

VAMHCS RESEARCH SERVICE HOT TOPIC

Vol. 9 No. 11
November 4, 2015

[ANOTHER new VA HIPAA Authorization form \(VAF 10-0943\)](#)

The VHA Privacy Office has issued a **NEW VA HIPAA authorization form: VA Form 10-0493 dated September 2015**. The new form has been uploaded on the **UM HRPO and VAMHCS R&D websites**.

- The main effect for VAMHCS is that our “VAMHCS Supplemental HIPAA Authorization” is no longer necessary!
 - This is because Page 5 of the new version is no longer specific to VHA research. Page 5 now applies to ***all optional*** storage of data or specimens for future research of any sort (VHA or non-VHA).
- Other differences are:
 - Page 2, section entitled “Use of Your Data or Specimens for other Research”: If you check any of the boxes in this section, then Page 5 of the 10-0493 will disappear.
 - ◆ The VHA Privacy office did this to ‘alleviate some burden in the situations when page 5 is unnecessary’, i.e. when there are no optional uses or storage of data/specimens.
 - ◆ **However, this creates a problem** when a study needs to check a box in the “Use of Your Data or Specimens for other Research” (P.2) but also has optional uses or storage of data/specimens and therefore needs P.5.
 - ◆ If you run into this problem for your study, please contact the R&D Service (Jessica Mendoza x6512 or Ann Kimball x6506).
 - Page 5 now also includes a choice about “further optional analysis of my specimens for the current study”.
 - ◆ Note that this has nothing to do with storage for future research.
 - ◆ Use this box if you have offered participants a choice on the informed consent form, asking their permission to use their specimens for optional analysis.
 - There is a calendar drop down box to allow for entry of a Version date in the footer and will automatically be filled in for each page.
 - When entering text into this fillable form, click on the text box and then “tab” to the next field which will then allow the user to enter in the information behind the

printed text. See the attached example from VHA Privacy Office for an idea of the number of characters allowed in each text box.

- The form date for the new VAF10-0943 is “September 2015” instead of “May 2014”

■ The [September 2015 VAF 10-0493](#) has been posted on the VAMHCS R&D website and the HRPO website. The VAMHCS Supplemental HIPAA Authorization has been taken down from the websites.

- VAF 10-10116, Revocation of Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research (Sept 2015) has also been posted on both websites. Use VAF 10-10116 if a participant wishes to revoke his/her authorization.

■ **Implementation:**

- Effective immediately, all new protocols that require HIPAA authorizations must use the [September 2015 VAF 10-0493](#).
- Currently active protocols DO NOT need to switch to the September 2015 VAF 10-0493 if the study has an accurate May 2014 VAF 10-0493 is in effect.
- However, if your protocol currently uses the VAMHCS Supplemental HIPAA Authorization, you ***may*** want to get rid of it in order to eliminate one more form (and signature) for participants.
 - ◆ Modify your protocol to use the [September 2015 VAF 10-0493](#) for all your future participants (you would not need to “re-HIPAA” any past or current participants).
 - ◆ In the Modification, be sure to state that you have discontinued the use of the VAMHCS Supplemental HIPAA Authorization.
 - ◆ You are not required to discontinue the VAMHCS Supplemental HIPAA Authorization. ***It is your choice.***
- Completing and using [September 2015 VAF 10-0493](#):
 - ◆ Use VAF 10-0493 for the main study.
 - ◆ Pages 1-4 MUST be completed (main study). In the “Study Title” section (page 1), please include the IRB HP number.
 - ◆ Page 5 is also completed ***only if*** (1) there is optional storage of data/specimens for ***future research*** or (2) if there is optional specimen analysis for the main study.
 - ◆ Use the [attached tutorial](#) for guidance on completing the form.
 - ◆ The template is set up in tabular format with a finite number of characters allowed in each text cell.

- ◆ Read the comment boxes throughout the tutorial for guidance in completing VAF 10-0493.
- ◆ Pre-fill all spaces and check-boxes that apply to the study.
- ◆ Remove all comment boxes, track changes, etc.
- ◆ Create a PDF version of your completed form. (This PDF version will be used for CICERO submission and for use with the participant). This can be done by converting it through *Adobe Professional*, or by *saving it as a PDF* by following these steps:
 - Open the completed fillable PDF version.
 - Choose “Print”.
 - In the “Printer” options, choose “PDF”.
 - Hit “Print”. The “Save” screen will come up.
 - Give the file a new name and save it.

If these methods do not work for you, it can also be done by obtaining a good quality *scanned* copy of the finished form.
- ◆ Insert an appropriate page 5 (if needed) into the PDF. Do this thru Adobe professional or by scanning the 5 pages into a single form
- ◆ Save both the Word and PDF versions in your local research documents file.
- ◆ Submit the PDF version in CICERO.
- ◆ At the time of the informed consent/HIPAA process with a study participant:
 - Use a hard copy of the approved PDF'd 10-0493.
 - The participant signs Page 4 of the 10-0493 *and* Page 5 of the 10-0493 (if applicable).

■ **WARNING:** If your 10-0493 does include a page 5, **DON'T FORGET PAGE 4!**

- Page 4 is the main signature page for participants to authorize you to use their data.
- Remember that if your study has a Page 5, participants must also sign page 4!
- Recent informed consent audits have revealed that participants sign the Page 5's (the last page) and forget to sign Page 4 (the main page).
- Participants are free not to sign page 5 (it is their choice whether or not to participate in the optional part of the study), but they **must sign page 4** if they want to participate in the main study.

■ **R&D Hot Topics Vol 9 No 1 and Vol 9 No 4 have been rescinded. The following points from these Hot Topics remain important:**

- **“Future Research”**: Research that will use data and/or specimens maintained within research data/specimen repository(ies) and that will occur only after further IRB and/or other applicable approvals have been obtained. If you store data or specimens solely for your current study (i.e., once the study is closed then the data or specimens will no longer be accessed), then “future research” does not

apply to your study and VAF 10-0493 p. 1-4 would be the only HIPAA authorization you would need.

- **Sub-studies** must have their own, separate HIPAA authorizations (10-0493 Sept 2015). This is because a sub-study is considered an unconditioned/optional research activity that requires an explicit authorization from the patient.
- **Genetic Information**: is considered protected health information and is covered by HIPAA.
- **Make sure that the information in your HIPAA authorization(s) are consistent with your informed consent form and with your CICERO protocol (including attachments)**:
 - ◆ If the ICF contains “opt-in” questions for (1) storage of data or specimens for future research and/or (2) optional analysis of specimens for the current study, then you will need to have a 5-page version of the September 2015 VAF 10-0493.
 - ◆ If data/specimens are going outside of VAMHCS (i.e. being used by or disclosed to) to a coordinating center, collaborators, other federal agencies, etc., the HIPAA authorization(s) need to state this. This includes use by or disclosure to the University of Maryland.
 - ◆ In general, ensure that the ICF and HIPAA authorization match in terms of what entities to list in the ‘Use or Disclosure’ section. This includes the University of Maryland, collaborators, entities listed in the templated language of the ICF, and other individuals or entities as applicable.
- **Revocation**: See the attached “Revocation of Authorization for Use & Release of Individually Identifiable Health Information for VHA Research” (VAF 10-10116). Participants should use VAF 10-10116 or they can write their own message to the PI.
- **The “HIPAA Omnibus Final Rule”** became effective on 3/26/13 with a compliance date of 9/23/13.
 - ◆ The “HIPAA Omnibus Final Rule” is an update to the “Health Insurance Portability and Accountability Act of 1996 (HIPAA)” Privacy Act.
 - ◆ The final omnibus rule enhances a patient’s privacy protections, provides individuals new rights to their health information, and strengthens the government’s ability to enforce the law.
 - ◆ It is not a VA-specific change.

- ◆ VA developed VA Form 10-0493 in response to the “HIPAA Omnibus Final Rule”, and designed it to prompt Investigators to provide required information to participants in an organized fashion that hopefully promotes compliance for Investigators and understanding for participants. The form covers the requirements for “conditioned” (not optional) and “unconditioned” (optional) components of the research.
- **Conditioned (not optional) v. Unconditioned (optional)**
 - ◆ Conditioned (NOT OPTIONAL) research components: The individual can participate in the study *‘on the condition that’* s/he agrees to the (“conditioned”) activities. The activities are *required in order to participate in the study*. If the individual does not wish to or cannot agree to the activit(ies), then s/he cannot become a participant.
 - The activities are necessary components of the main study.
 - They are specifically delineated in the informed consent form (ICF) and described in general terms in the HIPAA authorization.
 - ◆ Unconditioned (OPTIONAL) research components: The individual can take part in the main study *even if they do not want to participate in the ‘unconditioned’ activit(ies)*:
 - Unconditioned/Optional activities are *voluntary*;
 - For both the ICF and HIPAA Authorization, the unconditioned activities **MUST** be an “opt-in” for the participant and NOT an “opt-out”.
 - These are typically listed as opt-in items within ICFs.

For questions concerning this or other Research Service Bulletins or Hot Topics, contact:

Jessica Mendoza,
Human & Animal Research Protections Officer
Room 3D-158
410-605-7000 x6512
Jessica.mendoza@va.gov