

Quality Improvement Projects vs. Research Projects

Research projects require review/approval by an Institutional Review Board (IRB) to ensure compliance with federal regulations on human subjects protection. Quality Improvement (QI) projects do not require IRB review/approval because they are not research. To make a determination on whether your project is research or quality improvement, please follow these steps:

- 1. Read VHA Program Guide 1200.21 "VHA Operations Activities That May Constitute Research". You can find this guide at https://www.research.va.gov/resources/policies/handbooks.cfm.
- 2. Use the VA Electronic Determination Aid (VAEDA) to make a preliminary determination on whether your project is QI or Research. VAEDA is a decision support tool created to reduce variability in regulatory determinations for proposed research, quality improvement, program evaluations, and innovation projects. Project leaders will interact with VAEDA through a thorough question-and-answer process regarding their proposed project. The VAEDA tool will then produce a preliminary determination, based on the responses provided. VAEDA also has the capability to provide the user with next steps for the project, based on the determination and requirements for privacy, information security and IRB review (as applicable). VAEDA is accessible to all VA employees using your VA-issued credentials. Click here to access the VAEDA site from a VA networked computer: https://vhacdwdwhvda01.vha.med.va.gov/vaeda/home#/
- 3. If you have questions or concerns, you are welcome to contact Quality Management or Research Service for consultation.
- 4. From the VAEDA menu, you will be able to export a determination letter. If the determination is that your project is Quality Improvement, send it to your Service Chief for confirmation and for planning the next steps. If the determination is that your project is research, contact the NF/SG Human Research Protection Program (HRPP) at whentless-understanding-new-normalized-research-study@va.gov. HRPP will further evaluate the determination and will work with you on planning the next steps.
- 5. If an external publication is planned to share results from a Quality Improvement project, notify the NF/SGVHS Chief of Staff. Include an abstract or draft publication for approval before submitting to a journal.