

Louis Stokes Cleveland DVA Medical Center
Medical Research Service
Standard Operating Procedure

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SOP Title: Request for Research vs. Non-Research Operations Evaluation

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1. PURPOSE

To establish procedures for determining whether a VA operations or other process/quality improvement type activity constitutes research.

2. DEFINITIONS

- a. **Generalizable Knowledge.** For purposes of this SOP, 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. **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, 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.*

3. 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 fields).

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, 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:
 - All Employee Surveys, Voice of VA Surveys, and similar Surveys;
 - Cardiac Assessment Reporting and Tracking System (CART);
 - External Peer Review Program (EPRP);
 - Home and Community Based Care Quality Initiative;
 - Inpatient Evaluation Center (IPEC);
 - Mental Health Program Evaluation Center (Northeast Program Evaluation Center, Program Evaluation Resource Center, and Serious Mental Illness Treatment Resource and Evaluation Center);
 - National Center on Homelessness Among Veterans;
 - Office of Suicide Prevention;
 - System-wide Ongoing Assessment and Review Strategy (SOARS);
 - VA Surgical Quality Improvement Program (VASQIP); and
 - VHA Quality Improvement Initiative (VQuIP).
 - 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.

b. 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.

c. Activities Always Considered Research. For the purposes of this SOP, 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.*

4. Educational Activities. Educational activities are operations activities necessary to support VHA's 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).

4. CONSULTATION AND DOCUMENTATION

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.

5. 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 5b 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 for peer-reviewed publications based on non-research activities 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 SOP.
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/.*

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. 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 5d, the matter must be referred to the Under Secretary for Health for resolution.

f. Other Program Office Publications or Presentations. Other than peer-reviewed publications as described in subparagraph 5b, 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.

g. Other Publications or Presentations. Except as described in subparagraphs 5b, 5c, and 5f, 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.*

6. PROCEDURES

a. Whenever the research versus non-research status of an operations activity may be in doubt, the Project Leader must complete the “**Research vs Non-Research Operations Evaluation**” form and submit it to the Research & Development Committee (RD&C) Coordinator. The form can be found at: <https://www.clevelandvaresearch.org/study-forms-1> .

b. The R&DC Coordinator will:

- 1) Review the form for completeness, and if needed request additional information.
- 2) Forward the form to the ACOS/R, who will make the determination of research versus non-research

c. The ACOS/R will review the information, make a determination and sign and date the form. The form will be returned to the R&DC Coordinator and the Project Leader.

d. The R&DC Coordinator will save electronic copies of all determinations made and track them on a spreadsheet maintained on the Research Service drive.

e. Considerations for when a “**non-research**” determination is made. 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.

f. When a “**research**” determination is made the project may not be conducted as quality improvement and IRB and/or other applicable research subcommittee review and approval will be required. The project may not begin without all required research approvals.

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.