**Informed Consent Form (ICF) Template Instructions – More than Minimal Risk Parent/Guardian Consent**

Delete this page before submission

**Procedure:**

* **Use this template for: Full board applications requiring parent/guardian consent for a minor child.**
* Refer to the Guidance section of the WVU OHRP website for guidance on Informed Consent. The **Required Elements** MUST be included. **Additional Elements** are required as applicable.
* Modify and submit this template with the protocol application. Black text **CANNOT** be modified as it is IRB-Approved.
* **Initial Submission**: Submit a Word document AND a PDF.
* **Revisions:** Turn on **Track Changes**, make the suggested revisions and submit the tracked change version of the ICF along with a PDF **with** the changes accepted.
* **Final Submission:** Remove all older versions of the Word document and save and upload the final version as a PDF document after revisions are complete. Keep your Word document for future reference outside of the system.
* **WVU IRB Approval:** When the PDF version of the ICF is approved, the system will insert a WATERMARK on each page with the approval date, expiration date, and protocol number.
* The ICF containing the WATERMARK **must** be used for consenting participants, **including electronic consent forms**.

**General Instructions:**

* Language should be no greater than the 8th grade level (in lay language).
* Red text should be replaced with information related to the research study, change red text to black and delete red text that is not applicable before submission.
* Purple text is instructional and should be removed
* **Black text is required and approved by WVU legal counsel and cannot be changed or removed without IRB approval**.
* HEADER: Insert the WVU protocol number in the header of the IC document. Other protocol numbers can be inserted below the WVU number.
* HEADER: Add the Sponsor or Department Name next to the “Funding Source” in the header as applicable.
* FOOTER – Cannot be changed.

**Parent/Guardian Consent for “More than Minimal Risk” Research**

**Key Information for:**

**<Insert Title (or Short Title)>**

**This section should be one page**

*Please Note: The term “you” and “I” refers to your child when discussing their potential participation in this research study for the remainder of this consent form.*

You are being asked to participate as a human subject in the research described below. This page provides a summary of the research that may help you to decide whether you wish to participate. More detailed information can be found in the Informed Consent form beginning on the next page.

## What is the study about and how long will it last?

Briefly describe (in lay terms) the following

* The purpose of the study
* Activities that the participant is asked to do (For example, you will be asked to complete a survey, attend a focus group, procedure, office visit, etc.)
* How long it will take to complete the research study.

## Do you have to participate, and what are the benefits and risks?

Participation in this research study is entirely voluntary, and you are free to withdraw from the research at any time. If you do not wish to participate, please discuss alternatives with the <insert the name of the researcher or study doctor> or refer to the "Alternatives" section in the consent form.

Benefits from participation may include <Enter the benefits.> If there is no benefit, include: You may or may not directly benefit from participating in this research.

 Risks from participation in this study include: Enter critical risks and information to help a participant decide if they wish to participate or not.

## Who can you talk to if you have questions or concerns?

If you have any questions or concerns about this research or wish to withdraw, you can contact:

Research Study Contact Name <Enter Contact Name>, <Enter WVU Department> at <Enter Phone Number> or at <Enter Email Address>. Business Hours <Enter Days of the Week and Hours of Availability>

**For more information, please review the Informed Consent Form on the next page.**

**Parent/Guardian Consent for “More than Minimal Risk” Research**

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

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

**Co-Investigator(s) |** Remove this field or enter Co-I.

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

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

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

## Introduction

You have been asked to participate in this research study. The research has been explained to you by an authorized member of the research team.

If research is to fulfill degree requirements, include the text below

This research is being conducted to fulfill the requirements for a <insert degree> in <subject> from the Department of <enter the dept name> at West Virginia University. This research is being conducted under the supervision of the Principal Investigator listed above.

## What is the purpose of this study?

The purpose of this research is to <define the purpose of the study in lay terms.> WVU expects to enroll approximately <enter the number of participants enrolled by WVU researchers/sites> participants in the research study. If multi-site: A total of approximately <insert aggregate number of participants>, participants at all sites, are expected to be enrolled.

## What will you be asked to do?

If you decide to take part, this is what will happen:

This research study involves <identify and describe investigational procedures in an easily understandable way and with appropriate detail> and will take approximately <state how long it will take to participate in the study.>

Describe all standard of care procedures\activities that will occur separately from the investigational procedures\activities (those that are done specifically for the research). The standard procedures\activities are done regardless of the research.

Identify and describe the experimental procedures\activities in detail using lay language. Use a separate paragraph for each element\step. The description should include a timeline and be in chronological order of treatments, procedures, or activities that are specific to the research. Visuals or diagrams help enhance participant understanding.

An explanation of other investigational procedures\activities must be included. Include interviews or questionnaires that may be conducted or any other forms of data collection in addition to the experimental procedures\activities.

If interviewing participants or administering surveys, inform the participant that they will have an opportunity to review the questions before signing the consent form and that answering the questions is optional.

If multiple visits or interactions are required, provide a time estimate for each visit and the total time required to participate.

**Incidental Findings** **(IF APPLICABLE)**

If applicable, include the text below:

Generally, tests done for research purposes are not meant to provide clinical information. Because the Principal Investigators will not have access to information that identifies you, the research findings will not be provided to you. – or – Describe what incidental findings will be shared and how.

## What are the possible risks and discomforts?

Provide a description of risks or discomforts the participant may experience using lay language.

Indicate if the research involves a sensitive topic (i.e., suicide, sexual history, criminal activity). Add counseling information or other referral lists in this section.

When available – provide a table or listing of risks/side effects, categorized by "More Likely," "Less Likely," and "Rare."

1. **If applicable,** use the text below (21 CFR 50.25(b)(1).):

The treatment or procedure may involve risks you which are currently unforeseeable.

There is always the risk of uncommon or previously unknown side effect(s) or event(s).

1. **Use the following text as applicable**

Include text regarding:

* Risk to an unborn child and pregnancy considerations for both male, who may father a child, and female participants.
* Sensitive topics (i.e., suicide, sexual history, criminal activity). Insert the counseling or other referral list in this section.
1. If radiation is used, include the text below:

**Radiation Risk**

The amount of radiation (x-rays and scans to assess your disease) that you are exposed to during the research is considered standard of care for the disease. 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.

## If you don’t want to take part in this study, are there other choices?

If the only alternative is not to participate in the study, use the following text.

An alternative would be to not participate in this study.

If there are other alternatives for the participant to consider, use the following text.

Alternatives that could be considered include:

Indicate appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant (21 CFR 50.25(a)(4)).

Alternatives to this research should be discussed with your doctor. Participation in this study is voluntary; you do not have to participate.

## Will you benefit from taking part in this study?

Describe benefits to the participant related to the purpose of the research.

For example, "Your health may improve as a result of this drug therapy, but since it is not known whether this therapy will be effective in your case, you may not receive any benefit, or your condition may get worse."

If there is no direct benefit to the subjects, use the text below:

You may or may not directly benefit from participating in this research. The knowledge gained from this research may eventually benefit others.

**NOTE: Compensation is not considered a benefit and should be addressed in the “Will I receive any payment…” section of this document.**

## What will it cost you to participate?

For clinical research, use the following text.

Participants can consult with their insurance carrier before participation.

Clarify the responsible party for any costs incurred as a result of participation in the research.

Use one of the following two paragraphs:

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

OR

The research Sponsor, <insert sponsor name>, will pay for <insert the procedures the Sponsor will pay for> that would not be part of current therapy for your disease or condition. If you are assigned to the experimental therapy, the cost will be paid by the Sponsor, <insert sponsor name>.

## Will you receive any payment for taking part in this study?

Clearly explain the compensation, the amount, and intervals of payment. Explain compensation for participants who do not complete the study.

Use one of the following two options:

You will not be paid for participating in this study.

OR

You will be paid <enter the dollar amount paid or the compensation> for each visit. You can earn up to <enter the total amount that participants can earn>.

If you do not complete the study, you will be compensated <enter the text>.

For information regarding the method of payment, contact the Principal Investigator.

Unless the research is confidential, due to the sensitive nature of the research or has been awarded an NIH Certificate of Confidentiality, participants must be informed that they may be asked to provide their Social Security Number and verification of U.S Citizenship or Permanent Resident Status to receive payment.

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 Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

(Include regardless of the option chosen above) Your data, health information, research results, specimens, genomic data, or any and all other information related to this research or used in this research study may contribute to a discovery or treatment. In some instances, your data, your health information, your research results, your specimens, the discoveries or treatments, or any other information related to this research study (even if identifiers are removed) may be of commercial value. They may be sold, patented, or licensed by the Principal Investigator and West Virginia University for use in other research or the development of new products. You will not retain any property rights, and you will not be eligible to share in any monetary or commercial profit that the Principal Investigators, West Virginia University, or their agents may realize.

## Who will see the information that you give?

We will keep your records for this study as confidential as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including research and medical records, to only the individuals who are required to review this information. Your name will not be used in the publication of any information about the research.

Your research records and test results, just like hospital records, could be subpoenaed by court order or may be inspected by the Sponsor or federal regulatory authorities without your additional consent.

There are instances where the researcher is legally required to provide information to the appropriate authorities. This includes mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to you or others, such as suicide, child abuse, etc.

If funded by NIH and subject to data sharing policy include:

This research is funded by the National Institutes of Health (NIH) and is required to share certain data externally. The following information will be shared: <List specific variables/information that will be shared and where> You must list the specific information/variables that will be shared with the database. List the database name, location, and who manages it. This information must be congruent with what was approved in your grant.

Explain how the confidentiality of records identifying the participant will be maintained. Disclose any limits of confidentiality (i.e., sending recordings to a transcription agency, sharing records with study sponsor, mandatory reporting, and any possibility of loss of confidentiality due to media attention.)

Insert the text below if applicable.

Audiotapes or videotapes recorded of you will be secured and will be destroyed as soon as possible after the research is finished.

If the media will not be destroyed, provide detailed information regarding how long the information will be kept and how it will be secured.

Add the following information if online data collection/survey applies to study:

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data transmitted via the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of West Virginia University.

## Will your information be used for future research?

Insert one of the following statements about research involving the collection of identifiable private information or identifiable biospecimens**:**

Identifying information might be removed from your private information or biospecimens collected as part of this research. The information or biospecimens could be used for future research or distributed to another Principal Investigator for future research without obtaining additional informed consent.

**OR**

Your information or biospecimen collected as part of this research, even if identifiers are removed, will not be used or distributed for future research.

## Genetic Information Nondiscrimination Act (GINA) (Remove this section if not applicable.)

For research involving biospecimens, include whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequencing of that specimen).

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.

**Certificate of Confidentiality (CoC) (Remove this section if not applicable.)**

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH). This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a United States federal or state government agency sponsoring the project or program evaluation from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may permit them to release information to insurers, medical providers, or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your information. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent for release.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of <list the information that will be reported, such as child abuse and neglect, or harm to self or others.>

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document <restate what will be disclosed, such as research data in the medical record.>

**ClinicalTrials.gov (Remove this section if not applicable – Required for FDA research.)**

This section is required for controlled drug/device trials (except Phase 1 drug trials) and pediatric device surveillance trials. For information regarding an Applicable Clinical Trial (ACT), please refer to the following link: <https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf>.

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search the web site at any time.

## HIPAA Authorization (Remove this section if not applicable)

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 with 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:**

Patient – Data is from the participant

OR

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

**Persons/Organizations Receiving the Information:**

* The research site(s) conducting this study. Include as applicable: 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 - Required for FDA regulated research 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
* If applicable <Enter Foreign Regulatory Agency>
* 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 any 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:**

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)
* (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, 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.

PI Name:

Mailing Address:

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.

Include if applicable:

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 files related to your participation and request that the correction of information.

This Authorization will expire at the end of the research study unless you cancel it before that time, or the study has a specific end date which is <enter the study end date.>

## What happens if you get hurt or sick during the study?

More than Minimal Risk studies are required to specify whether medical treatment or compensation is available if injury (from participating in the research) occurs and, if so, information regarding the treatment and how to obtain additional information.

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

If the Sponsor is paying for treatment as a result of injury due to the research, use the following text.

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, <Enter Name> at <Enter Phone Number> if you are injured or for further information.

**OR**

If the Sponsor is not paying, and the insurance company or the participant will be billed, include the following text.

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, <Enter Name> at <Enter Phone Number> if you are injured or for further information.

## Contact Persons

**If you have any questions, concerns, or complaints about this research, contact**

Principal Investigator Name:

Telephone Number:

Co-Investigator:

Telephone Number:

Research Study Contact:

Telephone Number:

Business Hours:

**If an injury occurs or you become sick (related to participation), contact**

**During Business Hours**

Principal Investigator Name:

Telephone Number:

**Outside of Business Hours**

Contact Name:

Telephone Number:

For information regarding your rights as a participant in research or to talk about the research, contact the WVU Office of Human Research Protections (OHRP) at (304) 293-7073 or by email at IRB@mail.wvu.edu.

## Do you have to participate in this study?

Participation in this research study is voluntary. You are free to withdraw your consent to participate at any time. If you withdraw or do not wish to participate, your future care or status at West Virginia University will be affected.

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

Include if there is a required COI disclosure: <insert investigator name>, a person responsible for the conduct of this research study has been compensated for (insert nature of compensation -e.g., consulting, speaking, serving on a board) by the sponsor during the past 12 months. (change timeframe, if applicable)

Include for FDA Research:

If you choose to withdraw your participation from the research study, the data collected about you will remain a part of the research database and may not be removed. No additional information will be added to the database after you withdraw.

Include for WVU Students as participants:

If you do not wish to participate or if you choose to withdraw, your class standing, and grades will not be affected and will involve no penalty to you.

Include for WVU Employees as participants:

If you do not wish to participate or choose to withdraw, your employment status at West Virginia University will not be affected.

If there are any known circumstances where the Principal Investigator will terminate a participant without his\her consent (i.e., they miss the first 3 out of 7 sessions). Describe the circumstances.

**Do you want to be contacted with information about future studies?**

Future research may be conducted for which you are eligible. If you are interested in being contacted for future research, please indicate so by completing this section. Leaving the box blank is seen as **NOT** giving consent.

[ ]  Yes, I want to be contacted if future research studies, for which I am qualified, become available.

 [ ]  No, I **do not** want to be contacted if future research studies, for which I am qualified.

## Signatures

**Parent or Legal Guardian\Legal Representative Signature**

I willingly consent to my minor child's participation in this research and to authorizations such as HIPAA. Upon signing this form, you will receive a copy.

Printed Name:

Minor Child’s Name:

Signature:

Date:

**Consenting Individual Signature (Authorized Research Staff)**

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

Printed Name:

­­­­­Signature:

Date: