I. PURPOSE

The purpose of this memorandum is to establish policy and procedure for the VA Pittsburgh Healthcare System (VAPHS) for determining whether a Veterans Health Administration (VHA) facility-level operations activity constitutes research. It also establishes procedures for verifying and documenting the non-research status of certain facility-level operations activities prior to publication of findings outside the Department of Veterans Affairs (VA).

II. POLICY

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 Memorandum 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.

III. 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 may or may not 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

IV. PROCEDURES

A. Determining Whether an Operations Activity is Research or Non-Research

1. 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. The website can be accessed by going to: (http://www.pittsburgh.va.gov/Research/professionals.asp)

2. 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 review the decision tree (see Appendix A) to determine whether an activity meets the non-research activity definition. If there is question, the procedures outlined in Section IV.A.3. must be applied.

3. When Status is in Question

a. 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.

1) 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.

2) 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 on the Research Office website at http://www.pittsburgh.va.gov/Research/Human_Research.asp when requesting a determination.
b. 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.

c. 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.

B. 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. 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, should have documentation of the non-research status of the activities by the relevant Program Office prior to publication.

2. Other Peer-Reviewed Publications. 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. Documentation Content

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 Sharepoint site and the Research Office website 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 Attachment B.
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 Handbook 1058.05.

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.

V. RESPONSIBILITIES

A. Facility Director

1. Ensures overall implementation of this policy within the VAPHS.

2. Designates that the VAPHS IRB is charged with determining whether an activity is research or non-research when a need for a formal determination is required.

3. Serves as the final signatory on facility-level documentation that a given activity constitutes a non-research activity.

B. VAPHS IRB

1. Reviews any formal request for a non-research vs. research determination.

C. VA Lead Author

1. Ensures all required documentation regarding the research or non-research activity has been obtained in compliance with VHA Handbook 1058.05 and this MCM.

VI. REFERENCES

VHA Directive 1200.05; VHA ORD Program Guide 1200.21, VHA Operations Activities That May Constitute Research
VII. RESCISSIONS

Memorandum LD-077 dated April 4, 2016

VIII. CONCURRENCES

11, 001, 002, 00B, 003, 00S, 05, All Service Lines VPs, AFGE 2028

IX. EXPIRATION

This memorandum will automatically expire on April 4, 2022.

//Signed//
BARBARA FORSHA, MSN, RN, ET
Interim Medical Center Director

Attachment A – Memorandum: Documentation of Non-Research Activities prior to Publication/Presentation
DEPARTMENT OF VETERANS AFFAIRS

MEMORANDUM

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 Handbook 1058.05, 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 prior to publication/presentation.

2. I am proposing to submit the following publication/presentation, <<Title of Proposed Publication>>, 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.

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.

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.
(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.

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 Handbook 1058.05 (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

__________________________________ ______________
Ali F. Sonel, MD, FACC, FACP Date
Chief of Staff

Concur / Do Not Concur
Appendix A
Key Definitions

**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 may or may not constitute research.

**Research:** A systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge (i.e., produce information to expand the knowledge base of a scientific discipline or other scholarly field of study).

**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).

**Examples of Non-Research Operations Activities**

1. Quality Assessment and Quality Improvement activities designed for internal VA purposes (as determined by the relevant Program Office, VHA Network, or VHA facility), including routine data collection and analysis for operational monitoring, evaluation and program improvement purposes.
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.