

Constructing a VA Informed Consent Form in CICERO

As some of you probably already know, the “consent form builder” feature in CICERO is not yet operational.

This situation will change in the near future. There is a UMB team working hard on the problem. However, in the meantime, investigators must submit their own consent forms into CICERO. The consent forms that you submit to CICERO **MUST already be in the VA format*** and in the final version of the text you want in the consent form. For now, CICERO will not automatically put a Word version into VA format, nor will it take your old BRAAN version and automatically convert it to CICERO.

[*the VA form 10-1086 with which you are already familiar]

Instead, you must use the template supplied by the HRPO/CICERO (see instructions below), paste your content into the template, then upload this “VA version” into CICERO. When the protocol is approved, an HRPO staff person manually puts the IRB footers/IRB approval onto your form, saves it as a PDF and then uploads it into CICERO for you to access.

- ❖ DO NOT USE ANY CICERO ICF THAT DOES NOT HAVE THE IRB FOOTER.
- ❖ IF YOUR PROTOCOL HAS BEEN TRANSITIONED INTO CICERO, DO NOT USE ANY BRAAN VERSION OF THE ICF.
- ❖ IF YOUR PROTOCOL HAS BEEN CONDITIONALLY APPROVED, YOU MAY NOT USE ANY ICF UNTIL YOU HAVE ACHIEVED FULL APPROVAL (the CICERO consent form will not yet be “stamped”).

If you have an unusual form that does not seem to fit the template and you are having problems figuring out what to do (for example, some addendum forms, an odd signature page, etc), PLEASE contact your HRPO analyst. Because CICERO is so new to us and we are unfamiliar with its terminology and procedures, it is a good idea to work through problems with the analyst in real-time if possible. Always double-check the actions taken by yourself or the analyst to be sure it is what you were trying to accomplish.

Other tips:

- ❖ Choose the correct “University Statement” from the template. Toward the end of the template, there are two possible “University Statements”: one University Statement is to be used for minimal risk studies and the second University Statement is to be used for greater than minimal risk studies.

- Both statements include the VA injury statement; neither statement has the UM injury statement. Just remove the statement that does not apply to your study.
- ❖ If the Sponsor allows, remove the Sponsor injury statement as well, especially if it is contradictory to the VA statement.
 - ❖ Be sure to have a VA contact number on the ICF. If you do not have a VA contact number or pager, use the number of the Research Compliance Officer, x6512. IF YOU DO THIS, PLEASE NOTIFY THE RCO so that we will be able to contact you if we do receive a call.
 - ❖ VA ICFs ***MUST*** have three signature lines: the participant, a witness to the signature, and the person obtaining consent. Additional signature may be necessary, for example, an LAR signature, but DO NOT REMOVE THE LINES FOR WITNESS, PARTICIPANT OR PERSON OBTAINING CONSENT!

Instructions for obtaining the VA ICF template:

- ❖ Go to the HRPO website: <http://medschool.umaryland.edu/hrpo/> >>>
- ❖ Choose the “CICERO” tab on the left:
<http://medschool.umaryland.edu/ORAGS/hrpo/cicero.asp> >>
- ❖ Scroll to the BOTTOM of the screen to: “**Consent and Assent Form Templates; [Click Here](#) for instructions on the new Consent Form Process, and to download templates.**” >> Click on “**Click Here**”
- ❖ The new page, entitled “Consent Forms”, contains much important general information. However, about half-way down the screen, there is a section called: “Which consent form template should you use?” >>
- ❖ Choose #4: “**[VA Consent Form Template](#) – This template should be used if your study is being conducted at the Baltimore VA. [Click Here to download a blank VA Consent Form Template](#)”**
- ❖ Complete this template. *When it is final*, upload it into CICERO under section 7 – draft Consent Forms

Alternatively, the same template is available through the CICERO submission on the “**Draft Consent Form**” page under section 7.

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:

Jessica Mendoza, RN, BSN, CCRC
Acting Research Compliance Officer
Research Compliance Specialist

Rm 3-A-125

(410) 605-7000 x5591

Jessica.mendoza@va.gov

Can't put your finger on a past Hot Topic you know would solve your problem?
No problem. Check the Hot Topics archive on the Research Service website:

http://www.maryland.research.va.gov/hot_topics.asp

For comments, complaints or suggestions regarding the Research Service or
Office of Research Compliance, contact:
Jessica Mendoza, RN, BSN, CCRC
Acting Research Compliance Officer
Rm 3-A-125
(410) 605-7000 x6512
Jessica.mendoza@va.gov