POLICY NUMBER: 013

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

<table>
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<tr>
<th>R&amp;D Approval Date</th>
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<tr>
<td>July 23, 2013</td>
<td>1.2</td>
<td>Revised to adhere with requirements described in VAPHS MCM LD-077</td>
<td>4.0</td>
<td>July 24, 2013</td>
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<tr>
<td>November 23, 2010</td>
<td>1.1</td>
<td>Reformatted of original policy</td>
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<td>December 8, 2010</td>
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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 improvement/quality assurance projects. These projects frequently use research methodology, blurring the line between research and quality assurance. The VAPHS Research Office acknowledges that requiring submission of all QA/QI assurance projects to the IRB would unnecessarily burden both non-researchers and the IRB. However, when QA/QI projects meet the definition of human subjects research, they must be submitted to the IRB for review. Staff members are encouraged to review VAPHS Medical Center Memorandum, LD-077, VHA Operations Activities and Research for additional guidance.

Whenever the research vs. non-research status of facility-level QA/QI project is in question, the responsible individual must submit a request for a research vs. not research determination to the IRB. Individuals should follow the procedures outlined on the Research Office website (at http://www.pittsburgh.va.gov/Research/Human_Research.asp) when requesting a determination. The IRB may deem that the operations activity is research or is not research. Projects deemed research will require a formal submission to the IRB.

Staff members who conduct quality assurance projects should keep written documentation of their completed QA/QI worksheet with their project plan. 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.
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.”