# VA ECHCS RESEARCH OFFICE

## HOT TOPIC

## NEWEST VA HIPAA B AUTHORIZATION FORM (VA Form 10-0493)

We are providing this Research Hot Topic to help answer questions regarding the VHA Privacy Office's latest VA HIPAA B Authorization form: VA Form 10-0493, dated September 2015. We hope the following detailed information and template tutorial with VA ECHCS specific comments will be helpful.

This most recent version of the VA HIPAA B Authorization can be found on the COMIRB website → VA Eastern Colorado Health Care System affiliation page (found at the bottom of the COMIRB Home Page) and at the following link: http://www.ucdenver.edu/research/comirb/Pages/VADenver.aspx. From this linked site, scroll down to the bottom of the page and you will find the revised form within the 'VA Forms' section.

- The major benefit of using this new VA HIPAA B Authorization form is that our "VA Supplemental HIPAA Authorization" is no longer necessary! This is because Page 5 of the new version is no longer specific to VA research. Page 5 now applies to ***all optional*** banking of data and/or specimens for future research (VA or non-VA) and it also applies to conducting ***optional*** analysis of subjects' specimens for use the current study.
  - Other differences and important details:
    - The current version of the VA HIPAA B Authorization is dated September 2015 rather than May 2014.
    - Regarding Page 2, Section entitled 'Use of Your Data or Specimens for Other Research':
      - Checking any of the boxes in this section will cause Page 5 to 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 components in the study for banking of data and/or specimens.'
      - However, this can create a problem when a study requires mandatory banking of data and/or specimens and, therefore, needs to check a box on Page 2 under "Use of Your Data or Specimens for other Research" **and** the study also offers an optional component for banking of data and/or specimens or for conducting optional analysis for this study and, therefore, also needs Page 5.
      - If you run into this problem for your study, please contact Lynne Brandes or Connie Steinbrunn in the VA Research Office. (Their contact information is located at the end of this Hot Topic.)
    - Page 5, as mentioned above, includes a checkbox for 'further optional analysis of my specimens for the current study'.
      - ***Note*:** This has nothing to do with banking for future research.
      - Use this box if you have offered participants a choice in the informed consent form (ICF), asking their permission to use their specimens for optional analysis for the current study.

- There is a calendar drop down box to allow for entry of a Version Date in the footer of the form, which will then 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 the information behind the printed text. See the VHA Privacy Office template, with additional comments specific to VA ECHCS, for an idea of the number of characters allowed in each text box.
- The VA Form 10-0493, dated September 2015, has been posted on the VA ECHCS affiliate page of the COMIRB website. The VA ECHCS Supplemental HIPAA Authorization form has been removed from the COMIRB website.
- VA Form 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 COMIRB website → VA ECHCS affiliate page → VA Form section. VA Form 10-10116, is to be used if a participant wishes to revoke his/her authorization. **However**, there is a 'Revocation' section on Page 3 of the newest VA HIPAA B auth. form, which describes how the subject can write to the VA PI (address needs to be provided) to revoke his/her authorization, if you do not wish to use this Revocation Form.

**Implementation**:

- All new VA protocols that require VA HIPAA B Authorizations must use the September 2015 version of VA Form 10-0493.
- Currently active protocols DO NOT need to switch to the September 2015 VA FORM 10-0493 **if** the study has an accurate May 2014 VA FORM 10-0493 in effect.
- However, if your protocol currently uses the VA ECHCS Supplemental HIPAA Authorization, you ***may*** want to start using the new VA HIPAA B auth. to eliminate one more form for participants to sign and date.
  - If you want to switch to the new VA HIPAA B auth., submit a COMIRB Change Form to COMIRB stating you want to start using the September 2015 VA FORM 10-0493, which will incorporate both the information from the main HIPAA B Auth. as well as the VA supplemental HIPAA Auth. information, for all your future participants. (You should not need to "re-HIPAA" any past or current participants).
  - On the COMIRB Change Form, please be sure to state that you have discontinued the use of the VA ECHCS Supplemental HIPAA Authorization.
  - You are not required to discontinue the VA ECHCS Supplemental HIPAA Authorization. ***It is your choice***.
- Pages 1-4 MUST be completed for the main study.
- In the "Study Title" section on Page 1, **include the COMIRB number before the study title.** COMIRB will return the form back to you if the COMIRB # is not included.

- Page 5 is completed **only if** (1) there is **optional** banking of data and/or specimens for **future research** **OR (2)** if there is **optional** specimen analysis for the current main study.

- Template Tutorial:
  - Use this linked Template 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 VA ECHCS-specific comment boxes throughout the tutorial for guidance in completing VA FORM 10-0493.
  - Obtain the most current version of the VA HIPAA B Authorization from the COMIRB website, VA ECHCS affiliate page, VA Forms section.
  - Pre-fill all spaces and check-boxes that apply to the study.
  - Create a PDF version of your completed form. (This PDF version will be used for the COMIRB submission and for use with the participant). This can be done by converting the form through *Adobe Professional* or *by saving it as a PDF* 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.

    ***Note*:** If this method does 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 through 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 into InfoEd.
  - At the time of the informed consent/HIPAA auth. process with a study participant:
    - Use a hard copy of the COMIRB "noted" PDF version of the 10-0493.
    - The participant signs Page 4 of the 10-0493 ***and*** Page 5 of the 10-0493 **(if applicable).**

**CAUTION**: 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 the VA research study team 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 on Page 5 (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 portion(s) of the study), but they **must sign page 4** if they want to participate in the main study.

**FOR YOUR INFORMATION:**

- **Future Research:**
  - **Recruitment Database:** If your protocol is giving participants the option to be contacted for future studies, allowing the investigators to keep their contact information for the purpose of future recruitment, please note:
    - The recruitment database created under this current study will not be accessible once this study is closed **and** the recruitment data must be destroyed with the study closure per the destruction plan specified under the current study.
    - If you plan on storing (banking) subject identifiers for the purpose of re-contacting participants for future research after the current study closes, a separate recruitment database protocol must be submitted to COMIRB **prior** to closing the current study.
    - Page 5 of the VA FORM 10-0493 must be used.
  - **Banking of Data and/or Specimens for Future Research:** If your protocol is giving participants the option to have their data and/or specimen samples banked for future studies:
    - The data repository and/or biospecimens repository created under this current study will not be accessible once this study is closed, and the data and/or samples must be destroyed with study closure per the destruction plan specified under the current study.
    - If the investigator plans on banking data and/or biospecimens for future research after the current study closes, a separate data repository and/or biospecimens repository protocol must be submitted to COMIRB prior to closing the current study.

  ***Note:*** *If you are storing data or specimens solely during the time your current study is open, (i.e., you will not be banking data or specimens for future research, then 'future research' does not apply to your study and VA FORM 10-0493 pages 1-4 would be the only HIPAA B Authorization you would need.*

  - **Sub-studies** must have their own, separate HIPAA B authorizations (VA Form 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 (PHI) and is covered by HIPAA.
- **Please ensure that the information in your HIPAA B authorization(s) are consistent with your Informed Consent Form (ICF) and with your COMIRB 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 the 5-page version of the VA FORM 10-0493.
  - If data/specimens are going outside of VA ECHCS (i.e. being used by or

disclosed to) a coordinating center, collaborators, other federal agencies, etc., the HIPAA authorization(s) need to state this in the 'Disclosure' section on Page 2. This includes use by or disclosure to the University of Colorado Denver (UCDenver).

- In general, ensure that the ICF and HIPAA B Authorization match in terms of what entities are listed in the 'Who Will See My Research Information' in the ICF and 'Disclosure' section of the HIPAA B Auth. This includes the UCDenver, 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" (VA FORM 10-10116). If participants wish to withdraw their authorization, they can either use VA FORM 10-10116 or they can write their own revocation message to the PI using the VA PI's address listed in the VA HIPAA B Authorization on Page 3.

- **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 B 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 HIPAA or privacy-related questions, please contact the VA ECHCS Privacy Officers:

Jeff Day
VA ECHCS Privacy Officer
(Phone) 303-399-8020, ext. 2080
(Fax) 303-393-2861
(Email) Jeffrey.Day1@va.gov

**OR**

Lesley Petersen
VA ECHCS Privacy Officer
(Phone) 303-399-8020 ext. 2082
(Email) Lesley.Petersen2@va.gov

- For questions concerning this or other Hot Topics or for comments, complaints, or suggestions regarding the Research Service, please contact:

Lynne Brandes
Research Compliance Analyst
(Phone) 720-857-5087
(Email) Lynne.Brandes@va.gov

**OR**

Connie Steinbrunn
HRPP Coordinator
(Phone) 720-857-5106
(Email) Connie.Steinbrunn@va.gov

- For comments, questions, complaints, or suggestions regarding Research Compliance, please contact:

Chelle Yin
Research Compliance Officer
(Phone) 720-857-5084
(Email) Chelle.Yin@va.gov

- To add staff or colleagues to the Hot Topics distribution list, please contact:

Lori Calabrese
Program Support Assistant
Research Service (Phone) 303-399-8020 x 2755
(Email) Lori.Calabrese@va.gov