

Non-research Activity Determination Worksheet for Investigators

Instructions: In accordance with Department of Veterans Affairs Program Guide 1200.21 and VAPHS Medical Center Memorandum, LD-077, VAPHS employees may conduct certain operations activities which may or may not constitute research. In most cases, a formal determination regarding the research vs. non-research status is NOT required. However, whenever the research versus non-research status of an operations activity may be in question, a determination of the status must be made by:

- The relevant Program Office (if funded, mandated, managed, sponsored, or otherwise supported by a VHA Program Office, or that utilizes Program Office data)
- The responsible party's Network Director (if a Network-level initiated activity)
- The responsible party's Facility Director or an individual designated by the Facility Director to make such determinations (if a facility-level initiated activity). At VAPHS, this is the IRB Chair/Designated reviewer. Please submit the following items via email to vhaphthIRB@va.gov :
 - An abstract or project description outlining the purpose and aims of this project.
 - A completed copy of this worksheet (completed by the Responsible party).

Please be advised that you may be asked to submit additional items once the request is reviewed by the IRB Chairperson.

Project Title: Click or tap here to enter text.	
Responsible Staff Member: Click or tap here to enter text.	Role/Title: Click or tap here to enter text.
Department: Click or tap here to enter text.	
<p>This project is:</p> <p><input type="checkbox"/> <u>A Program Initiative/Mandate</u> – a project sponsored by VHA/VISN/Facility/Other that involves the VA or another funded agency specifying an internal process to be conducted.</p> <p><input type="checkbox"/> <u>An educational initiative with assessment</u> – a project that involves educating VA personnel/trainees that may include an assessment or questionnaire of materials presented</p> <p><input type="checkbox"/> <u>A Quality Improvement/Quality Assessment Project</u> – a range of activities conducted to assess, analyze, critique, and improve current processes of health care delivery/services within VAPHS</p> <p><input type="checkbox"/> <u>Other Operations activity</u></p>	
If this is a QI project, does the responsible staff member have supervisory responsibility and/or the authority to implement a corrective plan based upon the outcomes of the project? If NO, describe who would hold such authority and how the outcomes of this project would be communicated to that individual? : Click or tap here to enter text.	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Not applicable
Funding Source: (If None, please state) Click or tap here to enter text.	
Reason for the Project: <input type="checkbox"/> VHA Program Office Mandate/Initiative <input type="checkbox"/> VISN Mandate/Initiative <input type="checkbox"/> Facility Mandate/Initiative <input type="checkbox"/> Other, please describe: Click or tap here to enter text.	
Provide an explanation as to why you believe your project is not research: Click or tap here to enter text.	

CONDITIONS TO BE CONSIDERED FOR DETERMINATION OF RESEARCH VS. NON-RESEARCH OPERATIONS NOTE: All answers must be "YES" or "N/A" in order for the project to be considered NOT research. If any item is answered "NO" the project must be submitted to the IRB for review and approval.	YES	NO	N/A
For QA/QI Projects: there is a documented commitment, in advance of data collection, to a corrective plan given any number of outcomes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The project is designed and/or implemented for internal VA purposes in support of the VA mission(s).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The findings are designed to be used by and within VA (or by entities responsible for overseeing VA).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The project is not designed for the purpose of contributing to generalizable knowledge. ¹	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The project is not designed to produce information that expands the knowledge base of a scientific discipline (or other scholarly field). ¹	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The project is not funded or otherwise supported as research by the Office of Research and Development (ORD) or any other entity.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The project does not meet the definition of a clinical investigation as defined under Food and Drug Administration (FDA).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The project does not involve design characteristics typically reflective of research such as: <ul style="list-style-type: none"> • Double-blind interventions, • Use of placebo controls, or • Prospective patient-level randomization to clinical interventions not tailored to individual benefit. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

¹Any change made before, during, or after implementation which 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 the VAPHS IRB.

Responsible Party's Signature: _____

Date: _____