

March 6, 2012

VAMHCS page in CICERO has been significantly changed.

See significant new requirements that must be incorporated into new CICERO protocols,

The “VAMHCS Review Required” page in CICERO has been replaced with a more complete description of requirements for conducting research at the VAMHCS, ***including some new requirements that must be incorporated into new CICERO protocols NOW.***

Among the major changes are:

- The VAMHCS Information Security and Privacy Checklists for new protocols or for CRs and Mods must now be incorporated into the CICERO submission. Failure to do so could delay IRB review of your protocol.
- If your study is a “collaborative study” with the University, you must take this into account when designing the CICERO protocol.
- After the protocol is approved by the IRB, you must submit the protocol to the VAMHCS Research Service within 60 days of IRB approval.

These new requirements are **effective immediately** for ***any new protocol currently being drafted in CICERO.***

A copy of the new “VAMHCS Review Required” page is pasted below for your convenience. Particularly significant points are highlighted in yellow. Please read for details.

If you have further questions, please contact: [Jessica Mendoza](#), VAMHCS Human & Animal Research Protections Officer, at jessica.mendoza@va.gov, 410-605-7000 x6512.

View: VA Review Required

VA Maryland Health Care System Review Required

- 1 **Note:** Based on the answers you provided, this is a VA study. You must obtain approval of the VAMHCS R&D Committee before you may engage in any research activity at the VA. After this protocol is approved by the IRB, you must submit the protocol to the VAMHCS Research Service **within 60 days of IRB approval.**

HOWEVER, VA regulations require the following items to be addressed **as part of your CICERO application NOW**. Please do the following **NOW** as part of this CICERO submission:

1. Information security and privacy requirements must be reviewed by the VAMHCS Information Security Officer (ISO) and Privacy Officer (PO) prior to IRB review & approval (whether full board or expedited). **Therefore, please do the following NOW as part of this CICERO submission:**
 - Download the [Information Security and Privacy Checklist for New Protocols](#), or the [Information Security and Privacy Checklist for CRs and Mods](#) and when you complete the CICERO sections on "Privacy", "Confidentiality", "Data", "Additional Documents" or other applicable sections with the elements of the checklist in mind. Be sure that your CICERO application answers all the questions on the Information Security & Privacy Checklist.
 - Using a separate document to answer questions not asked in CICERO is highly recommended.
 - Complete the checklist and **upload the completed checklist and any associated documents into the "Additional Documents" section of CICERO.**

2. "Collaborative studies" (studies in which both the VA and the UM have some engagement in the research) require additional decisions and documentation with regard to overall protocol design. (This does not apply to studies that are completely VA (for example, fully VA funded, occurring completely at the VAMHCS or with VA staff, etc.) **If this study is a "collaborative study", please do the following NOW as part of this CICERO submission:**
 - Download the [Guidelines and Template for Developing a "VA-UM Collaborative Protocol](#) and complete the [Template](#) and the applicable CICERO sections with the elements of the template in mind. Use of the [Collaborative Study Decision Flowchart](#) and the [VAMHCS Reviewer Guide for Separation of VA vs. Non-VA Research](#) is strongly recommended.
 - It is possible that you may need to consider options such as:
 - creating separate identical UM and VA protocols with data to be combined at the end;
 - creating a single protocol with one VA consent form & HIPAA authorization that clearly describes VA and UM elements;
 - creating a single protocol with two consent forms & HIPAA

- o other clearly describes UM elements; o other scenarios are possible.
- o Complete the [Template](#) for Developing a `VA-UM Collaborative Protocol and **upload the completed template** and any associated documents into the "Additional Documents" section of CICERO

Additional VA requirements that must be in place to obtain VAMHCS R&D Committee approval following IRB approval:

- Principal investigator and all research staff engaged in the research at the VAMHCS must be VA employees or have "without compensation" (WOC) appointments.
- VA credentialing of applicable members of the research team.
- Research scopes of practice for applicable members of the research team.
- VA mandatory trainings certificates must be current
- Review by the VAMHCS Subcommittee on Research Safety (SRS) (RPSS Form)
- VAMHCS Investigational Drug Service arrangements (as applicable)
- VAMHCS Radiation Safety review (as applicable)
- Cooperative Research and Development Agreement (CRADA) (for industry and some NIH studies)

Details are available on the "[Worksheet for Submissions to R&D Committee \(Human Studies\)](#)" or at the VAMHCS R&D Committee office (410-605-7000 x6506).

2 (This section is unchanged)

3 **Confirm** - You have read the above information and understand that in addition to this IRB application form (CICERO), you are required to send a submission to the VAMHCS R&D Committee **within 60 days of receiving IRB approval**.

Yes No
