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)**?

NO → *

YES ↓

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

NO → *

YES ↓

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

YES → *

NO ↓

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

YES → *

NO ↓

Is the activity funded or supported **as research**?

YES → *

NO ↓

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

YES → *

NO ↓

Does the activity include **double-blind interventions**?

YES → *

NO ↓

Does the activity include **placebo controls**?

YES → *

NO ↓

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

YES → *

NO ↓

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**?

YES → *

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**?

YES → *

NO ↓

* This Operations Activity constitutes **RESEARCH**

* **INSTITUTIONAL REVIEW BOARD (IRB)** approval is required

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