Instructions: In accordance with [VHA Program Guide 1200.21](https://www.research.va.gov/resources/policies/ProgramGuide-1200-21-VHA-Operations-Activities.pdf), “VHA Operations Activities1 That May Constitute Research”, VAPORHCS 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 VAPORHCS Research Office by sending a scanned, signed copy to pvamc-irb@va.gov or via fax to 503-273-5152. Please reference the [VHA Operations Activities That May Constitute Research Program Guide](https://www.research.va.gov/resources/policies/ProgramGuide-1200-21-VHA-Operations-Activities.pdf) for an overview of how a decision between research and non-research activities is determined.

|  |
| --- |
| **Project Title**:       |
| **Responsible Project Lead**:       | **Email**:       |
| **Department**:       | **Role/Title**:       |
| **Are VAPORHCS Medical Center nurses members of the project team?** *If yes, once a determination is made, a copy of this signed form will be sent to the* *Evidence Based Practice Nursing Committee* | YES  NO |
|  |
| **CONDITIONS TO BE CONSIDERED FOR DETERMINATION OF****RESEARCH VS. NON-RESEARCH OPERATIONS** |
| **NOTE:** If answers to questions 1 through 11 are marked **“TRUE”** the project is more than likely not research. *For answers that are marked “false,” please provide an explanation in the text fields below regarding how this project may still be QA/QI or contact* *pvamc-irb@va.gov* *for guidance.* | **TRUE** | **FALSE** |
| 1. The project is designed and/or implemented for internal VA purposes in support of the VA mission(s).
 |  |  |
| 1. The findings are designed to be used by and within VA (or by entities responsible for overseeing VA).
 |  |  |
| 1. The project is not designed for the purpose of contributing to generalizable knowledge.**2**
 |  |  |
| 1. The project is not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field).**2**
 |  |  |
| 1. The project is not funded or otherwise supported as **research** by the Office of Research and Development (ORD) or any other entity (including the Center for Healthcare Equity Research and Promotion [CHERP] or the VISN 4 Competitive Pilot Project Funding [CPPF] program).
 |  |  |
| 1. The project does not involve administration, dispensing and/or use of any drugs, devices and/or biologics.
 |  |  |
| 1. The project does not involve design characteristics typically reflective of research, e.g.:
* Double-blind interventions
* Use of placebo controls
* Prospective patient-level randomization to clinical interventions not tailored to individual benefit
 |  |  |
| 1. The proposal includes provisions to ensure that the safety, rights, and welfare of patients and staff are appropriately protected as applicable.3
 |  |  |
| 1. The project is **not** intended to meet the requirements set forth by a masters program (or other university level degree program) that requires “research” be conducted.
 |  |  |
| 1. 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.
 |  |  |
|  |
| **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.**  |
| **Objectives(s):** *What is the purpose of the project? What are the issues/questions being addressed and why?*  |
| **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 analyses.*  |
| **Impact/Significance:** *What will be done with resulting information?* |

Signature of Responsible Project Lead4: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name of Responsible Project Lead: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| *For projects that involve using/collecting data from sites other than those covered by the VAPORHCS*1. *If the project is being conducted/coordinated at a site other than the VAPORHCS:*

Signature of Medical Center Director:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: ­­­\_\_\_\_\_\_1. If your project includes obtaining data or participation from VA sites other than those covered by the VAPORHCS you must request approval from the facility director(s) prior to initiating the project at those facilities.
 |

**For VAPORHCS IRB Office Use Only Below This Line**

VAPORHCS ACOS/R&D Determination:

*Note: The VAPORHCS ACOS/R&D has been designated by the VA Portland Health Care System Director and the VISN20 Network Director to serve as the individual who will evaluate and document the determination for projects conducted at the following VISN20 facilities: Alaska, Spokane, Walla Walla, Roseburg, and White City.*

 Not Research. The ACOS/R&D 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.

 Research Project. As designed this project requires review by an IRB or other appropriate review committee *prior* to initiation. Please refer to the VAPORHCS R&D [website](http://www.va.gov/portlandresearch) for guidance.

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

|  |
| --- |
| ACOS/R&D or IRB Analyst Comments:  |

VAPORHCS ACOS/R&D Signature and Date: ­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reference:

[VHA Program Guide 1200.21](https://www.research.va.gov/resources/policies/ProgramGuide-1200-21-VHA-Operations-Activities.pdf): VHA Operations Activities That May Constitute Research

1Examples of operations activities include activities designed for internal VA purposes, including routine data collection and analysis for operational monitoring, evaluation and program improvement purposes, VHA system redesign activities, patient satisfaction surveys, case management and care coordination, policy and guidance development, benchmarking activities, Joint Commission visits and related activities, medical use evaluations, business planning and development such as cost-management analyses, underwriting, and similar activities.

2Any 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.

3Potential risks (including physical, psychological, social, financial, privacy, and confidentiality, and other foreseeable risks) associated with non-research operations should be evaluated and appropriate protections established to mitigate them.

4Please 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 5 years after publication and in accordance with any applicable records retention schedules. A copy will also be retained by Research Service and Quality & Performance Service.