Operational Activities versus Research

VHA ORD Program Guide 1200.21, VHA Operations Activities that May Constitute Research and VHA Directive 1200.05, outline specific requirements related to determining the difference between VHA Operations Activities and VHA Research. This guidance document summarizes those requirements and describes what is necessary for determining between research and operational activities.

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 guidance is necessary to ensure that all VHA research activities are appropriately identified and reviewed and that those operations activities that do not constitute research are appropriately documented.

Definitions

A. **Research:** A systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge. In accordance with the definition of generalizable knowledge (SEE III.C), 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).

B. **Systematic Investigation**: 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.

C. **Generalizable Knowledge:** 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.

D. **Operations Activities**: 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 <u>may or may not</u> constitute research.

E. **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).

F. **Operations Activities Constituting Research**: An operations activity may constitute research if 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.

G. **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.

H. **Activities Always Considered Research:** The following activities are always considered research:
1. Activities funded or otherwise supported as research by Office of Research and Development (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.*

I. **Activities Deemed not to be Research**: The following activities are deemed not to be research under the Federal Policy for the Protection of Human Subjects (Common Rule) in Title 38 Code of Federal Regulations Part 16 (38 CFR 16.102(l)), published January 19, 2017:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions

Determining Whether an Operations Activity is Research or Non-Research

Research Activities:

Any operations activity conducted at VAPHS which meets the definition of research must be submitted to the VAPHS Research Office for review and approval by the appropriate research review committees (i.e., VAPHS Institutional Review Board, VAPHS Institutional Animal Care and Use Committee, VAPHS Research Scientific Evaluation Committee, VAPHS Institutional Biosafety Committee/Subcommittee on Research Safety). In addition, such research must be approved by the VAPHS Research and Development Committee and a letter from the Associate Chief of Staff for Research and Development must be issued before the research can be initiated. Individuals interested in conducting such research should visit the VAPHS Research Office Website for additional information regarding the submission process.

Non-Research Activities:

Individuals conducting activities that meet the definition of non-research operations activities are not required to submit to any VAPHS research review committee(s). Individuals are encouraged to determine whether an activity meets the non-research activity definition.

When Status is in Question

Whenever the research versus non-research status of an operations activity may be in doubt, a determination of such must be documented as expeditiously as possible.

a. 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.

b. The status of all other non-research operations activities must be documented by the lead VA author's Network Director (for Network-level operations activities) or by the lead VA author's Facility Director (for facility-level operations activities), or by the individual designated by the Facility Director to make such determinations. At VAPHS, the Institutional Review Board Chair, Vice Chair, or other qualified voting member designated by the Chair, has been designated by the Facility Director to make such determinations. Therefore, when the research versus non-research status is in question, the responsible individual must submit a request for a QA/QI determination to the Investigational Review Board (IRB). Individuals should follow the procedures outlined below when requesting a determination.

1) Complete the [Non-research Activity Determination Worksheet for Investigators](). If after completing this worksheet you believe your project does qualify as non-research, you do not need to submit this worksheet. Only submit this worksheet if you are unsure of whether your project is research or an operational activity.
2) Email the completed Non-research Activity Determination Worksheet for Investigators and the project abstract to the VAPHS IRB at [VHAPTHIRB@va.gov]()
3) The IRB Office will route your abstract and worksheet to appropriate IRB leadership for review. This review process may take up to 2-4 weeks. Communication will be routed through the IRB office.
4) An email will be sent with the determination approval signed by the appropriate IRB leadership.

c. 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.

d. 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 Office of Research Oversight (ORO) and Office of Research and Development (ORD) regarding the activity.

Publication of Non-Research Activities

Publication in peer-reviewed journals (including electronic peer-reviewed journals) of findings from non-research activities requires documentation of the non-research status of the activities prior to publication.

1. <u>Program Office Peer-Reviewed Publications</u>. 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, should have documentation of the non-research status of the activities by the relevant Program Office prior to publication.

2. <u>Other Peer-Reviewed Publications</u>. Publication in peer-reviewed journals (including electronic peer-reviewed journals) of findings from non-research activities other than those through a Program Office should have 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.

3. <u>Documentation Content</u>
   The "Documentation of Non-Research Status prior to Publication/Presentation" memorandum must be used to ensure that all required content has been obtained. This form is available on the Office of the Director's Share point site and must be routed to the Medical Center Director through the Lead Author's Service Line Vice President, Chief of Staff and Deputy Director for all appropriate concurrences and signatures. A sample template is included in below

   a. A copy of the manuscript to be published, including the name and VA duty station or institutional affiliation of each author and co author.

   b. 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 VHA Program Guide 1200.21.

   c. The signature of the documenting official. In the case of facility-level activities, this will be the Facility Director.

   d. Each VA author and coauthor must retain a copy of the documentation for a minimum of 6 years after publication and in accordance with any applicable records retention schedules.

DEPARTMENT OF　　　　　　　　**MEMORANDUM**
VETERANS AFFAIRS

Date:　Click or tap here to enter text.

From:　Click or tap here to enter text.

Subj:　Documentation of Non-Research Activities prior to Publication/Presentation

To:　Facility Director (00)

1. In accordance with VHA Program Guide 1200.21, publication in peer reviewed journals (including electronic peer-reviewed journals) or presentation/dissemination of findings from non-research activities requires documentation of the non-research status of the activities <u>prior to</u> publication/ presentation.

2. I am proposing to submit the following publication/ presentation, <u><<Title of Proposed Publication>></u> , which reports findings from the following non-research VHA operations activities: *Provide a brief description of the operations activities related to this publication/presentation. Include the name of the project, reason the project was carried out, individual (or individuals) responsible for project and date(s) of data collection.*

   Click or tap here to enter text.

3. As an author of the publication/ presentation referenced above (copy attached), I attest that the findings reported in the publication/ presentation were derived from activities that:
   a. Were designed and implemented for internal VA purposes, and
   b. Were not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field).
   c. Were not funded or otherwise supported as research by Office of Research and Development of any other entity.
   d. Were not clinical investigations as defined under Food and Drug Administration (FDA)[1].
   e. Do not meet the definition of research.
   (Provide the following for *each VA author: Remove or add lines as necessary*)

   Lead Author Signature: _____　　Date: _____
   Lead Author Name: Click or tap here to enter text.　　VA Duty Station: Click or tap here to enter text.

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[1] 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.

Co-Author Signature: _____   Date: _____
Co-Author Name:Click or tap here to enter text.   VA Duty Station: Click or
tap here to enter text.

Co-Author Signature: _____   Date: _____
Co-Author Name:Click or tap here to enter text.   VA Duty Station: Click or
tap here to enter text.

Co-Author Signature: _____   Date: _____
Co-Author Name:Click or tap here to enter text.   VA Duty Station: Click or
tap here to enter text.

Attestation of Designated Program Office or Facility Official

As the designated representative of the VA Pittsburgh Healthcare System, I have reviewed the activities reported in the publication/presentation and attest that these activities did not constitute research as described in VHA Program Guide 1200.21 (See Appendix A for key definitions).

Concur/Do Not Concur

_____   _____
Click or tap here to enter text.   Date
Service Line VP

Concur/Do Not Concur

_____   _____
Click or tap here to enter text.   Date
Chief of Staff

Concur / Do Not Concur

_____   _____
Click or tap here to enter text.   Date
Deputy Director

Approve / Do Not Approve

_____   _____
Click or tap here to enter text.   Date
Director