

## VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE RESEARCH

**1. PURPOSE.** This Veterans Health Administration (VHA) Handbook establishes procedures for determining whether a VHA operations activity constitutes research. It also establishes procedures for verifying and documenting the non-research status of certain operations activities prior to publication of findings outside the Department of Veterans Affairs (VA). ***NOTE:** The requirements of this Handbook supplement (but do not supersede or replace) other requirements for review, approval, or tracking of VA publications (for example, requirements issued by the VA Office of Public and Intergovernmental Affairs, the VHA Office of Communications, or the VHA Office of Research and Development).*

**2. SUMMARY OF MAJOR CHANGES.** This is a new VHA Handbook that:

a. Provides procedures for determining if a VHA operations activity constitutes research and is therefore subject to VHA requirements for research.

b. Provides procedures for verifying and documenting the non-research status of certain operations activities prior to publication of findings outside VA.

**3. RELATED ISSUES.** VHA Directive 1058, VHA Directive 1200, VHA Handbook 1058.01, VHA Handbook 1058.03, VHA Handbook 1200.01, VHA Handbook 1200.05 and VHA Handbook 1200.12.

**4. RESPONSIBLE OFFICE.** The Office of Research Oversight (ORO)(10R) is responsible for the contents of this Handbook. Questions may be referred to (202) 266-4580.

**5. RESCISSIONS.** None.

**6. RECERTIFICATION.** This VHA Handbook is scheduled for recertification on or before the last working day of October 2016.

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## VHA OPERATIONS ACTIVITIES THAT MAY CONSTITUTE RESEARCH

### 1. PURPOSE

This Veterans Health Administration (VHA) Handbook establishes procedures for determining whether a VHA operations activity constitutes research. It also establishes procedures for verifying and documenting the non-research status of certain operations activities prior to publication of findings outside the Department of Veterans Affairs (VA). **NOTE:** *The requirements of this Handbook supplement (but do not supersede or replace) other requirements for review, approval, or tracking of VA publications (for example, requirements issued by the VA Office of Public and Intergovernmental Affairs, the VHA Office of Communications, or the VHA Office of Research and Development). The requirements of this Handbook are intended to enhance the openness and transparency of VA's scientific activities.*

### 2. BACKGROUND

VHA research activities are subject to a variety of requirements under the purview of the following VHA program offices:

a. The Office of Research and Development (ORD) is the primary VHA office responsible for developing national policy related to all VHA research activities.

b. The Office of Research Oversight (ORO) is the primary VHA office responsible for advising the Under Secretary for Health and exercising oversight concerning all matters of research compliance.

c. The National Center for Ethics in Health Care is the primary VHA office responsible for addressing the complex ethical issues that arise in patient care, health care management, and research. The National Center for Ethics in Health Care serves as a resource on issues of clinical, organizational, and research ethics.

In VHA, certain activities are primarily designed to fulfill VA's research and development mission and are, therefore, clearly subject to the regulations, policies, and ethics standards that govern research. However, certain other activities that are not primarily designed to fulfill VA's research and development mission may, nonetheless, constitute research and be subject to the requirements that govern research.

In particular, operations activities primarily designed to support one of VA's non-research missions may, on occasion, constitute research under applicable regulations or policy. This Handbook is necessary to ensure that all VHA research activities are appropriately identified and reviewed.

### 3. SCOPE

The requirements of this Handbook apply to all operations activities conducted by individuals when acting as VHA employees, including full and part-time employees, without compensation (WOC) employees, and employees under the Intergovernmental Personnel Act (IPA) of 1970. These requirements supplement, but do not replace, other requirements applicable to VA personnel, including VA and other Federal requirements for the conduct of research and requirements related to publications or presentations by VA personnel.

### 4. DEFINITIONS

The following definitions are intended for use only within this Handbook.

a. **Generalizable Knowledge.** For purposes of this Handbook, generalizable knowledge is information that expands the knowledge base of a scientific discipline or other scholarly field of study. Systematic investigations designed to develop or contribute to generalizable knowledge constitute research. Thus, systematic investigations designed to produce information to expand the knowledge base of a scientific discipline or other scholarly field of study constitute research.

b. **Operations Activities.** Operations activities are certain administrative, financial, legal, quality assurance, quality improvement, and public health endeavors that are necessary to support VHA's missions of delivering health care to the Nation's Veterans, conducting research and development, performing medical education, and contributing to national emergency response. Operations activities may or may not constitute research.

c. **Program Office.** A Program Office is any office within the VHA Office of the Under Secretary for Health. A Program Office includes all of its component offices and subdivisions, regardless of physical location. ***NOTE:*** *The organization chart for the VHA Office of the Under Secretary for Health may be found on the VHA Web site. Information about oversight of research conducted by employees of VHA Program Offices may be found in VHA Handbook 1058.06.*

d. **Research.** Research is a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge. Thus, for purposes of this Handbook, and in accordance with the definition of generalizable knowledge in subparagraph 4a, research may be defined as a systematic investigation designed to produce information to expand the knowledge base of a scientific discipline (or other scholarly field of study). ***NOTE:*** *Research typically involves the testing of concepts by the scientific method of formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis or question to expand the knowledge base of a field of study. Purely clinical use of an FDA-approved medication or product for an unlabeled indication is not considered research. (However, VA may require informed consent for treatment if safety and efficacy have not been established. If in doubt, providers must contact Pharmacy Benefits Management (PBM) for guidance.) Research is further discussed in the Federal Policy (Common Rule) for the Protection of Human Subjects in Title 38 Code of Federal Regulations Part 16 (38 CFR 16) in VHA Directive 1200; and in VHA Handbooks 1200.01 and 1200.05.*

e. **Systematic Investigation.** A systematic investigation is an activity that is planned in advance and that uses data collection and analysis to answer a question. Although research must include systematic investigation, non-research operations activities also include systematic investigation to ensure reliable outcomes. Systematic investigation does not, in and of itself, define research. *NOTE: Examples of systematic investigations that may or may not constitute research, include (but are not limited to) activities involving questionnaires or surveys; observations; focus groups; interviews; analyses of existing data; analyses of biological specimens; medical chart reviews; epidemiologic reviews or analyses; program evaluations; and quality assessment, quality improvement, and quality management.*

f. **VA Facility.** A VA facility is any entity that is operated by VA, including but not limited to, VA hospitals, medical centers, and health care systems; space owned, leased, or rented by VA; and space that is “shared” with a non-VA entity. A VA facility may include multiple campuses and satellite components.

g. **VA Facility Director.** A VA facility Director is the Director of a VA medical facility or a VA Health Care System.

## 5. DETERMINING WHEN OPERATIONS ACTIVITIES CONSTITUTE RESEARCH

a. **Non-Research Operations Activities.** Activities that are not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field) do not constitute research. Thus, a VHA operations activity does not constitute research if both of the following criteria are satisfied:

(1) The activity is designed and implemented for internal VA purposes (i.e., its findings are intended to be used by and within VA or by entities responsible for overseeing VA, such as Congress or the Office of Management and Budget); and

(2) The activity is not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field).

b. **Examples of Non-Research Operations Activities.** Routine data collection and analyses associated with the following VA activities do not typically constitute research, in and of themselves:

(1) Quality assessment and quality improvement activities designed for internal VA purposes (as determined by the relevant Program Office, VHA Network, or VHA facility per par. 6), including routine data collection and analysis for operational monitoring, evaluation, and program improvement purposes. Examples include, but are not limited to the routine data collection and analysis activities of the following VA programs:

- (a) All Employee Surveys, Voice of VA Surveys, and similar Surveys;
- (b) Cardiac Assessment Reporting and Tracking System (CART);
- (c) External Peer Review Program (EPRP);

(d) Home and Community Based Care Quality Initiative;

(e) Inpatient Evaluation Center (IPEC);

(f) Mental Health Program Evaluation Center (Northeast Program Evaluation Center, Program Evaluation Resource Center, and Serious Mental Illness Treatment Resource and Evaluation Center);

(g) National Center on Homelessness Among Veterans;

(h) Office of Suicide Prevention;

(i) System-wide Ongoing Assessment and Review Strategy (SOARS);

(j) VA Surgical Quality Improvement Program (VASQIP); and

(k) VHA Quality Improvement Initiative (VQuIP).

(l) Public Health Investigations.

(2) VHA systems redesign activities, patient satisfaction surveys, case management and care coordination, policy and guideline development and related evaluation activities, and benchmarking activities and similar comparisons.

(3) Competence or qualification reviews of VA employees and health care professionals, including performance evaluation activities; provider and health plan performance evaluations; root cause analyses; peer review activities; training and education of health care and non-health care professionals; accreditation, certification, licensing, and credentialing activities; and Joint Commission visits and related activities.

(4) Medical reviews, medication use evaluations (MUEs), legal analyses, auditing services, and regulatory compliance programs, including fraud and abuse detection, ORO reviews and investigations, VHA Medical Inspector (MI) investigations and national assessments, and activities of the Office of Inspector General (OIG).

(5) Business planning and development, such as cost-management and planning analyses related to managing and operating an entity; business management and general administrative activities; and financial auditing activities.

(6) Underwriting and other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits and ceding, securing, or placing a contract for reinsurance of risk relating to health care claims.

c. **Operations Activities Constituting Research.** An operations activity may or may not constitute research, depending on whether the activity is designed to produce information to expand the knowledge base of a scientific discipline (or other scholarly field of study).

(1) An operations activity is designed to develop or contribute to generalizable knowledge if the conceptualization, plan, or implementation of the activity is supplemented or modified in order to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study). For example, if an operations activity is designed to include collecting “extra” data or performing “extra” analyses not needed for internal operations purposes in order to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study), then the activity constitutes research.

(2) It is important to distinguish data collection for non-research operations purposes from subsequent use of the collected data for research purposes. For example, if data collected for an internal evaluation of a VA program are subsequently accessed and analyzed in a different way in order to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study), the subsequent analysis using the collected data constitutes research. However, if these data are subsequently accessed and analyzed in a different way for operations purposes, the activity does not constitute research.

(3) An activity that was initially designed as a non-research operations activity subsequently becomes research if it is supplemented or modified in order to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study). In such situations, the modifications and additions to the original activity constitute research. Components of the original activity that were not used to expand the knowledge base of a scientific discipline (or other scholarly field of study) remain non-research activities. For example, if identifiable patient data originally collected for non-research operations purposes are subsequently accessed and combined with additional data in order to produce information that expands the knowledge base of a scientific discipline (or other scholarly field of study), the activities performed to obtain the additional data and analyze the combined data constitute research. Uses of the original data for operations purposes unrelated to this research activity remain non-research activities.

(4) The fact that a particular activity is mandated by Congress or another oversight body or authority has no bearing on whether or not the activity meets the definition of research.

d. **Activities Always Considered Research.** For the purposes of this Handbook, the following activities are always considered research:

(1) Activities funded or otherwise supported as research by ORD or any other entity.

(2) Clinical investigations as defined under Food and Drug Administration (FDA) regulations. *NOTE: This includes studies of FDA-regulated drugs, devices, and biologics, regardless of whether the investigation or comparison requires an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE), and regardless of whether the investigation or comparison involves approved or unapproved (i.e., off-label) uses.*

e. **Consideration of Design Characteristics.** Although high-quality research requires sound methodological design, non-research operations activities also employ sound design to ensure reliable outcomes that fulfill program needs. Sound design characteristics do not, in and of themselves, define research. In determining whether an activity constitutes research, it is

important to consider carefully whether design characteristics are included for the purpose of fulfilling operational needs versus expanding the knowledge base of a scientific discipline or other scholarly field of study. Careful review is warranted in making such determinations. For example, the use of a particular design characteristic (e.g., stratification) that is necessary to generate information required for prudent programmatic decision-making constitutes a non-research operations activity as long as the activity was not designed to expand the knowledge base of a scientific discipline (or other scholarly field of study). However, use of the same design characteristic (e.g., stratification) in order to produce information to expand the knowledge base of a scientific discipline (or other scholarly field of study) does constitute a research activity.

(1) Certain design characteristics (particularly double blind interventions, use of placebo controls, and prospective patient-level randomization to clinical interventions not tailored to individual patient benefit) are almost always associated with research. Consultation with ORO and ORD is strongly recommended prior to the use of such design characteristics outside research.

(2) Other design characteristics are often associated with research but may also be used in non-research, operations activities. Their use in non-research operations activities must be based on and justified by well-defined operation needs. Inclusion of design characteristics for the purpose of producing information that expands the knowledge base of a scientific discipline (or other scholarly field of study) constitutes research. Examples of design characteristics for which particular care may be needed to ensure that their use is based on well-justified operations needs include prospective randomization to treatment interventions, prospective comparisons of clinical interventions, prospective designation of matched pairs, and interventions with patients to collect clinical information that is not medically necessary.

f. **Educational Activities.** Educational activities are operations activities necessary to support VHA's medical education mission, including training health care and other professionals, may constitute research if the activities are designed to expand the knowledge base of a scientific discipline or other scholarly field. However, such activities do not constitute research if they are designed and implemented for internal VA purposes, or are not designed to expand the knowledge base of a scientific discipline (or other scholarly field).

## 6. CONSULTATION AND DOCUMENTATION

a. **Consultation and Documentation.** Individuals conducting operations activities have a responsibility to consult their supervisor as soon as possible whenever there may be doubt about the research versus non-research status of an operations activity.

(1) Whenever the research versus non-research status of an operations activity may be in doubt, a determination of such status by the relevant Program Office, VHA Network, or VHA facility must be documented as expeditiously as possible.

(2) Documentation prior to initiation of the activity is strongly encouraged when patients will not be fully informed of the reasons for treatment recommendations or assignments to



specific treatments or when publication of findings from operations activities outside VA is reasonably anticipated.

b. **Risks and Prevention.** Individuals conducting non-research operations activities (as well as the relevant Program Office, Network, or facility) incur a particular obligation to ensure that the safety, rights, and welfare of affected patients and staff are appropriately protected. Potential risks (including physical, psychological, social, financial, privacy, confidentiality, and other reasonably foreseeable risks) associated with non-research operations activities must be thoroughly evaluated, and appropriate protections must be established to mitigate them. Documentation of risk analysis, consultation, and the resultant protections is strongly encouraged when more than nominal risk may be involved, or may be perceived to be involved.

c. **Program Office Operations Activities.** The status of non-research operations activities that are funded, mandated, managed, sponsored, or otherwise supported by a VHA Program Office, or that utilize Program Office data, must be documented by the relevant Program Office. *NOTE: Use of Program Office data bases may be subject to the requirements of VHA Handbook 1200.12, as well as to specific Program Office requirements. A Data Use Agreement (DUA), Data Transfer Agreement (DTA), or other written agreement may be required.*

(1) Program Office Directors (or Chief Officers) must notify ORO in writing of the title of any officials designated to provide such documentation. ORO must maintain a list of such officials on its Web site.

d. **Other Operations Activities.** The status of non-research operations activities other than those described within subparagraph 6c must be documented by the lead VA author's Network Director (for Network operations activities) or Facility Director (for facility operations activities), or other individual designated in writing by the Network or Facility Director.

e. **Additional Consultation.** When unable to reach a determination about the research versus non-research status of an operations activity, the relevant Program Office, Network, or facility officials are encouraged to request joint, written guidance from ORO and ORD regarding the activity. *NOTE: ORO and ORD must consult with the National Center for Ethics in Health Care as warranted. Procedures for requesting joint ORO-ORD guidance are found on the ORO Web site at [www.va.gov/oro/](http://www.va.gov/oro/).*

## 7. PUBLICATION AND PRESENTATION OF NON-RESEARCH FINDINGS

a. **Publication and Presentation Do Not Define Research.** Publication or presentation outside VA of findings from non-research operations activities or other non-research activities does not, in and of itself, constitute research.

b. **Program Office Peer-Reviewed Publications.** Publication in peer-reviewed journals (including electronic peer-reviewed journals) of findings from non-research activities that were funded, mandated, managed, sponsored, or otherwise supported by a VHA Program Office, or that utilized Program Office data, requires documentation of the non-research status of the activities by the relevant Program Office prior to publication.

c. **Other Peer-Reviewed Publications.** Publication in peer-reviewed journals (including electronic peer-reviewed journals) of findings from non-research activities other than those described in subparagraph 7b requires documentation, prior to publication, of the non-research status of the activities by the lead VA author's Network Director (for Network operations activities) or Facility Director (for facility operations activities), or other individual designated in writing by the Network or Facility Director.

d. **Documentation Content.** Documentation content is documentation for peer-reviewed publications (as described in subpar. 7b and 7c) based on non-research activities and must include:

(1) A copy of the manuscript to be published, including the name and VA duty station or institutional affiliation of each author and coauthor.

(2) An attestation, signed by each VA author or co-author, that the reported findings were not derived, in whole or in part, from activities constituting research as described in this Handbook.

(3) The signature of the documenting official. *NOTE: A sample format for documentation of non-research activities is provided on ORO's Web site at [www.va.gov/oro/](http://www.va.gov/oro/).*

(4) Each VA author and coauthor must retain a copy of the documentation for a minimum of 5 years after publication and in accordance with any applicable records retention schedules.

e. **ORO Access.** Access to, and copies of, the documentation described in subparagraph 6d must be provided to ORO promptly upon request.

f. **Contested Documentation.** Should the ORO Chief Officer, the Chief Research and Development Officer, the Chief Ethics in Health Care Officer, or any other VA official contest the documentation described in subparagraph 7d, the matter must be referred to the Under Secretary for Health for resolution.

g. **Other Program Office Publications or Presentations.** Other than peer-reviewed publications as described in subparagraph 7b, publication, presentation, or dissemination of findings from non-research activities that were funded, mandated, managed, sponsored, or otherwise supported by a VHA Program Office, or that utilized Program Office data, is subject to the requirements of the relevant Program Office.

h. **Other Publications or Presentations.** Except as described in subparagraphs. 7b, 7c, and 7g, publication, presentation, or dissemination outside VA of findings from non-research activities is subject to the requirements of the lead VA author's Network or facility, as applicable. *NOTE: The requirements of this paragraph supplement (but do not supersede or replace) other requirements for review, approval, or tracking of VA publications based on non-research activities (for example, requirements issued by the VA Office of Public and Intergovernmental Affairs or the VHA Office of Communications). The requirements of this paragraph do not apply to re-publication or re-presentation of data already in the public domain.*

**8. REFERENCES**

- a. Title 38 CFR Part 16, Protection of Human Subjects.
- b. VHA Directive 1058, The Office of Research Oversight.
- c. VHA Directive 1200, VHA Research and Development Program.
- d. VHA Handbook 1058.01, Research Compliance Reporting Requirements.
- e. VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research.
- f. VHA Handbook 1058.06, Research Conducted by Employees of VHA Program Offices.
- g. VHA Handbook 1200.01, Research and Development (R&D) Committee.
- h. VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.
- i. VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research.