**Only Minimal Risk
Consent Information and HIPAA Form**

Principal Investigator

Department

Protocol Number

Study Title

Co-Investigator(s)

Sponsor (if any)

 **Contact Persons**

Click here to enter text.

In the event you experience any side effects or injury related to this research, you should contact Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at (304) \_\_\_-\_\_\_\_\_. (After hours contact: Dr. \_\_\_\_\_\_\_\_\_\_\_\_ at (304) \_\_\_-\_\_\_\_\_). If you have any questions, concerns, or complaints about this research, you can contact Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at (304) \_\_\_-\_\_\_\_\_.

For information regarding your rights as a research subject, to discuss problems, concerns, or suggestions related to the research, to obtain information or offer input about the research, contact the Office of Research Compliance at (304) 293-7073.

In addition if you would like to discuss problems, concerns, have suggestions related to research, or would like to offer input about the research, contact the Office of Research Integrity and Compliance at 304-293-7073.

 **Introduction**

You, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, have been asked to participate in this research study, which has been explained to you by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. This study is being conducted by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in the Department of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at West Virginia University with funding provided by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ or sponsored by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

 **Purpose(s) of the Study**

Explanation of the purpose of the study

 **Description of Procedures**

This study involves \_\_\_\_\_ [describe procedures in appropriate detail] and will take approximately \_\_\_\_ [state how long it will take to participate in the study] for you to complete. You will be asked to fill out a questionnaire regarding \_\_\_\_ [state what the questionnaire is about]. This will take approximately \_\_\_\_\_\_ [state how long it will take to complete the questionnaire]. You do not have to answer all the questions. You will have the opportunity to see the questionnaire before signing this consent form.

 **Discomforts**

There are no known or expected risks from participating in this study, except for the mild frustration associated with answering the questions.

 **Alternatives**

You do not have to participate in this study.

Alternatives that could be considered in your case include:

 **Benefits**

You may not receive any direct benefit from this study. The knowledge gained from this study may eventually benefit others.

 **Financial Considerations**

[If planning to pay participants, explain fully and clearly any fees or bonuses and how they will be paid, including proration. Unless the study is confidential, the WVU consent form must inform subjects that they will be asked to provide their Social Security Number and verification of U.S Citizenship or Permanent Resident Status to receive payment. For confidential studies only name and address are required.]

You will be paid \_\_\_\_\_\_\_\_ for each visit, up to a total of \_\_\_\_\_\_\_. If you withdraw before the end of the study, no additional payments will be made.

You will earn extra credit for participating in this study. Other options are available for earning the same extra credit.

 **Confidentiality**

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities without your additional consent.

Audiotapes or videotapes will be kept locked up and will be destroyed as soon as possible after the research is finished.

In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent.

 **HIPAA**

We know that information about you and 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 for research purposes.

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/West Virginia University Hospitals

 **Persons/Organizations Receiving the Information**

(delete any that do not apply)

• The research site(s) carrying out this study. This includes UHA or UHA Affiliated, WVU, WVU

Medicine, or the covered entities under the purview of West Virginia University, collaborating institutions, affiliate institutions, and component institutions. It also includes each site’s research staff 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.
• 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.
• Foreign Regulatory Agencies
• (Sponsor) and the people and companies that they use to oversee, manage, or conduct the research.
• The members and staff of any Institutional Review Board (IRB) that oversees this research study.
• West Virginia University Office of Research Compliance and Office of Sponsored Programs.
• West Virginia University Clinical Trials Research Unit.

 **The Following Information Will Be Used**

(specify PHI required, delete sections that do not apply) Information from your existing medical records and new information about you that is created or collected during the 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**

(delete sections that do 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**

PI Name and Full Contact Information

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.

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).

 **Voluntary Participation**

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time.

Refusal to participate or withdrawal will not affect [your class standing or grades, as appropriate] and will involve no penalty to you. Refusal to participate or withdrawal will not affect your future care, or your employee status at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

You have been given the opportunity to ask questions about the research, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy.

I willingly consent to participate in this research.

 **Signatures**

Signature of Subject

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

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

Signature of Investigator or Co-Investigator

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