

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH



Name of Study Volunteer: _____

Date of Birth: _____ Medical Record Number: _____

NAME OF THIS RESEARCH STUDY: <Title>

UMB IRB APPROVAL NUMBER: <IRB number>

RESEARCHER'S NAME: <PI name>

RESEARCHER'S CONTACT INFORMATION:

<Service / Center name>

VA Maryland Health Care System (VAMHCS)

<Street Address>, <Room number>

<Phone number>

Comment [jlm1]: Use information related to the PI's VA appointment

This research study will use health information that identifies you. If you agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR DISCLOSED:

- Billing and payment information and the medical information required to justify it.
- Research tests
- Demographic information
- Health information, Specimens collected (if applicable)
- If HIV, sickle cell anemia, drug and/or alcohol abuse treatment information is to be disclosed, list it specifically here.

[INCLUDE ALL ITEMS THAT APPLY, including other items or categories not listed]

Comment [jlm2]: Add or delete items as applicable to your study.

Comment [jlm3]: Remove this phrase throughout this template once the study-specific authorization is complete

Federal laws require this researcher to protect the privacy of this health information. He/she will disclose it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR DISCLOSE THIS INFORMATION:

- Dr. <PI name> and his/her research team.
- The sponsor of the study, <sponsor>, or its agents, such as data repositories or contract research organizations.
- Organization that will coordinate health care billing or compliance such as the Veterans Affairs Maryland Health Care System (VAMHCS), the University of Maryland Medical System (UMMS), offices within University of Maryland School of Medicine (UMSOM); the University of Maryland, Baltimore (UMB); University Physicians, Inc. (UPI) and the faculty practices of the UMB.
- Your health insurer to pay for covered treatments

[INCLUDE ALL ITEMS THAT APPLY]

Comment [jlm4]: Add or delete items or parts of these items, as applicable to your study.

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WHERE YOUR INFORMATION WILL BE STORED:

Information about you, gathered in connection with this study, will be stored at <state location; for example: “at the University of Maryland”, or at the “VA Maryland Health Care System” or “within the Department of Veterans Affairs”, etc.> and will be under the ownership, control and security of < state the location where the data is being stored>.

THE PURPOSE FOR THE USE OR DISCLOSURE OF THIS INFORMATION:

- The information will be used or disclosed for research study purposes.
- Your personal use (if you request it).
- <Future research> (if it is placed in a data repository).
- *Your health insurer to pay for covered treatments*
[INCLUDE ALL ITEMS THAT APPLY]

Comment [jlm5]: Add or delete items as applicable to your study.

THIS AUTHORIZATION WILL EXPIRE

- <At the end of the research study>
- <At another endpoint>
- <Will not expire> (for the creation and maintenance of a research database or repository).
[INCLUDE ALL ITEMS THAT APPLY]

Comment [jlm6]: Choose one of the items or another timeframe applicable to your study.

Comment [jlm7]: Specify the endpoint

YOU CAN REVOKE THIS AUTHORIZATION AT ANY TIME.

To revoke this Authorization, send a letter to this researcher stating your decision. He/she will stop collecting health information about you/your child. This researcher might not allow you to continue in this study. He/she can use or disclose health information already gathered.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you receive at:
 - Veteran Affairs Maryland Health Care System (VAMHCS)
 - University Physicians, Inc. (UPI)
 - University of Maryland Medical System (UMMS)

Your treatment, payment, enrollment, or eligibility for benefits will not be affected if you do not sign this authorization.

- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the VAMHCS, UMSOM, UMB, UPI, or UMMS to give it to them.
- This researcher will take reasonable steps to protect your individually-identifiable health information [IIHI]. However, federal protection laws may not apply to people or groups outside the VAMHCS, UMSOM, UMB, UPI, or UMMS. It is possible that IIHI 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.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask this researcher how to get a copy of this information from him/her.

Comment [jlm8]: This is a new addition. Explain to participants that once their information is disclosed to another party (one of the parties you've listed above), the VA has no control as to how those parties use the information.

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My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to disclose my protected health information with this researcher for the purposes described above.

Signature: _____ Date: _____
(Participant)

Signature*: _____ Date: _____
(Personal representative/legal authority)*:

Name (printed) _____

**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.*

Comment [jlm9]: This is for study team information. Study team must be aware that, if the participant cannot sign for him/herself, HIPAA is more restrictive on who can sign HIPAA authorizations than the rules for surrogate consent. An individual qualified to be an LAR for informed consent may not necessarily be eligible to sign the HIPAA authorization.

Privacy Questions? Call the VAMHCS Privacy Officer (410-605-7000 x3152) with questions about your rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.