VHA Operations Activities That May Constitute Research

Is the Operations Activity designed (and/or implemented) for internal VA purposes in support of the VA mission(s)?

YES

Are the activity’s findings designed to be used by and within VA (or by entities responsible for overseeing VA)?

YES

Is the activity designed for the purpose of contributing to generalizable knowledge?

NO

Is the activity designed for the purpose of expanding the knowledge base of a scientific discipline or scholarly field of study?

NO

Is the activity funded or supported as research?

NO

Is the activity a clinical investigation as defined under Food and Drug Administration (FDA) regulations?

YES

Does the activity include double-blind interventions?

NO

Does the activity include placebo controls?

NO

Does the activity include prospective patient-level randomization to a clinical intervention not tailored to individual patient benefit?

YES

Has the activity been 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?

NO

Has the purpose of the activity changed so that it is now designed or intended to expand the knowledge base of a scientific discipline or scholarly field of study or otherwise contribute to generalizable knowledge?

NO

This Operations Activity is NOT RESEARCH.
Institutional Review Board (IRB) approval is not required.
Documentation of non-research status is (i) required prior to peer-reviewed publication, and (ii) encouraged whenever non-research status may be questioned.

REVISED 1/24/2012