

POLICY NUMBER: 013

APPROVAL DATE: 12/07/2010

EFFECTIVE DATE: 12/08/2010

TITLE: Quality Assurance/Quality Improvement Projects

1.0 PURPOSE

This policy describes the procedures and responsibilities of VAPHS employees and the VAPHS Institutional Review Board regarding the conduct and review of Quality Assurance/Quality Improvement Projects at VAPHS.

2.0 REVISION HISTORY

Date	Revision #	Change	Reference Section(s)
November 23, 2010	1.1	Reformatting of original policy	

3.0 SCOPE

This policy applies to all VAPHS employees involved in the conduct of Quality Assurance/Quality Improvement projects at VAPHS.

4.0 POLICY

As a part of hospital operations, service lines are expected to complete quality assurance projects. These quality assurance projects frequently use research methodology, blurring the line between research and quality assurance. The VAPHS Research Office acknowledges that requiring submission of all quality assurance projects to the IRB would unnecessarily burden both non-researchers and the IRB. However, when quality assurance projects meet the definition of human subjects research¹, they must be submitted to the IRB for review. Staff members are urged to compare their written project plan to the QA/QI Worksheet to determine if they should submit their project to the IRB. If any question exists as to the status of the project, it should be submitted to the IRB for a formal determination. The IRB may deem the effort as QA/QI or as Human Subjects Research.

The Research Office also acknowledges that some quality assurance projects evolve into research studies based on the data generated. Staff members should be aware of the criteria for quality assurance determinations, and immediately report to the IRB when they feel that the project will cross the line into research or will produce publishable results. In some cases this may occur during the data collection, but it may also occur after the data are analyzed. Note that in such cases a research plan must be submitted to the IRB prior to any peer review. In this plan, investigators must clearly identify the quality assurance portion of the investigation, describe any additional analyses of the existing data or additional data collection that may be planned, and provide adequate justification for why the project was not submitted to the IRB prior to data collection.

Compliance with this policy will be assessed on an annual basis by various means including but not limited to direct audits as well as audits of peer reviewed publications. Staff members who conduct quality assurance projects are strongly encouraged to file their completed QA/QI worksheet with their project plan to facilitate this assessment. Staff members should also keep in mind that use of protected health information for health care operations such as QA/QI projects do not require individual patient authorization, however any use of such protected health information for research purposes requires either written patient authorization approved by the IRB or a documentation of

waiver of such authorization by the IRB. Failure to obtain such approvals for activities that could be deemed human subjects research could result in civil and criminal penalties in accordance with the Health Insurance Portability and Accountability Act.

// Signed //

Gretchen L. Haas, PhD
Research and Development Committee Chair

// Signed //

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ⁱ VA regulations at 38 CFR 16.102(d) define **research** as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. VA regulations at 38 CFR 16.102(f) define **human subject** as “a living individual about whom an investigator (whether professional or student) conducting research obtains either (1) data through intervention or interaction with the individual; the interaction includes communication or interpersonal contact between the researchers and the subject; or (2) identifiable private information.” **Private information** includes information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record), and information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. **Identifiable** means that the identity of the individual is or may readily be ascertained by the investigator or associated with the information. FDA regulations at 21 CFR 56.102(c), define **research** as “... any experiment that involves a test article and one or more human subjects...” The FDA regulation further states that “...The terms research, clinical research, clinical study, study, and **clinical investigation** are deemed to be synonymous for purposes of this part.” 21 CFR 56.102(e) defines **human subject** as “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.” FDA regulations at 21 CFR 812.3(p) define a human subject as “a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.”