Decision Flowchart for VA-UM Collaborative Studies

Do you have a dual appointment w the VA and the UM?

YES

Is your study completely a UM study?

YES

STOP HERE

NO

Is your study completely a VA study?

YES

Submit the protocol to VAMHCS R&D Committee following IRB approval

YES

Does your study comprise elements from both the UM and the VA?

YES

Decide on study design

YES

Submit the protocol to VAMHCS R&D Committee following IRB approval

STOP HERE

A single integrated VA + UM study

A single ICF that clearly defines what is “VA” and what is “UM” “1-1 Study”

A single integrated VA + UM study

TWO ICFs: one ICF is “VA only” (10-1086) but mentions the UM portion that the participant will also sign; one ICF “UM only” but mentions the VA portion that the participant will also sign.

“1-2 Study”

Two separate studies whose data will be combined

One “entirely VA” study and one “entirely UM” study.

Both studies go through CICERO as separate, independent entities, each with its own “VA only” or “UM only ICF.

One site will be designated as the “local data coordinating center”

“2-2 Study”

VA is the Coordinating Center for an external/non-UM multicenter trial

Depending on “engagement in the research”, could possibly be an exempt project with no ICF.

“1-0 Study”

Submit the protocol to VAMHCS R&D Committee following IRB approval

Design the protocol(s) with VA and UM activities clearly delineated

January 24, 2012