**Advarra Mandatory Language Document**

**For**

**WEST VIRGINIA UNIVERSITY**

**INFORMED CONSENT FORM**

|  |  |
| --- | --- |
| **Sponsor / Study Title:** | **Sponsor Name / “Protocol Title”** |
| **Protocol Number:** | **Protocol Number** |
| **Principal Investigator:****(Study Doctor)** | **«PiFullName»** |
| **Telephone:** | **«IcfPhoneNumber»** |
| **Address:** | **«PiLocations»** |

**INSTURCTIONS FOR ADVARRA STAFF**

*The client has requested for Advarra to insert this language on their behalf. The client confirmed the study teams should be able to handle any discrepancies, but additional contacts are* reliance@mail.wvu.edu .*or the IRB email address –* *IRB@mail.wvu.edu*.

**FINANCIAL CONSIDERATIONS**

*Advarra staff: Add the following language under the Financial Considerations section or the most applicable section of the consent.*

Your information may be provided to the appropriate parties for billing and/or payment purposes. Please be advised that any compensation received for participation in a research study, including a gift card, is considered taxable income and must be reported to the IRS. If you are a WVU employee or a WVU student-employee, you are required to report the total amount of compensation received for your participation in a research study to the WVU Tax Services Office upon receipt of payment.

Your data, health information, research results, specimens, genomic data only include as appropriate, or any and all other information related to this research study and used in this research study may contribute to a new discovery or treatment.  In some instances, your data, your health information, your research results, your specimens, these discoveries or treatments, or any other information related to this research study may be of commercial value and may be sold, patented, or licensed by the investigators and West Virginia University for use in other research or the development of new products.  You will not retain any property rights nor will you share in any money that the investigators, West Virginia University, or their agents may realize.

**RADIATION RISK SECTION**

*Advarra staff: This is to be added to the procedure risks section. Use this as the intro paragraph and follow with any APPLICABLE exam risks language such as X-Rays, MRI’s CT scans, etc.*

The amount of radiation (x-rays and scans to assess your disease) that you are exposed to during the research is considered the standard of care for your condition. The risks of these procedures will be explained to you by your doctor and the staff involved in your care. Risks from radiation exposure are cumulative (they increase) over time.

**COMPENSATION FOR INJURY LANGUAGE:**

*Advarra staff: This is to be inserted in the comp for injury section in addition to sponsor language.*

*Option 1: Sponsor will pay*

If you are injured as a result of participation in this research, treatment will be available. <Sponsor> will pay for this care. There is no commitment to provide any compensation for research-related injury. You have not released this institution from liability for negligence. Please contact the Principal Investigator at the telephone number listed on the first page of this form if you are injured or for further information.

**OR**

*Option 2: The Sponsor is NOT paying*

If you are injured as a result of this research, treatment will be available. This care will be billed to you or your insurance company. There is no commitment from WVU to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the Principal Investigator at the telephone number listed on the first page of this form if you are injured or for further information.

*Always add the following for option 1 and option 2:*

WVU does not maintain funding to pay for treatment if you are injured or become sick from participation in this research study.

**GINA LAW**

*Advarra staff: Insert for applicable genetic studies / sub-studies*

The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request the genetic information provided for this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use the genetic information provided for this research when making decisions to hire, promote, or fire you or for setting the terms of your employment.

GINA does not protect against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

West Virginia's genetic discrimination laws protect patients from discrimination by health insurers or employers. As a result, health plans or insurance companies cannot raise your rates based on genetic information about you or commit any other form of illegal discrimination. Additionally, employers in West Virginia cannot use your genetic information to make informed decisions related to your employment.

**HIPAA AUTHORIZATION**

*Advarra staff: Delete sponsor HIPAA language and INSERT WVU HIPAA. If no sponsor HIPAA, insert this WVU HIPAA in the main body of the consent above the signature blocks . Please remove this section if PHI is not involved in the study.*

West Virginia University is dedicated to protecting the privacy of your information. As part of the protection, we are required to obtain your written authorization (permission) before we may use or disclose your protected health information (PHI) or share it for research purposes.

You can decide to sign or not to sign this authorization. However, if you choose not to sign this authorization, you will not be able to take part in the research. The choice you make about participation in this research study will not affect your access to medical care.

**Persons/Organizations Providing the Information:**

Participant – Data is from the participant

OR

West Virginia University Hospitals\WVU Medicine\WVUHS – Data is obtained from medical records.

**Persons/Organizations Receiving the Information:**

Delete or add information as applicable:

* The research site(s) carrying out this study. Include as applicable: UHA or UHA Affiliates, WVU, WVU Hospitals, West Virginia University Health System (WVUHS), and other affiliate sites, including the research and medical staff at the site(s).
* Health care providers who provide services to you as part of this research study.
* Laboratories and others that view your health information as part of this study in agreement with the study protocol.
* If applicable, required for FDA regulated research The U.S. 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.
* If applicable Enter: Foreign Regulatory Agencies
* If applicable Enter: Sponsor Name and the people and companies that they use to oversee, manage, or conduct the research.
* The members and staff of the Institutional Review Board that oversees this research study.
* The West Virginia University Office of Human Research Protections and the West Virginia University Office of Sponsored Programs.
* If applicable: Enter the Research Unit or Department

**The Following Information Will Be Used:**

This information could include new or existing information about you, 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 delete any information that does not apply.

* Review of your data for quality assurance purposes
* Publication of study results (without identifying you)
* (Include the following options if applicable) 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 the disease, or improving the design of future clinical trials.

**You may cancel this HIPAA Authorization at any time by writing to the Principal Investigator.**

All cancellations must be in writing to the Principal Investigator at the address listed on the first page of this form.

If you cancel this Authorization, any information that has been collected for the research study to date 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.

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 research study until the Sponsor has completed all work related to the study. At that time, you may ask to see the information related to your participation and request corrections to the information.

This Authorization will expire at the end of the research study unless you cancel it before that time.

**SIGNATURE BLOCKS:**

*Advarra staff: If signature blocks have a header, it should include reference to both consent and authorization. Remove references to Authorization is HIPAA is not included.*

## Signatures and Authorization

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

**Participant Signature**

I willingly consent to participate in this research (if applicable) and authorization of HIPAA.

| Signature of Participant  |
| --- |
| Printed Name |  | Date |

**Consenting Individual Signature**

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

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