

HIPAA CONSENT FORM**AUTHORIZATION (CONSENT) TO PERMIT THE USE AND DISCLOSURE OF IDENTIFIABLE
MEDICAL INFORMATION (PROTECTED HEALTH INFORMATION)
FOR RESEARCH PURPOSES**

Study Title: (Insert study title here)

Principal Investigator: (Insert PI name here)

Participant's Name: _____

SSN: _____

1. What is the purpose of this form?

The research study in which you are participating may help researchers learn more about the causes, or how to prevent and treat your condition. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

By signing this document, you will authorize the Veterans Health Administration (VHA) to provide (insert name of Principal Investigator) and his or her research team to access your protected health information.

2. What personal health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter a research study, information that will be used and/or released may include (but not limited to) the following:

- The history and diagnosis of your disease;
- Specific information about the treatments you received, including previous treatment(s) you may have had;
- Information about other medical conditions that may affect your treatment;
- Medical data, including laboratory test results, measurements, CT scans, MRIs, x-rays, and pathology results;
- Information on side effects (adverse events) you may experience, and how these were treated;
- Long-term information about your general health status and the status of your condition;
- Data that may be related to tissue and/or blood samples that may be collected from you; and
- Numbers or codes that will identify you, such as your social security number and medical record number.

3. Why do the researchers want your personal health information?

(Insert reason for use of personal health information here)

4. Who will be able to use your personal health information?

(Insert your institution and department) will have access to the data that includes protected health information.

(Insert your institution and department) will use your health information for research. As part of this research, the below listed groups may have access to your information: (insert all groups that will have access to or receive information)

- The study's sponsor or representative of the sponsor;
- Public Health agencies and other government agencies as authorized or required by law;
- Other people or organizations assisting the company(ies) sponsoring the research with the research efforts;
- Central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed in the bullets above;
- The Office of Human Research Protection (OHRP) and/or Food and Drug Administration (FDA); and
- The Marshall University Office of Research Integrity (ORI) and the Marshall University Institutional Review Board (IRB).

Also, if you feel your health information has not been adequately protected, you may contact or visit the Office of Research Integrity (ORI) at:

Office of Research Integrity
401 11th Street, Suite 1300
Huntington, WV 25701
(304) 696-7320

5. How will information about you be kept private?

Only researchers will have access to your information. We will not release personal health information about you to others except as authorized or required by law and institutional policy. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected and may be subject to re-disclosure by the recipient.

6. What happens if you do not sign this permission form?

Taking part in a research study is completely voluntary and there is no penalty if you choose not to participate. If you decide not to sign this permission form you will not be able to take part in the research study for which you are being considered. The choice is completely up to you. This will not affect your rights as a VHA patient, including treatment, payment, enrollment or eligibility for benefits.

7. If you sign this form, will you automatically be entered into the research study?

No, you cannot be entered into any research study without further discussion and a separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

8. What happens if you want to withdraw your permission?

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time. This will not affect your rights as a VHA patient, including treatment, payment, enrollment or eligibility for benefits.

To withdraw your permission, please contact the principal investigator at the number listed below. The study team will make sure your written request to withdraw your permission is processed correctly.

(Insert contact information for the principal investigator or study coordinator)

9. How long will this permission last?

If you agree by signing this form that researchers can use your personal health information, this permission has no expiration date **OR** will expire at the end of the research study **OR (describe dates or circumstances under which authorization will expire)**. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are your rights regarding access to your personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your personal health information kept by (insert department). You do not have the right to review and/or copy records kept by the study sponsor or other researchers associated with the research study.

Signatures

You agree that your personal health information may be used for the research purposes described in this form.

Signature of Participant or Participant's Legal Representative

Date

Printed Name of Legal Representative (if applicable)

Representative's Authority to Act for Patient

Signature of Person Obtaining Permission

Date

Printed Name of Person Obtaining Permission