NOTE: Investigator financial conflict of interest requirements are currently addressed in VHA Handbook 1200.01 §15 and VHA Handbook 1200.05 §9 and §17.*

(4) VA research will be conducted, for the benefit of Veterans and to support the overall missions of VA, within a functional framework of rules that are supportive of scientific inquiry; observant of Federal statutes, regulations, and VA policies; and informed by operant values (e.g., fairness, respect, and benevolence as values for policies relating to human subject research).

(5) As a matter of policy, the promotion of a culture of scientific integrity is woven into VA research requirements related to the protection of human subjects, privacy and confidentiality of personal information, research safety and laboratory security, laboratory animal welfare, research data security, standards of ethics and professional conduct, and avoidance of financial conflicts of interest. *NOTE: These requirements are discussed further in the 1058 and 1200 series of VHA Handbooks and VHA Handbook 1660.03.*

(6) The conduct of VA research is a privilege that is granted in a framework of responsibilities.

(7) VA implements a functional administrative framework for research through its VHA Office of Research and Development (ORD).

(8) VA implements robust mechanisms for oversight of compliance through its VHA Office of Research Oversight (ORO).

(9) VA research policies will be assessed and revised regularly, as appropriate, to ensure utility and overall effectiveness, and will include mechanisms for continuing quality assessment and improvement. Such mechanisms may include time-limited applicability (i.e., all policies are approved with an expiration date, facilitating periodic review and revision); informative assessments, both internal and external; and required reviews by local oversight and management entities.

(10) VA will afford appropriate whistleblower protections to VA employees who have a reasonable belief of scientific integrity concerns, including, but not limited to, the protections described in title 5 of the United States Code, Section 2302.

b. Ensuring the Credibility of VA Research. To ensure the credibility of VA research, it is VA policy that every aspect of VA research (including administration, conduct, and oversight) is governed by specific regulations, policies, and guidelines that establish VA's research priorities, funding mechanisms, administration, conduct, and oversight (see paragraph 9, References).

(1) VA research priorities are based upon VA's mission and the needs of the Nation's Veterans.

(2) Mechanisms for the support of VA research are based on the principles of scientific merit.

(3) Specific VA research studies, research investigators, research centers, and research sites are determined based on VA's established research priorities and on scientific merit as identified through processes of peer review.

(4) It is VA policy to ensure that its research incorporates appropriate protections to safeguard the rights, health, and welfare of human research subjects; the welfare of laboratory and other research animals; and the safety of research investigators and other participants.

(5) It is VA policy to preserve the integrity of all research-related information, ensure the privacy and confidentiality of research data, and uphold applicable professional and governmental standards of conduct for research.

(6) Requirements for the conduct of VA research involving human subjects are based on the principles of respect for persons, benevolence, and justice as expressed in the *Belmont Report*, the *Helsinki Accords*, and the *Federal Policy (Common Rule) for the Protection of Human Subjects* at 38 C.F.R. Part 16.

(7) Requirements for the conduct of VA research with animals are based on the principles articulated by the Animal Welfare Act and the *Public Health Service Policy (PHS) on Humane Care and Use of Laboratory Animals*, and verified in VA research by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

(8) Requirements for the conduct of VA basic science and laboratory research are based on the principles expressed in the Department of Health and Human Services (HHS) *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* and applicable National Institutes of Health *Guidelines for Research Involving Recombinant DNA Molecules*.

(9) VA policy includes formal procedures to investigate and adjudicate allegations of research misconduct (i.e., fabrication, falsification, and plagiarism) in VA research in accordance with the *Federal Policy on Research Misconduct*. VA policy specifically includes formal procedures for governmentwide nonprocurement debarments and suspensions for impropriety in VA research in accordance with applicable regulations, OMB guidelines and VA requirements.

(10) Other requirements for VA research embody principles founded on applicable standards for privacy and confidentiality of personal information, including applicable provisions of the Privacy Act and the Health Insurance Portability and Accountability Act; good clinical practice standards as incorporated into Food and Drug Administration (FDA) regulations and requirements; and adherence to sound business and management practices and Federal ethics standards, including the criminal conflict of interest laws and the Standards of Ethical Conduct for Employees of the Executive Branch.

(11) VA has established the VHA National Center for Ethics in Health Care (NCEHC) to address the complex ethical issues that arise in patient care, health care management, and research. Guided by the premise that ethics is essential to quality, the National Center for Ethics in Health Care serves as a resource center for VA leaders and staff on issues in clinical, organizational, and research ethics.

(12) Strong working relationships between and among ORD, ORO, and NCEHC ensure that VA's research adheres to the highest scientific, regulatory, and ethical standards.

(13) Each VA research facility is responsible for ensuring that it has fulfilled all the requirements for conducting and overseeing a research program in adherence with the applicable laws and policies referenced in this Directive.

(14) At the facility level, each VA facility that permits research is responsible for obtaining all required registrations and approvals (e.g., Institutional Review Board (IRB) registration; Institutional Biosafety Committee (IBC) registration; Federalwide

Assurance (FWA) for human subject research; PHS Animal Welfare Assurance), and maintaining accreditations (e.g., Association for the Accreditation of Human Research Protection Program (AHRPP); AAALAC).

(15) The facility-level framework for research administration is required to include management of both the research portfolio (e.g., with respect to required reviews and approvals) and research personnel (e.g., with respect to required credentialing, training, and scope-of-practice assurances).

(16) Each research facility is required to establish a local framework for the administrative management of research and for the review and approval of specific research protocols, and each facility must appoint a Research Compliance Officer (RCO) to conduct mandatory audits as required by ORO.

(17) Review, approval, and continuing oversight of VA research are to be provided by authorized committees and subcommittees, populated with qualified members, including, as applicable, the facility's Research and Development Committee (R&DC) for internal program management and oversight; designated IRB(s) for human subject research; Institutional Animal Care and Use Committee (IACUC) for laboratory animal research; and Subcommittee on Research Safety (and, when appropriate, the IBC) for research involving chemical and/or biological hazards.

(18) In addition to assurances of safety and security, the review and approval of VA research requires thoughtful assessment of scientific merit, including structured peer review, and the relevance of the research to the VA mission and the benefit of Veterans.

(19) Research committee and subcommittee functions are to be supplemented by the research-specific services of the facility's Privacy and Information Security Officers.

(20) VA investigators are responsible for knowing and adhering to all requirements applicable to their research studies.

(21) Through a committee of field representatives, VA research investigators and the leaders of VA facility research programs keep ORD aware of emerging issues of importance to the VA research community and the fulfillment of VA's statutory research mission.

c. Free Flow of Scientific and Technological information. VA recognizes that open communication among scientists and engineers, and between these experts and the public, accelerates scientific and technological advancement, strengthens the economy, educates the Nation, and enhances democracy.

(1) Dissemination and acquisition of information is a critical element of VA research in that it maximally promotes advances in health care for Veterans and the general public.

(2) Consistent with applicable privacy and classification standards, it is VA policy to promote the appropriate free flow and exchange of scientific and technological information in the scientific and medical communities as well as awareness of VA research among broader audiences.

(3) VA investigators are encouraged to report their work at professional meetings and in scientific, technical, and medical publications, and to participate in the activities of their professional organizations, in compliance with applicable conflict of interest laws and the Standards of Conduct for Employees of the Executive Branch.

(4) VA implements a variety of programs through the VHA ORD to encourage the free flow of scientific and technological information. Examples include:

(a) Special field-based centers and programs that bring together multi-disciplinary groups of VA investigators to study issues of concern to Veterans, promote innovative research and train new investigators.

(b) The Technology Transfer Program, charged with translating research results into practice, educating inventors on their rights and obligations and assisting in commercialization of new products.

(c) Proactive efforts to increase awareness of VA research accomplishments among key stakeholder groups and the public, including targeted outreach to Veterans Service Organizations (VSOs), frequent briefings for members of Congress and Congressional staffers, joint research initiatives with the Department of Defense (DoD), collaborative programs involving VA academic affiliates and industry, and active participation in professional medical and scientific conferences.

(d) Publication of the Journal of Rehabilitation Research and Development, which covers an area of research of particular interest to Veterans and key Veterans organizations.

(5) Through the VHA Office of Academic Affiliations (OAA), VA promotes a dynamic partnership with the Nation's medical and associated health professions schools to provide high quality health care to America's Veterans and to train new health professionals to meet patient care and research needs within VA and the Nation.

(6) It is VA policy to continuously strengthen its academic affiliation program, which now constitutes the most comprehensive academic health system partnership in history, to foster the appropriate free flow of medical, scientific, and technological information.

(7) Through the VHA Office of Public Health, VA promotes a variety of programs to educate health care professionals and to enhance the dissemination and use of scientific and technological information to improve Veterans' health and advance the missions of VA through prevention and treatment, outreach, surveillance and attention to the needs of special populations, including women Veterans.

(8) Consistent with VA's missions and the objectives of open government, VA will expand and promote access to scientific and technological information by making VA research findings and the products of VA research available to the public in accordance with accepted scientific standards, except as properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum.

(a) Through the VHA ORD, VA will develop, to the extent practicable, a mechanism to provide public internet access to the results of VA-funded research grants and any relevant products resulting from those grants.

(b) To the extent practicable, VA will expand and promote access to the scientific and technological information underlying its policies by making such information available on-line and in open formats. As appropriate, this will include data, research citations (including unpublished meta-analysis and systematic reviews of the scientific literature), and models underlying regulatory proposals and policy decisions.

d. Application of Scientific and Technological Findings to Clinical Care, Health Care Operations, and Public Health. VA recognizes that scientific and technological findings are routinely applied in the day-to-day operations of a health care delivery system. Health care professionals have an obligation to provide and appropriately apply all relevant clinical, scientific, and public health knowledge to the care of patients. VA shares this responsibility as the governing organization for the nation's largest health care system.

(1) It is VA policy that clinical care, health care operations and public health decisions are informed by sound scientific data and rigorous analyses that have been protected from inappropriate political influence.

(2) Nothing in VA policy will interfere with a health care professional's obligation to provide relevant medical information to patients.

(3) VHA deploys a variety of national patient education materials that incorporate scientific and technological findings.

(4) VHA's national clinical practice standards (e.g. clinical practice guidelines, clinical performance measures) integrate scientific findings as applicable and feasible.

(5) VHA's national health professions training and education programs strive to convey the appropriate application of scientific and technological findings.

e. Conveying VA Scientific and Technological Information to the Public. As a taxpayer-supported government enterprise, VA is rightfully expected to share information on its research programs and research results. VA strives to ensure openness and transparency in the use of data and other scientific and technological

findings. The American public has a right and a need to know how public funds are expended and how scientific and technological findings are applied in VA.

(1) It is VA policy to communicate VA scientific and technological findings to the public, to the extent practicable and appropriate, in formats that enhance public understanding by including a clear explanation of underlying scientific assumptions; the accurate contextualization of uncertainties; and a description of probabilities associated with both optimistic and pessimistic projections, including best-case and worst-case scenarios where applicable.

(2) VA and its employees have a responsibility to ensure that VA receives proper acknowledgment for VA-supported science in articles, presentations, interviews, and other professional activities in which VA scientific and technological findings are publicized or recognized.

f. Conveying VA Research Findings to the Public. The nature of scientific and medical research carries with it great potential to draw attention from the public and news media. To ensure that communication about research is timely, accurate, and as comprehensive as possible, it is VA policy to conduct proactive efforts to increase awareness of VA research and its results among key stakeholder groups including Veterans service organizations, Congress, VA academic affiliates, the scientific and medical community, and the public. VHA's ORD Communications Office provides public affairs and communications support to VA's nationwide research program in biomedical, health services, rehabilitation and clinical research. The ORD Communications Office produces special reports, brochures, news releases and a variety of other publications for ORD and works closely with the VA Office of Public and Intergovernmental Affairs to publicize VA's many research results. Efforts in this regard include:

(1) Notification of news media of selected VA research findings deemed of potentially high interest or great significance in advancement of VA's mission, including the promotion of quality health care for Veterans and the public.

(2) Publication of annual reports on the overall VA research program and specific topics of special interest, e.g., State of VA Research and Gulf War Report.

(3) Publication of newsletters on VA research.

(4) Briefings to Congress and Veterans service organizations.

(5) Outreach to Veterans and their families and caregivers.

(6) Use of the internet — including social media and video sites — to ensure timely flow of information resulting from VA research.

(7) An annual VA Research Week presented at VA headquarters and every VA research facility in the Nation that presents the latest findings and new areas of study, and reviews past VA research accomplishments.

6. PUBLIC COMMUNICATIONS

a. VA Science and Technology Experts May Speak to Media. It is VA policy that VA science and technology experts, including VA research investigators, may speak to news media and the public about their VA work with appropriate coordination through their immediate supervisor and the relevant VA public affairs office.

(1) VA officials, including VA public affairs officers, may not direct VA scientists and technology experts to alter scientific and technological research findings for political, programmatic, or public relations purposes.

(2) VA officials, including VA public affairs officers, may neither ask nor suggest that VA scientists and technology experts alter the presentation of their scientific findings in a manner that may compromise the scientific integrity of the those findings.

(3) In accordance with VA's Public Affairs Guidance Handbook, all VA employees, including VA research investigators and other VA science and technology experts, are required to coordinate any media queries or opportunities for promotion with the relevant VA public affairs office before agreeing to appear or provide comments. The purpose of this requirement is to allow VA's public affairs office to monitor national media interest in VA activities and ensure that all officials speaking on behalf of VA are providing the Department's views. In response to media interview requests about the scientific and technological dimensions of VA's accomplishments, VA will offer articulate and knowledgeable spokespersons who can, in an objective and nonpartisan fashion, describe and explain these dimensions to the media and the American people.

(4) VA research investigators must, when presenting or discussing their VA work with news media, make a serious and good-faith effort to obtain appropriate recognition for VA.

(5) When speaking to media, VA science and technology experts, including VA research investigators, have an obligation to make clear whether they are articulating official VA policy versus their own professional findings, judgments, or conclusions.

(6) The VA Office of Public and Intergovernmental Affairs, with advice from the VHA Office of Communications and VHA ORD, is responsible for coordinating media queries and for the public promotion of VA research findings through available media channels. Disputes about whether to speak with news media will be resolved through consultation among the Office of Public and Intergovernmental Affairs, VHA Office of Communications and VHA ORD. If necessary, the Deputy Assistant Secretary for Public Affairs may seek guidance from the Office of the Secretary.

(7) VA employees, including research investigators, must not independently, or through academic affiliation, promote their VA work to the media through news releases, inquiries about interviews, or other similar media outreach activities without coordination through the Office of Public and Intergovernmental Affairs.

NOTE: Publication of scientific and technological findings in the peer reviewed scientific literature or the presentation of scientific and technological findings at a scientific conference or through a published abstract is not considered promotion of scientific and technological findings under this paragraph.

b. Research Publications and Presentations. All publications and presentations of VA research findings must contain an acknowledgment of VA's support in accordance with VHA Handbook 1200.19.

(1) VA research investigators who are authors of clinical and research manuscripts, abstracts, books, book chapters and presentations relating to their work at VA must acknowledge VA employment and comply with the applicable criminal conflict of interest laws and Standards of Conduct for Executive Branch Employees governing teaching, speaking and writing related to their official duties.

(2) Failure to acknowledge VA support or employment may result in a discontinuation of current VA research funding, ineligibility to receive future VA research funding, and/or revocation of the privilege to conduct VA research.

7. USE OF FEDERAL ADVISORY COMMITTEES

a. VA Advisory Committees. As an important component of VA health care, VA establishes and maintains various advisory committees to provide the scientific advice needed to fulfill VA's missions. These advisory committees operate under the provisions of the Federal Advisory Committee Act (FACA), as amended.

b. Transparency. Transparency is the fundamental principle of FACA where public access to meetings is presumed and public commentary is invited. VA has standardized or revised numerous processes and procedures to improve the efficiency of VA's advisory committee operations and to hold them more accountable and focused on VA priorities. These internal policies include limiting membership size and number of terms; requiring written justifications for renewal of discretionary committees; submission of an annual operations plan and annual assessment on committee's effectiveness; department-wide criteria for membership balance, and standardized formats for VA responses to committee recommendations.

c. Ensuring the Independence of Scientific Advisory Committees. It is essential that VA has access to the best objective scientific advice and that its scientific and technological activities be conducted with input from a broad representation of individuals interested in the success of VA's missions.

(1) It is VA policy to develop advisory committee membership that represents diverse professional and personal qualifications and expertise, including committee subject matter expertise, experience in military service, military deployments, working with Veterans, and working in large and complex organizations. This also includes, to the extent possible, Veterans of diverse eras and branches of service, as well as diversity in race/ethnicity, gender, religion, disability, and geographical background.

(2) To ensure the process for recruiting and selecting members for these advisory committees tasked with giving scientific advice is standardized and maintains the integrity of a clear and transparent selection process, it is VA policy to:

(a) Enhance the recruitment for new advisory committee members, as practicable, by announcing advisory committee membership vacancies in the Federal Register annually.

(b) Provide professional biographical information (including current and past professional affiliations) on appointed advisory committee members, in accordance with the Privacy Act and other statutory/regulatory considerations, on VA's website to illustrate the members' qualifications for serving on the committee.

(c) Ensure that advisory committee membership is fairly balanced in terms of points of view represented with respect to the functions to be performed by the committee.

(d) Select committee members based on expertise, knowledge, and contributions to the relevant subject area, with consideration given to availability of the individual to serve, the individual's ability to work effectively on advisory committees, and the diversity of the committee's members.

(e) Make all conflict-of-interest waivers granted to committee members publicly available.

(f) Ensure that all advisory committee reports, recommendations, and products, except when explicitly stated in the advisory committee's charter or a prior agreement between VA and the committee, are treated solely as the findings of such committees rather than of VA, and thus are not subject to intra- or inter-agency revision.

8. PROFESSIONAL DEVELOPMENT OF VA SCIENCE/TECHNOLOGY EXPERTS

a. Promotion of Professional Development. VA actively promotes and facilitates the professional development of its employees consistent with their job responsibilities, applicable ethics requirements, and policies regarding political appointees. To this end, VA:

(1) Encourages the publication of VA scientific and technological findings in peer-reviewed, professional, or scholarly journals.

(2) Encourages the presentation of VA scientific and technological findings at professional meetings.

(3) Encourages VA employees to become editors or editorial board members of professional or scholarly journals.

(4) Encourages VA employees to participate fully in professional or scholarly societies, communities, task forces, and other specialized bodies of professional societies, including service as officers or on governing boards to the extent permitted by law.

(5) Permits VA employees to receive honors and awards for their scientific and technological findings and discoveries with the goal of minimizing, to the extent practicable and permitted by law, disparities in the potential for private sector and public sector scientists to accrue the professional benefits of such honors or awards.

b. VA Research Career Development Programs. The ORD research career development program is designed to attract, develop, and retain talented VA researchers in areas of particular importance to VA by providing a well-constructed, mentored research development experience. The Research Career Development Program is an award series under which both clinically and non-clinically trained post-doctoral researchers may gain mentored research time intended to prepare awardees for positions as Department of Veterans Affairs (VA) investigators.

c. Continuing Training and Development of VA Investigators. ORD offers VA researchers multi-faceted development opportunities through diverse training options. Computer-based training is mandated in areas including data integrity, ethics, privacy, and human research protections. A plethora of other computer based training is available, with individual investigator selections targeted to match the specific activities in which the investigator will be engaged at the VA. National VA Research conferences routinely and systematically address local accountability issues on an annual basis. Investigators are encouraged to include travel funds in their grants to facilitate participation in academic conferences outside the VA.

9. REFERENCES

a. Federal Statutes

(1) Title 5 U.S.C. Section 552, Freedom of Information Act: Public Information.

(2) Title 5 U.S.C. Section 552a, The Privacy Act of 1974: Records Maintained on Individuals.

(3) Title 5 U.S.C. Section 1213, Provisions Relating to Disclosures of Violations of Law, Gross Mismanagement, and Certain Other Matters.

- (4) Title 5 U.S.C. Section 2302, Prohibited Personnel Practices.
- (5) Title 5 U.S.C. Appendix, Federal Advisory Committee Act.
- (6) Title 7 U.S.C. Sections 2131-2159, Animal Welfare Act.
- (7) Title 38 U.S.C. Section 7303, Functions of Veterans Health Administration: Research Programs.
- (8) Title 38 U.S.C. Section 5705, Records: Confidentiality of Medical Quality-Assurance Records.
- (9) Title 38 U.S.C. Section 5701, Records: Confidential Nature of Claims.
- (10) Title 38 U.S.C. Section 7307, Office of Research Oversight in Veterans Health Administration.
- (11) Title 38 U.S.C. Section 7331, Protection of Patient Rights: Informed Consent.
- (12) Title 38 U.S.C. Section 7332, Protection of Patient Rights: Confidentiality of Drug Abuse, Alcoholism and Alcohol Abuse, Human Immunodeficiency Virus (HIV) Infection, and Sickle Cell Anemia Medical Records.
- (13) Title 38 U.S.C. Section 7334, Protection of Patient Rights: Regulations.
- (14) Title 42 U.S.C. Section 262, Regulation of Biological Products.
- (15) Title 42 U.S.C. Section 263, Preparation of Biological Products by Service.
- (16) Title 42 U.S.C. Section 1320d, Health Insurance Portability and Accountability Act.

b. Federal Regulations

- (1) Title 2 C.F.R. Part 180, OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement).
- (2) Title 2 C.F.R. Part 810, OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Department of Veterans Affairs)
- (3) Title 5 C.F.R. Part 1209, Practices and Procedures for Appeals and Stay Requests of Personnel Actions Allegedly Based on Whistleblowing.
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