

New VAMHCS Research Informed Consent Template

A new version of the VAMHCS research informed consent form (ICF) template has been posted on the [Research Service website](#), the [HRPO website](#) and in CICERO.

This template changes the content of the VA ICF (see specifics below) including some required statements for the VA and some prompts for additional information when applicable, especially with regard to “collaborative” protocols.

The March 2012 VA template that is currently in use changed the visual formatting of the ICF but not the content. ***This version changes the content of the informed consent document*** and maintains the March 2012 visual format.

Therefore, ***you can no longer simply copy-paste sections from your UM version to your VA ICF***, at least not without some forethought and conscious review.

We have preserved the March 2012 UM templated ICF language to the greatest extent possible, but you must be aware of the differences that may now affect your VAMHCS ICF.

About the new template

- This template can be differentiated from the prior template by the presence of the following version date in the lower right corner of the footer: **“VAMHCS template v. 103012”**
- The template is highly annotated to point out differences from the UM template and to also instruct you on how to complete some sections. VA-specific language, prompts, and instructions are in red. For this reason, some VA-required passages are also in red (instead of black).
- Remaining portions of the UM template are in blue and black. For those portions, it may be possible to copy-paste from your UM ICF. One difference may occur when you need to differentiate VA from UM research activities for collaborative studies.
- As always, be sure to remove all comments boxes and other instructions before submitting your final version for review. Also be sure that the final ICF is in a consistent font, is in black (unless a color is intended to improve the participant’s understanding), and has correct spelling and grammar.

Effective dates:

- **New protocols:** This template is effective November 19, 2012 for new VA or VA+collaborative protocols that have not yet been submitted to the IRB (**they are in DRAFT state in CICERO or have not yet been submitted to review**).
 - New protocols submitted to or undergoing review in CICERO from now through 11/18/12 will not be affected.
 - Beginning 11/19/12, a new version of the VA ICF will be required for all new VA or VA+collaborative protocols.
- **Continuing reviews:** Beginning with the December 13, 2012 R&D Committee (RDC) meeting, the RDC will require the new VA ICF.
 - Protocols that do not have the new VA ICF template will be required to submit a CICERO modification to obtain the new ICF.
 - Study enrollment will NOT be interrupted if the modification request is submitted in CICERO within 10 working days. However, prolonged delay in obtaining the new ICF may result in suspension of study activities at the VA until a proper ICF is approved.
- **Modifications:** This template is effective November 19, 2012 **for modifications that involve changes in the consent form**. However, it is recommended that when you submit modification requests for non-ICF modifications, you also consider modifying the VA ICF at the same time. It will save you time and additional transactions if you already have a revised ICF at the time of VA RDC annual review (see above).

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