**Informed Consent Form (ICF) Template Instructions**

Delete this page before submission

* **Use this template for: Full Board More than Minimal Risk (MMR) protocol applications requiring a minor child assent signature. Refer to the WVU ORHP website for information on assent and parent/guardian signatures.**
* 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 older Word versions and save and upload the final version as a PDF document after revisions are complete.
* **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 representative of the age and mental capacity of the minor child.
* 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.

**Minor Assent 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 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.

## Introduction

You have been asked to be in a research study. Research studies are done when doctors want to try to find new ways of treating people.

Your parent(s) know about this research study.

## Why are you being invited?

Use lay language and ensure that the language and information is age appropriate.

You are invited to be in this study because <insert the reason why they are being asked (i.e. you have a certain type of cancer or blood disease).> The reason for doing this study is <identify and define the purpose of the study in lay terms.>

## What will you be asked to do?

Use lay language and ensure that the language and information is age appropriate.

If you are in the study, you will <list duration of participation using phrases such as “come to your doctor’s office 4 times” or “be in the hospital for one week.> When you get out of the hospital, you will come to <e.g., the doctor’s office> for a check-up.

If you decide to be in the study, it will last about <state how long it will take to participate.>

If a pregnancy test will be conducted due to the research, explain whether the parent(s) will be informed of the results.

Describe whether there is payment for participation, and if so, who will receive payment (the child or the parent/guardian/legally authorized representative.)

## Will anything make you feel bad while you are in the study?

Example language as applicable.

Some of the questions may be hard to answer and you may not like trying to answer them.

The medicine you take may make you feel sick.

 It may hurt a little when they take blood.

There is also a chance that something could happen that we do not know about.

## Will anything good happen while you are in the study?

Describe benefits to the subjects.

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

This study may not help you, but what we learn from the study may help other people.

## Who will know you are in the study?

Your family and your doctor and nurses will know that you are in the study. If anyone else is given information about you, they will not know your name. A number or initials will be used instead of your name.

## What if you don’t want to be in the study?

You do not have to be in this study. No one will be mad if you do not sign this paper or even if you change your mind later. You can ask the researcher or study nurse questions any time about anything in this study. You can also ask your parent(s) questions you might have about the study.

## Signatures

**Minor Participant Signature**

I have been allowed to ask questions and my questions were answered. I agree to be in this research. I understand I will receive a copy of this after I sign it.

Printed Name:

Signature:

Date:

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

Printed Name:

Signature:

Date: