

## VAMHCS RESEARCH SERVICE HOT TOPIC

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### New VAMHCS HIPAA Authorization Form is effective immediately.

Effective immediately, a new, stand-alone VAMHCS HIPAA Authorization will be required for all VAMHCS research studies that require HIPAA authorizations.

- The new form and a tutorial are attached to this Hot Topic and are also available on the VAMHCS Research Service Website ([http://www.maryland.research.va.gov/research/human/human\\_subject\\_forms.asp](http://www.maryland.research.va.gov/research/human/human_subject_forms.asp), [http://www.maryland.research.va.gov/research/human/forms/Tutorial\\_VAHIPAA.pdf](http://www.maryland.research.va.gov/research/human/forms/Tutorial_VAHIPAA.pdf)) and the UMB HRPO website (<http://www.hrpo.umaryland.edu/consents.asp>).
- The changes are as follows:
  - The phrase “you/your child” has been replaced simply with “you” or “your”.
  - The word “share” has been replaced with the word “disclose”.
  - The header contains the VAMHCS logo, making it easily identifiable as the VAMHCS form to be used,
  - “Researcher’s Contact Information” now prompts for the VAMHCS appointment and contact information. The PI must be identified as a VA investigator.
  - “Specific Health Information” contains an extended list of possibilities. There may be additional possibilities such as “DNA sequencing”, “RNA sequencing”, etc. Remove the items that do not apply to your study; add items that do apply.
  - “People and Organizations Who Will Use/Disclose...”: fill in applicable information within the brackets; add or remove items as needed.
  - “Where Your Information Will Be Stored” is a new section. Fill in applicable information within the brackets; add additional information as applicable.
  - “The Purpose for the Use or Disclosure of this Information” is a new section. A list of possibilities is presented. Remove the items that do not apply to your study; add items that do apply.
  - “This Authorization Will Expire” is a new section, split from the revocation statement in the UMB form. Please give consideration to an informative answer from the list provided or another endpoint that applies to your study.
  - “Additional Information”, 3<sup>rd</sup> bullet contains the following additional sentence as required by the VHA: *“It is possible that I/HI disclosed through this authorization may no longer be protected by Federal laws or regulations and may therefore be subject to re-disclosure by the recipients”*.
  - The signature line for ‘Personal representative/legal authority’ contains an explanation in italics below the signature block. If your study does not

allow for the use of a personal representative, then this signature line and note should be removed.

- *An individual who is qualified as a LAR [Legally Authorized Representative] to provide informed consent on behalf of a prospective research subject may not always qualify as a personal representative for purposes of consent to use or disclose a human subject's PHI (i.e. signing a HIPAA authorization) . ). Only the following individuals may sign a HIPAA authorization: (a) The individual. (b) A court-appointed legal guardian. (c) A person legally authorized in writing by the individual (or the individual's legal guardian) to act on behalf of the individual (i.e., [Power of Attorney]). (d) If the individual is deceased, then Executor of Estate, next-of-kin, or other person who has authority to act on behalf of the individual.*
- If there is a possibility that LARs may be needed for informed consent for your study, then you should apply for a HIPAA waiver for instances where the participant may not have a court-appointed legal guardian or a legally authorized representative (DPOA).

- ▣ “Privacy Questions?” now contains the contact information for the VAMHCS Privacy Office.
- ▣ Footer shows the version date (08.11.2011) and asks for identifiers of the participant. This is to ensure that pages remain with the correct participant.
- ▣ The revised HIPAA authorization must be used for all new participants as you enroll them in currently active protocols and for all new protocols.
  - ▣ This will require modification requests to the IRB (through CICERO) for use of the new forms adapted to your studies. Please begin submitting your modifications as soon as possible.
  - ▣ Already-enrolled participants do not need to be “re-HIPAA’d” unless the IRB requires it.
  - ▣ As of 10/13/11 the VAMHCS R&D Committee will not approve new studies without the new HIPAA forms.
  - ▣ As of 10/13/11 the VAMHCS R&D Committee will require the new HIPAA forms for continuing review and modifications.

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

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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](http://www.maryland.research.va.gov/hot_topics.asp)

For comments, complaints or suggestions regarding the Research Service or Office of Research Compliance, contact:

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