**Research Consent | HIPAA Authorization**

**Principal Investigator (PI) |** Click here to enter text.

**Department |** Click here to enter text.

**Co-Investigator(s) |** You can remove this field as necessary or enter Co-Is.

**Sponsor or Funding Source |** Click here to enter text.

**WVU IRB Protocol # |** Click here to enter text.

**Study Title |** Click here to enter text.

**Subject’s Name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject’s ID | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**HIPAA Authorization**

We know that information about your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

**Persons/Organizations Providing the Information**

Specify as appropriate

Patient (data are from the participant)/West Virginia University Hospitals/ WVU Medicine/ WVUHS (data are from records)

**Persons/Organizations Receiving the Information**

Add applicable information and/or delete any information that does not apply.

* The research site(s) carrying out this study. This includes UHA or UHA Affiliates, WVU, WVU Hospitals, West Virginia University Health System (WVUHS). It also includes each site’s research and medical staff.
* Health care providers who provide services to you as part of this research study.
* Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
* If applicable, The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law. ***(Required for FDA regulated research.)***
* (If applicable,) Foreign Regulatory Agencies
* (Sponsor name, if applicable) and the people and companies that they use to oversee, manage, or conduct the research.
* The members and staff of any institutional review board that oversees this research study.
* The West Virginia University Office of Human Research Protection and the West Virginia University Office of Sponsored Programs.
* Enter your own Research Unit or Department (if applicable)

**The Following Information Will Be Used**

Specify the PHI that is viewed or recorded for the study and delete any sections that do not apply.

Information from your existing medical records, and new information about you that is created or collected during this study, such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, EKG results, demographic data, pulmonary tests, imaging scans, and study forms.

**The Information is Being Disclosed for the Following Reasons**

Add applicable information and/or delete any information that does not apply.

* Review of your data for quality assurance purposes
* Publication of study results (without identifying you)
* Other research purposes such as reviewing the safety or effectiveness of the study drug and other products or therapies; conducting performance reviews of the study drug; evaluating other products or therapies for patients; developing a better understanding of disease; improving the design of future clinical trials

**You may Cancel this Authorization at Any Time by Writing to the Principal Investigator**

Enter the PI name and full contact information (specifically a mailing address). Only written cancelation of Authorization is permissible.

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re-disclose it and then the information may no longer be protected by federal regulations.

(Keep this paragraph, as appropriate) You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time, you may ask to see the study doctor’s files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time (or has a specific expiration date).

**Signatures and Authorization**

You have been given the opportunity to ask questions about the research and your authorization of HIPAA, and you have received answers concerning areas you did not understand. Upon signing this form, you will receive a copy.

**Participant Signature**

I have read this form and all of my questions about this form have been answered. By signing below, I acknowledge that I have read and accept all of the above. I willingly consent to participate in this research and authorization of HIPAA.

| Signature of Subject or Subject’s Legal Representative | | |
| --- | --- | --- |
| Printed Name |  | Date |

**Consenting Individual Signature**

The participant has had the opportunity to have questions addressed. The participant willingly agrees to their authorization of HIPAA within this research study.

| Signature of Person Obtaining Informed Consent | | |
| --- | --- | --- |
| Printed Name |  | Date |

**Contact Information**

The contact information of the subject or authorized representative who signed this form should be filled in below.

Address:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (daytime)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (evening)

E-mail Address (optional): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_