REMOVE THIS PAGE!

**Assent Template Instructions**

Please read the following instructions carefully. Modify this template for use in your own research and submit the final version to the IRB for review and approval along with your protocol submission. Other templates are provided on the [IRB Forms](https://oric.research.wvu.edu/services/human-subjects/forms) page of the WVU Office of Human Research Protection (OHRP) website. [New Rule Consent Criteria](https://oric.research.wvu.edu/services/human-subjects/common-rule-updates/consent-criteria) can be found on the site as well. If you have any questions, please contact the WVU OHRP at 304-293-7073 or at IRB@mail.wvu.edu.

* Anything in red should be completed with information specifically for your study. Purple text provides instructions for specific sections and identified required and additional elements of informed consent that are required when appropriate.
* When finished, please remove the remaining instructions including the **purple** text and make all of the **red** text black to match the rest of the document.
* Text not applicable to your study and highlighting of text should beremoved from the template **before** submitting it for review. Ensure to remove all tracked changes noted in your final version. **Note:** Submitting a tracked change word version of the ICF as well as the final pdf version of the ICF is advantageous for a prompt review.
* **Remove this instruction page from the final version of your Assent Form.**
* **Save and upload the final version as a pdf document.**
* Upon review and approval, the system will watermark each page of the PDF file. The watermark will contain the approval date and the expiration date, along with the protocol number.

**Key Information Page:**

* This should be a concise summary of the important information, about your study, that a participant would want to know.
* This is a required section of all informed consent forms for protocol approved by the IRB following January 21, 2019 Common Rule update.
* **This summary should not be longer than a single page.**

**Detailed Informed Consent Form:**

* The WVU Protocol Number **must** be in the header of the Consent Form. If the research has another protocol tracking number, you may place it underneath the WVU Protocol Number.
* Assent Forms should be written at an age appropriate level.
* If there is no sponsor for the research, please remove the ‘Funding Source or Sponsor’ section in the header of Consent Form **or** list the applicable Department providing support for the project.

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**Key Information/Oral Script for:**

**Insert Title (or Short Title) of Study**

You are being asked to be in a research study. This page will tell you the main information that may help decide if you want to be in the study; there will be more information about the study on the next page.

## Why is this research being done and what is involved?

In this section, briefly describe (in lay terms):

* The purpose of the study
* What the participant is asked to do (For example: You will be asked to complete a survey, attend a focus group, and complete a follow-up survey.)
* How long it will take them to complete the research study.

## Do I have to participate and what are the risks involved?

You do not have to be in this study. You can quit at any time. If you do not want to be in the study, there are other things you can do. Please talk to your parents and the (pick one: researcher or study doctor) about other options. More information about other options is in the “Alternatives” section in the main assent form. State whether there is a benefit to the subject. If there is no direct benefit to the subjects, use this text: This study may not help you, but what they learn from the study may help other people.

Things that may happen to you from being in this study are State the most important reason(s)/risk(s) why a participant may NOT want to volunteer for this study considering the participant’s perspective.

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

If you have any questions or concerns about this research or want to quit being in the study, you can contact Study Contact Name at business hours contact information from the Dept. of insert dept. name of contact at West Virginia University and tell them you do not want to be in the study.

**For more information, please see the Assent Form.**

**Assent for Research | More than Minimal Risk**

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

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

**Co-Investigator(s) |** You can 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, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, are being asked to be in a research study, that has been explained to you by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. This study is being done by insert PI names and degrees in the Department of insert PIs WVU Department at West Virginia University, along with insert Co-I names and degrees. (If applicable) Funding or the money for this research is provided to WVU by [insert funding source]. (If applicable,) Your parents know about this study too.

## Purpose

Be sure that the Purpose is written in lay terms with no technical terms or jargon and is age appropriate. If it is necessary to use such wording, be sure to define the term in language that is easily understood by people with no experience in your field and is age appropriate. Identifying that the study involves research and the purpose of the research are **required elements of informed consent.**

You are being asked to join 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.

## Description of Procedures

Identifying the procedures or activities to be followed is **a required element of informed consent.** Be sure that the procedures or activities are written in age appropriate lay terms with no technical terms or jargon. If it is necessary to use such wording, be sure to define the term in language that is easily comprehended by ordinary people with no experience in your field.

Identify and describe the experimental procedures or activities. Use a separate paragraph for each element/step of the treatment(s) or activities. The description should include a timeline and be explained in chronological order of treatments, procedures, and/or activities that are specific to the research. Visuals or diagrams are helpful to enhance subject understanding.

Identifying any experimental procedures or activities is **a required element of informed consent.** As applicable, please describe that standard of care procedures or normal activities as well.

If multiple visits or interactions, please give an approximate time of how long each visit will take and the length of time to complete the study in total. Notifying subjects of the expected duration of participation in the research **is a required element of informed consent.**

In this study, you will be asked to identify and describe investigational procedures in a way that is easily understandable and with appropriate detail (i.e. answer some questions about… and talk with me and other people doing this study about…have blood taken….) This will take you about state how long it will take to participate in the study.

## Risks and Discomforts

Notifying subjects of any reasonably foreseeable risks or discomforts due to their participation in the research is a **required element of informed consent.** An **additional element of informed consent** includes notifying subjects that the research may involve risks which are currently unforeseeable.

(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 while you are on the study. It may hurt a little when they draw blood. There is also a change that something could happen that we do not know about yet.

## Benefits

Notifying subjects of any benefits to the subject or to others which may reasonably be expected from the research is a **required element of informed consent.** 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.

## Financial Considerations *(Remove this section if not applicable)*

Include the most appropriate language.

You will not be paid to be in this study. - OR - You will be given enter the dollar amount paid or the compensation to be in this study. You can get up to enter the total amount that participants can earn. You should talk with your parents about how you would like to use this.

## Confidentiality

Clearly explain the extent, if any, to which the confidentiality of records identifying the subject will be maintained. Disclose any limits of confidentiality. This is a **requirement of informed consent.** The information you tell the people doing this study will be kept as private as allowed legally. If we write up papers or publish anything from this research, we will not include your name or anything that could let people know who you are without getting your permission again.

This sentence should be kept only if these are a part of your study; if not, remove this sentence. You may be videoed or recorded in this study. Those tapes/videos will be destroyed as soon as possible after this study is over.

Remove as applicable: One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens is a **required element of informed consent.**

1) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

**OR**

2) A statement that the subject’s information or biospecimen collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

## Voluntary Participation and Other Options

Notifying subjects that “participation is voluntary” and “refusal to participate or discontinuation of their participation will involve no penalty or loss of benefits to which the subject is otherwise entitled” is a **required element of informed consent.** Notifying subjects of any appropriate alternative procedures or courses of treatment that might be advantageous is a **required element of informed consent.**

You do not have to be in this study. No one will be mad at you if you do not want to be in the study or if you want to quit. Remove if there are no other alternatives. (As applicable,) There might be other options for you if you do not want to be in the study. You can talk your parent(s) and study doctor or person doing this study about other options. Please ask any questions you would like to about the study. You can ask your parents or guardian about the research as well.

## Signatures

You have been allowed to ask questions about the research, and all of your questions were answered. You will get a copy of this paper after you sign it.

**Participant Signature**

I willingly consent/assent to participate in this research.

| Signature of Subject or Subject’s Legal Representative |
| --- |
| 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 |