

WPBVAMC Request for Determination of Research Status

Title of Project:

Increase in percentage of OR first case on-time starts

Director of Project or Responsible Contact:

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Identify the VA Program under which the work was completed (e.g., patient care, education, quality assurance, quality management, etc.). If that national Program Office has registered an opinion regarding the research vs. non-research nature of the project, attach documentation of that opinion to this form.

Patient care

Project Summary: Please provide a paragraph (500 words or less) describing the purpose (e.g. quality assurance, quality improvement, case report, report of program development/ implementation, program evaluation) and procedures of the project, and your plans for communicating the findings. Please note any deadlines or other relevant information.

This is not research, as it is actually a performance improvement project. The OR is monitored by the National Surgery Office, and the West Palm Beach VAMC is currently not meeting the goals set for timely first case OR starts.

The surgeons will be observed for arrival to OR pre-op holding room and tracked for timeliness. Those that are late will be notified by the Surgical Service via email. This process will continue for several months with the hopes of eventually improving our timeliness and meeting National goals. Of note, other factors will also be tracked such as timeliness of patient arrival, timely labs, timely instrumentation availability, nursing and anesthesia provider timeliness, etc.

Ms Sandy Morel (student CRNA from doctorate program at UM School of Nursing) will be championing this project as part of the requirements for her degree.

SCREENING QUESTIONS: Is this Project RESEARCH?

Answering “NO” to either question below is indicative of RESEARCH and the project protocol will need to be submitted for research committee review.

Is the project designed and/or implemented solely for internal VA purposes in support of a VA mission?

Yes No

YES indicates that nothing is added to the design beyond what is needed to achieve the identified VA purpose and the project does not have an additional aim to develop or contribute to generalizable knowledge outside VA. (For example: collecting data or performing analysis beyond what is needed for the original VA purpose of the activity.)

Are the findings of this activity intended to be used exclusively by and within VA or by entities responsible for overseeing VA?

Yes No

Answering “YES” to any of the questions below is indicative of RESEARCH and the project protocol will need to be submitted for research committee review.

Is the activity designed for the purpose of contributing to generalizable knowledge?

Yes No

If NO, identify a purpose related to VA operations that justifies the design of the project:

As discussed above, this is a performance improvement project.

Is the activity designed to expand the knowledge base of a scientific discipline or scholarly field of study?

Yes No

Is the activity funded or supported as research?

Yes No

If YES, describe the source of funding and provide the title of the program or project that received funding:

As discussed above, this is a performance improvement project.

Is the activity a clinical investigation as defined under Food and Drug Administration (FDA) regulations?

Yes No

Does the activity include double-blind intervention?

Yes No

Does the activity include a placebo control?

Yes No

Does the activity include prospective patient-level randomization to a clinical intervention?

Yes No

Has the activity been supplemented or modified before, during, or after implementation in order to produce information to expand the knowledge base of a scientific discipline or scholarly field of study or to otherwise contribute to generalizable knowledge?

Yes No

Has the purpose of the activity changed so that it is now designed or intended to expand the knowledge base of a scientific discipline or scholarly field of study or otherwise contribute to generalizable knowledge?

Yes No

Has the purpose of the activity been shared with the Information Security Officer (ISO) and Privacy Officer (PO)?

Yes No

Signatures:

Howard R Maisel MD
Project Director or Responsible Contact

Howard R Maisel MD 2/27/2020
Printed name and Date

This project has been reviewed according to VA West Palm Beach procedures and has been determined to be non-research; oversight by WPBVAMC Research Committee is not required.

SAC or R&DC Representative

Printed name and Date

NOTES:

(1) Additional review is required prior to presentation or publication of data from a non-research activity outside VA. The principal author or presenter should complete the *WPBVAMC Publication Review Form* and submit it along with the manuscript or presentation in its near final form to the IRB Coordinator to initiate review.

(2) Publication or presentation of non-research activities outside VA does not, in and of itself, constitute research. (See VA Handbook 1058.05.)

Addendum A

Definitions Related to Research

(Excerpts from VHA Handbook 1058.05)

Research: A systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge.

Systematic Evaluation: An activity that is planned in advance and that uses data collection and analysis to answer a question.

Generalizable Knowledge: information that expands the knowledge base of a scientific discipline or other scholarly field of study.

These definitions refine to further to define research at the VA as: **“A planned activity that uses data collection and analysis and is designed to produce information that expands 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. Although research must include systematic investigation, non-research operations activities also include systematic investigation to ensure reliable outcomes. Systematic investigation does not solely define research. Examples of systematic investigations that may or may not constitute research, include (but are not limited to) use of questionnaires or surveys; observations; focus groups; interviews; analyses of existing data; analyses of biological specimens; medical chart reviews; epidemiologic reviews or analyses; program evaluations; and quality assessment, quality improvement, and quality management.

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.

An operations activity may or may not constitute research depending on whether the activity is designed to produce generalizable knowledge.

Non-research Operations Activities: An activity is not designed to produce generalizable knowledge when it is designed and implemented for internal VA purposes. Thus, quality assessment and quality improvement activities including routine data collection and analyses associated with VA activities such as case management and care coordination, policy and guideline development, benchmarking activities and medication use evaluations do not typically constitute research.

Operations Activities Constituting Research: If the conceptualization, plan or implementation of the activity is supplemented or modified in order to produce generalizable knowledge. 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 generalizable knowledge the activity constitutes research.