**More Than Minimal Risk
Consent and HIPAA Form**

Principal Investigator

Department

Protocol Number

Study Title

Co-Investigator(s)

Sponsor

 **Contact Persons**

PI Name and Full Contact Information: PI Name, MD, Assistant Professor, Division of Hematology/Oncology 1 Medical Center Drive, Morgantown, WV 26506, Division of Hematology/Oncology, 1 Medical Center Drive, Morgantown, WV 26506

In the event you experience any side effects or injury related to this research, you should contact Dr. PI Name at (304) 598-4500. (After hours, contact the Hematology/Oncology Doctor on call t at (304-598-4000). If you have any questions, concerns, or complaints about this research, you can contact Dr. PI Name, at (304) -598-4500.

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**

It has been explained to you that you have [disease or condition of the targeted subjects] which is resistant to standard therapy. You have been invited to participate in this research study which involves an investigational agent [list the investigational agent], which has not yet been approved by the Food and Drug Administration (FDA) for treating their condition for a period of [list the expected duration of participation]. The purpose of this study is to evaluate the effectiveness and side effects of [investigations agent] and to learn more about your disease.
WVU expects to enroll approximately [number of subjects] subjects; a total of approximately [number of subjects] subjects at all sites are expected to participate in this study.

 **Description of Procedures**

This study involves receiving an investigational agent [list investigational agent] or [list standard treatment] for a period of up to [list expected duration of participation]. [Investigational agent] is a new experimental therapy and [standard treatment] is the current therapy for your disease. It is not clear at the present time which of the therapies is better for you.

For this reason, the therapy offered will be based upon chance using a method of selection called randomization (like flipping a coin) [or list the method of assigning investigational versus standard treatment]; your chances of receiving the experimental therapy are approximately the same as that of receiving current therapy [or explain the chances of each subject receiving experimental vs. standard treatment].[Describe experimental treatment regimen in detail using a separate paragraph for each element of the treatment. This should include a timeline or chronological order of treatments and/or procedures.]We will draw about one teaspoon of blood every time you come in for a treatment. A total of about 12 teaspoons will be drawn during the course of the study.

Treatment will be stopped if your disease becomes worse or if your physician determines that this treatment is not in their best interest. 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. [If audiotaping or videotaping is involved, the consent form must inform subjects of that procedure.]There are anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. [Include when there are anticipated circumstances under which the investigator may terminate participation of a subject.]

 **Risks and Discomforts**

Drugs often have side effects. The drugs used in this program may cause all, some, or none of the side effects listed. In addition, there is always the risk of uncommon or previously unknown side effects. [When feasible, provide a table or listing of risks or side effects, categorized by “more likely”, “less likely”, “rare”.]

Example: Drug A often causes…; is less likely to cause…; in rare cases may cause…. Drug B often causes…; is less likely to cause…; in rare cases may cause…. Drug A may interact with Drug B and cause…. There may be other interactions that the researchers cannot predict.

Having blood drawn may cause bruising, bleeding, or in rare cases infection.

This study also requires you to undergo \_\_\_\_\_\_\_\_ X-rays of your \_\_\_\_\_\_\_. Exposure to X-ray radiation is associated with increased risk of \_\_\_\_\_\_\_\_\_\_. Your doctor will be checking you closely to see if any of these side effects or problems are occurring.

This study may involve risks to the unborn child. For this reason, women who are pregnant will not be accepted. If you are a woman who could become pregnant, you will not be allowed to participate in this study until you have had a pregnancy test and the test has indicated that you are not pregnant. You must use a medically approved method of birth control while you are on this study.

Men who are able to father a child should never have unprotected sex with a woman while in this study because it is not known if the drug is present in semen or sperm.

 **Alternatives**

You do not have to participate in this study.

Alternatives that could be considered in your case include:

 **Benefits**

Possible benefits that may result from your participation include the improvement of your health, but since it is not known whether either therapy will be effective in your case, you may not receive any benefit or your condition may worsen. The knowledge gained from this study may eventually benefit others.

 **Financial Considerations**

You may wish to consult your insurance carrier prior to entering this study.
[Investigators must clarify who pays for or who is responsible for any costs incurred as a result of participation in the research.]

There are no special fees for participating in this study, but any expense associated with current therapy or treatment of side effects will be billed to you or to your insurance company.

The study sponsor, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, will pay for the additional X-ray examinations that would not be part of current therapy for their disease. If they are assigned to the experimental therapy, the cost will be paid by \_\_\_\_\_\_\_\_\_\_\_\_, the study sponsor.

[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.

 **Voluntary Compensation**

If you are injured as a result of this research, treatment will be available. Responsibility for this treatment will be borne by: 1) the sponsor; 2) the insurance company; OR 3) by you. [Select all applicable parties] In the event that you are physically injured as a result of participating in this research, care will be available. You will, however, be responsible for the charges for the care. There is no commitment 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 investigator, (name) at (phone number) if you are injured or for further information.

 **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 (including the FDA if applicable) without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to your child or to others, such as suicide, child abuse, etc.

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.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

 **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 Medicine

 **Persons/Organizations Receiving the Information**

• 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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