VA ANN ARBOR HEALTHCARE SYSTEM

DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF QUALITY MANAGEMENT
PROGRAM GUIDE

For

QUALITY IMPROVEMENT PROJECTS

Handbook……What May Constitute Quality Improvement Project

PROGRAM GUIDE FOR QUALITY IMPROVEMENT PROJECTS

Contents

PURPOSE

The purpose of this program guide is to assist VA Ann Arbor staff and students with determining eligibility for quality improvement (QI) projects. It will also assist with differentiating quality improvement projects from research. This program guide sets forth the expectations, process for applying and approval of QI projects. It is also to clarify the requirements for presenting and/or publishing the results of QI projects.

BACKGROUND

In VHA certain activities are primarily designed to fulfill VA's research and development mission while others are designed to support VA's non-research mission. These non-research mission activities could be quality improvement projects. The QI projects are very different than research projects and have different requirements. While VHA research activities are subject to a variety of requirements, QI projects must be identified in the beginning and must follow established guidelines. This program guide is to ensure that all non-research activities are appropriately identified, and the established guidelines are followed.

SCOPE

The requirements of this Program Guide apply to all non-operational QI activities conducted by individuals when acting as VHA employees: full time, part time and without compensation employees as well as interns and students.

DEFINITIONS

Definitions and acronyms used within this Program Guide:

- **Generalizable Knowledge.** Generalizable knowledge is information that expands the knowledge base of a scientific discipline or other scholarly field of study. Systematic investigations that are designed to develop or contribute to generalizable knowledge constitute research.
- **HIPPA.** Healthcare Information Privacy and Portability Act**.**
- **Nominal Risk.** Minimal risk**.**
- **Operations Activities.** Operations activities are administrative, financial, legal, quality assurance, quality improvement, public health endeavors that are necessary to support VHA's missions of delivering health care to the Nation's Veterans, performing medical education, and contributing to national emergency response. Operations activities may or may not constitute research**.**
- **ORD.** Office of Research and Development.
- **ORO.** Office of Research oversight.
- **PHI.** Personal Health Information.
- **QSVR.** Quality, Safety, Value and Risk

- **Research.** Research is a systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge. Given the definition of generalizable knowledge, research may also be defined as a systematic investigation designed to produce information to expand the knowledge base of scientific discipline (or other scholarly field of study).
- **RDC.** Research and Development Committee.
- **Systematic Investigation.** A systematic investigation is an activity that is planned 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 itself, define research.

ELIGIBILITY DETERMINATION

Before starting your QI Project read this section carefully, read the questions in the application on page 11, and follow the flow cart (Appendix B) to determine if your project is a quality improvement or a research project. In general activities designed to produce information that expands the knowledge base of a scientific discipline or other scholarly field are considered research. Activities funded or otherwise supported as research by Office of Research Development (ORD) or any other sponsor are also considered research. If your project meets the research criteria refer to the Research Share Point VAAAHS Research Services.

Non-Research Activity

A. Non-Research Operational Activities: The VHA operations activity does not constitute research if both of the following criteria are satisfied:

1. The activity is designed and implemented for internal purposes, that means the finding from this project are intended to be used by and within VA.
2. The activity is **not** designed to produce information that expands the knowledge base of a scientific discipline or another scholarly field.

B. Activities deemed not to be research under the Federal Policy for Protection of Human Subjects (Common Rule in Title 38 Code of Federal Regulations Part 16, published Jan 19, 2017**):**

1. Scholarly and journalistic activities.
2. Public Health surveillance activities.
3. Collection and analysis of information for criminal justice
4. Authorized operational activities such as homeland security or other national security missions

C. Examples of Non-Research Operational Activities: Routine data collection and analysis associated with the following activities do not typically constitute research.

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;

i. All Employee survey or similar survey;
ii. Primary Care Quality Initiatives;
iii. Inpatient Care Quality Initiatives;
iv. VHA Quality Improvement Initiatives (VQuIP);
v. VA Surgical Quality Improvement Program (VASQIP);
vi. Public Health Investigations;
vii. Cardiac Assessment Reporting and Tracking System (CART);
viii. External Peer Review Program (EPRP);
ix. Home and Community Based Care Quality Initiative;
x. National Center on Homelessness Among Veterans;
xi. Mental Health Program Evaluation Center;
xii. Office of Suicide Prevention;
xiii. System-wide Ongoing Assessment and Review Strategy (SOARS);

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 healthcare professional, including performance evaluation activities; provider and health plan performance evaluations; root cause analyses; peer review activities; training and education of healthcare 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 Office of the Medical Inspector (OMI) 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 and entity; business management and general administrative activities; and financial audit related activities.
6. Underwriting and other activities related 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.
7. Educational activities that are designed and implemented for internal VA purposes and are not designed to expand the knowledge base of a scientific discipline.

APPLICATION SUBMISSION

After reviewing the above section if your project does qualify for quality improvement project, please complete the application for approval (Appendix A).

VA REVIEW OF QUALITY IMPROVEMENT PROJECT SUBMISSION

Quality Improvement (QI) project application will be reviewed by the representatives from the Quality, Safety, Value and Risk department (QSVR). They will approve, disapprove or ask for modifications. If approved as a QI/QA project, QSVR will submit the application with their approval to the Medical Center Director requesting a letter of support. If unable to reach a determination about the non-research status of a QI project, the Research and Development Committee will be contacted for guidance.

CONSULTATION

Individuals conducting operations activities have the responsibility to consult their supervisor or advisor as soon as possible whenever there may be any doubt about the status of a QI project.

WAITING FOR APPROVAL LETTER

You will be notified by letter about the decision about approval or rejection. It is possible that you will be requested to provide more information or modify your project, or it could be determined not to be a QI project. If your project is determined to be research, you will be referred to VAAAHS Research Services. No part of the project may be started before receiving an approval letter. No patient data may be collected for the project while waiting for an approval letter.

DATA USE AND STORAGE FOR YOUR PROJECT

You must be committed to protect personal information called PI and protected health information called PHI. HIPPA policy is followed very strictly when conducting activity involving PHI. Patient data can only be stored on the computers owned by VA facility. Personal computer or USB drive cannot be used. Patient information cannot be taken out of VA even when deidentified. You may need to complete an application to request data access by filling an application called Data Use Agreement Form.

RISKS ASSESSMENT AND PREVENTION

Individuals conducting quality improvement projects as non-research activities as well as the relevant Program Office, Network or facility incur an obligation to ensure that safety, rights and welfare of affected patients and involved staff are appropriately protected. Potential risks including confidentiality, privacy, physical, psychological, social, financial and any other reasonable risks associated with QI projects 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.

PRESENTATION OF FINDINGS

Findings of the QI project must be presented to the appropriate VA Ann Arbor Stakeholders. The presentation must include outcomes and shared learning.

PUBLICATIONS OF FINDINGS

- **Peer-reviewed Publications.**
  Publications in the VA require approval of Medical Center Director in the form of written permission. Submit the document for permission following the sample outline (Appendix C). Publications in peer-reviewed journals including electronic peer-reviewed journals of finding from non-research activities such as quality improvement projects should be documented as non-research prior to publication along with the name of the site where activity was conducted. This includes the activities that were funded, managed, sponsored or otherwise supported by a VHA Program office or that utilized Program Office data.

- **Documentation Content.**
  Documentation content for peer-reviewed publications based on non-research activity status should include:
  1. A copy of the manuscript, to be published, including the name and VA duty station or institutional affiliation of each author and co-author.
  2. An attestation, signed by each VA authors or co-authors, that the reported findings were not derived, in whole or in part, from activities constituting research.
  3. The signature of the Medical Center Director will be needed for publication. A sample format for documentation of non-research activities for publication is provided in (Appendix C).
  4. Each VA author and coauthor should retain a copy of the documentation for a minimum of 6 years after publication and in accordance with any applicable records retention schedules.

- **ORO Access**
  Access to and copies of the documentation on how the results of the activity will be used, including a description of any future uses of results of the activity should be provided to ORO upon request.

- **Contested Documentation**
  Should the Chief Research and Development Officer, the ORO Executive Director, the Chief Ethics in Health Care Officer or any other VA official contest the documentation, the matter must be referred to the Under Secretary for Health, VHA, for resolution.

- **Other Publications or Presentations**
  Other non-peer reviewed publication, presentations, or dissemination of findings from non-research activities that were funded, mandated, managed, sponsored or otherwise supported by a VISN or VA facility is subject to the requirements of the lead VA authors' Network or facility as applicable.

APPENDIX

A. QI Project Eligibility Application
B. Project Eligibility Determination Process
C. Sample Format for Documentation for Publication

Appendix A

QI PROJECT ELIGIBILITY APPLICATION

Initial Application for Quality Improvement Project Eligibility (Non-Research) Determination

Applicant: Please complete the form below, including the questions. When completed, e-mail this form to the QM at (Tisha.Crowder-Martin@va.gov)

Date: _____

Title of Project: _____

Name of Project **Leader**,_____

Project Leader's Contact Information:

Department: _____Supervisor:_____

Work Phone:_____ E-mail Address: _____

Name of Project, **Co-leader** (If applicable)_____

Project Co-Leader's Contact Information:

Department: _____Supervisor:_____

Work Phone:_____ E-mail Address: _____

Name of Project **Supervisor at the site of the project**: _____

Supervisor's Contact Information:

Department: _____Station (Work Area):_____

Work Phone:_____ E-mail Address: _____

Name of Project **VA AA Clinical Advisor of the project**: _____

Supervisor's Contact Information:

Department: _____Station (Work Area):_____

Work Phone:_____ E-mail Address: _____

Name of Project **Faculty advisor (if student)**: _____

Faculty advisor's Contact Information:

Department: _____Station (Work Area):_____

Work Phone:_____ E-mail Address: _____

Attach a file to this form that includes the following:

- State what you have identified as the problem to be addressed by your project.
- Summarize what you intend to do for your project. Please try to limit your summary to 500 words or less. However, please do not sacrifice clarity for brevity.
  - Include permission letter from your supervisor.
- Include any background information, need for interventions, aim of the project, site of the project, interventions in detail, expected outcomes, data and literature references to support your position.

Please also include the name and contact information of the contact person if the site is not Ann Arbor Health Center.

Instructions: Place cursor in box above; go to ***Insert*** tab → ***Text*** group → ***Object*** → ***Create from file*** tab (display as icon, DO NOT LINK)

Answer the following questions:

		Yes	No
1.	Is the project funded or otherwise supported as research by any entity (such as NIH, FDA, ORD, etc.)?	☐	☐
2.	Is the process change being implemented at more than one site/institution? Details about the institution (s) other than Ann Arbor Health Care Center.	☐	☐
3.	Does the project involve subject recruitment? (*Subject Recruitment* is the process of soliciting and selecting subjects for participation).	☐	☐
4.	Will subjects be randomized to treatments/processes? (*Randomization* means that all people in the population of interest have the same probability of being selected to be included in the study)	☐	☐
5.	Do you plan to publish results or present at professional meetings?	☐	☐
6.	Does participation in the project pose any risk to the subjects? (*Risk* is the chance or likelihood that an undesirable event or effect will occur)	☐	☐
7.	Can the information be modified by people directly involved in the process on a regular basis without formalized amendment to the initial proposal?	☐	☐
8.	Does language of hypothesis or question being tested specify a single place and time?	☐	☐
9.	Do treatments or tests exceed usual care? (*Usual care* means that no additional burdens on participants beyond what would be normally expected or normally experienced during care, program participation or role expectations)	☐	☐
10.	Is the intent or design of the project to generate results to a broader scientific community than just Ann Arbor?	☐	☐

If answer to questions 1-4 and/or 9-10 the QI/QA project will be reviewed by the Research and Development Committee (RDC). It must be submitted to RDC for review. If answer is no to questions 1-4 and/or 9-10 submit your application to Quality Safety Value and Risk (QSVR) department for review. Prior to publication submission the Associate Chief of QSVR and/or Research or their designee will review the manuscript.

Signature:

This Section is for Reviewer's Use (do not complete)

Final Designation of Project:

☐ Non-Research

Continuing Review Frequency: ☐ 12 Months

Project ID Assigned: _____

☐ Research (complete Non-Research Designation Letter – Initial Review form)

☐ Unable to determine. Incomplete of insufficient information provided.

☐ Unable to determine. Referred to Research and Development Committee.

Comments:

APPROVED_____

DISAPPROVED

MODIFICATION SUGGESTED _____

Key Words: _____

Signature/Date:

Title…….

Appendix B

QI Project Flow Chart

QI Project Flow Chart Revised.pdf

Appendix C

Documentation of Non-Research Activities for Publications Outside the VA

Title of Proposed Publication:

Author Attestations

As an author of the publication referenced above (Copy attached), I attest that the findings reported in the publication were not derived, in whole or in part, from activities constituting research as described in VHA Program Guide 1200.21. The project generating these findings was conceived and conducted as a non-research operations activity involving (PROJECT DESCRIPTION).

(Provide the following for each author)

Lead Author Signature	Date
Lead Author's Name	VA Duty Station
Co-Author Signature	Date
Co-Author's Name	VA Duty Station
Co-Author Signature	Date
Co-Author's Name	VA Duty Station
Co-Author Signature	Date
Co-Author's Name	VA Duty Station

(Add additional co-authors information as relevant)

Attestation of Designated Official

As the Director or Director-designated representative of the VA Ann Arbor, I have reviewed the publication and author attestation(s) and attest that findings reported in publication did not arise from activities that constituted research as described in the program guide.

Ginny L. Creasman, Pharm.D., FACHE Medical Center Director VA Ann Arbor Healthcare System	Date

REFERENCES

Program Guide: 1200.21 VHA Operational Activities That May Constitute Research (2019) Department of Veterans Affairs, Office of Research and Development