VA Pittsburgh Healthcare System (VAPHS)
Human Research Protection Program (HRPP)
Policy for Quality Assurance/Quality Improvement Projects

POLICY H-013

VA Pittsburgh Healthcare System
Pittsburgh, PA 15240

Service Line(s):
Research

Signatory Authority:
Steven H. Graham, MD, PhD, ACOS/R&D

Effective Date:
December 21, 2021

Responsible Owner:
ACOS/R&D

Recertification Date:
March 31, 2025

1. PURPOSE AND AUTHORITY

A. This policy describes the procedures and responsibilities of VAPHS employees and the VAPHS Institutional Review Board (IRB) regarding the conduct and review of Quality Assurance/Quality Improvement Projects at VAPHS.
B. This policy applies to all VAPHS employees involved in the conduct of Quality Assurance/Quality Improvement projects at VAPHS.
C. As a part of hospital operations, service lines are expected to complete quality improvement/quality assurance projects. These projects frequently use research methodology, blurring the line between research and quality assurance. The VAPHS Research Office acknowledges that requiring submission of all QA/QI assurance projects to the IRB would unnecessarily burden both non-researchers and the IRB. However, when QA/QI projects meet the definition of human subjects research, they must be submitted to the IRB for review. Staff members are encouraged to review VHA ORD Program Guide 1200.21, VHA Operations Activities That May Constitute Research.
D. Whenever the research vs. non-research status of facility-level QA/QI project is in question, the responsible individual must submit a request for a research vs. not research determination to the IRB. Individuals should follow the procedures outlined in the Research Office Guidance on Operational Activities versus Research available on VAIRRS/IRBNet. when requesting a determination. The IRB may deem that the operations activity is research or is not research. Projects deemed research will require a formal submission to the IRB.
E. Staff members who conduct quality assurance projects should keep written documentation of their completed QA/QI worksheet with their project plan. Staff members should also keep in mind that use of protected health information for health care operations such as QA/QI projects do not require individual patient authorization, however any use of such protected health information for research

purposes requires either written patient authorization approved by the IRB or a documentation of waiver of such authorization by the IRB. Failure to obtain such approvals for activities that could be deemed human subjects research could result in civil and criminal penalties in accordance with the Health Insurance Portability and Accountability Act.

2. **PROCEDURES**

A. Principal Investigators should complete the Non-research Activity Determination Worksheet for Investigators, available on VAIRRS/IRBNet.
If after completing this worksheet the Principal Investigator believes the project qualifies as an operational activity not constituting research, no further action is required, however, the worksheet should be kept for documentation purposes. Only submit this worksheet if the Principal Investigator is unsure of whether the project is research or an operational activity.
The completed Non-research Activity Determination Worksheet for Investigators and the project abstract can be emailed to the VAPHS IRB at VHAPTHIRB@va.gov for its assistance in making a determination.

B. The IRB Office staff will route your abstract and worksheet to appropriate IRB designee for review. Communication will be routed through the IRB staff. An email will be sent with the formal determination signed by the IRB designee. The IRB may deem that the operations activity is research or is not research. Projects deemed research will require a formal submission to the IRB.

C. Documentation of the non-research determination 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.

3. DEFINITIONS

None

4. REFERENCES

A. VHA ORD Program Guide 1200.21, VHA Operations Activities That May Constitute Research https://www.research.va.gov/resources/policies/ProgramGuide-1200-21-VHA-Operations-Activities.pdf

B. VHA Directive 1200.05, Requirements for the Protection of Human Subjects, https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171

C. VAPHS Guidance 037 Operational Activities versus Research, https://gov.irbnet.org/release/export/download.jsp?libId=47211

5. REVIEW

This policy is reviewed at recertification, when there are changes to the governing document (for example, national policy or an accreditation body mandate), and any regulatory requirement for more frequent review.

6. RECERTIFICATION

This Policy is scheduled for recertification on or before the last working day of March 2025. In the event of contradiction with national policy, the national policy supersedes and controls.

7. SIGNATORY AUTHORITY

Charles Atwood, MD
Chair, Research and Development Committee
Date Approved: December 21, 2021

Dates Recertified: December 21, 2021

Steven Graham, MD, PhD
Associate Chief of Staff Research and Development Department
Date Approved: December 21, 2021

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: SOP is available at: http://vhapthsqlirb.v04.med.va.gov/VAIRBProd/