

Instructions: In accordance with [VHA Program Guide 1200.21](#), “VHA Operations Activities That May Constitute Research,” VANEOHS employees may conduct certain operations activities which may or may not constitute research. Whenever the research versus non-research status of an operations activity may be in question, a determination of the status must be made.

Please submit this form to the VANEOHS Research Service by uploading a PDF copy with electronic signature to VAIRRS/IRBNet; instructions are available at [VANEOHS Research Submissions: Non-Research Determinations](#). Please reference the [VHA Operations Activities that May Constitute Research](#) decision tree for an overview of how a decision between research and non-research activities is determined.

Project Title:	
Project Lead:	
Email/Phone:	
Department/Service:	

CONDITIONS TO BE CONSIDERED FOR DETERMINATION OF RESEARCH VS. NON-RESEARCH OPERATIONS	TRUE	FALSE*
*NOTE: For answers that are marked “false,” you must provide an explanation on page 3.		
1) The project is designed and/or implemented for internal VA purposes in support of the VA mission(s).	<input type="checkbox"/>	<input type="checkbox"/>
2) The findings are designed to be used by and within VA (or by entities responsible for overseeing VA).	<input type="checkbox"/>	<input type="checkbox"/>
3) The project is not designed for the purpose of contributing to generalizable knowledge.	<input type="checkbox"/>	<input type="checkbox"/>
4) The project is not designed to produce information that expands the knowledge base of a scientific discipline (or another scholarly field).	<input type="checkbox"/>	<input type="checkbox"/>
5) The project is not funded or otherwise supported as research by the Office of Research and Development (ORD) or any other sponsor.	<input type="checkbox"/>	<input type="checkbox"/>
6) The project does not involve administration, dispensing and/or use of any drugs, devices and/or biologics.	<input type="checkbox"/>	<input type="checkbox"/>
7) The project does not involve design characteristics typically reflective of research, e.g.: <ul style="list-style-type: none"> • Double-blind interventions • Use of placebo controls • Prospective patient-level randomization to clinical interventions not tailored to individual benefit 	<input type="checkbox"/>	<input type="checkbox"/>
8) The proposal includes provisions to ensure that the safety, rights, and welfare of patients and staff are appropriately protected as applicable.	<input type="checkbox"/>	<input type="checkbox"/>
9) The project is not intended to meet the requirements set forth by a master’s program (or other university level degree program) that requires “research” be conducted.	<input type="checkbox"/>	<input type="checkbox"/>
10) The activity will not be 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 otherwise contribute to generalizable knowledge.	<input type="checkbox"/>	<input type="checkbox"/>



PROJECT DESCRIPTION

Reason for Project

Locally initiated

Mandated by _____

In the following fields, please provide enough information about the proposed project that a reviewer understands why and how the work will be performed. Please define all acronyms. Failure to address the following will delay determination of your project.

1. **Objectives(s):** *What is the purpose of the project? What are the issues/questions being addressed and why?*

2. **Methodology:** *How will the work be conducted and where? Who will be involved? Please be detailed in how the work will be conducted including data collection and analysis.*

3. **Impact/Significance:** *What will be done with the resulting information?*

Signature of Responsible Project Lead: _____ Date: _____

Print Name of Responsible Project Lead: _____



**Provide an explanation below for responses marked “false” on page 1.
Please number your responses to indicate the question (#1-10) you are addressing.**

FOR VANEOHS RESEARCH OFFICE USE ONLY BELOW THIS LINE

Not Research. VANEOHS has determined that based on the responses above and the proposed project description approval by an IRB or other review committee is not needed. The project is considered to be non-research VHA operations activity. If the results of this project are presented or published they cannot be presented as research, nor does it have research approval.

- Any change made before, during, or after implementation that results in an intent to expand the knowledge base of a scientific discipline or scholarly field of study, or otherwise contribute to generalizable knowledge, constitutes research and must be submitted to an IRB or other pertinent review committee.
- Please note it is the responsibility of this individual and/or each VA author and coauthor (in cases of publication) to retain a copy of this form signed by the ACOS/R&D for a minimum of 6 years after publication and in accordance with any applicable records retention schedules. A copy will also be retained by Research Service.

Research. As designed, this project requires review by an IRB or other appropriate review committee *prior* to initiation. Please contact the R&D Coordinator (christina.bennett2@va.gov) for more information.

Additional information is needed to make a determination. See comments below.

ACOS/R&D Comments:

ACOS/R&D Signature: _____ Date: _____