**Informed Consent Form (ICF) Template Instructions – Non-Medical**

Delete this page before submission

* **Use this template for: Non-Medical protocol applications (OMR and MMR).**
* 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 to each individual research protocol.
* Black text **CANNOT** be modified as it is approved by the WVU IRB and General Counsel’s office.
* Modify and submit this template with the protocol application.
* **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, or WVU IRB approved alternative **must** be used for consenting participants, **including electronic consent forms developed using REDCap or Qualtrics.**

**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 prior to submission.
* 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.

# Non-Medical Informed Consent for Research

**Key Information for:**

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

**This section should be one page**

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

By doing this study, we hope to learn (describe the goal of the study). Your participation in this research will last about (state in hours, days, months, years).

**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> .

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.>

**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.**

# Non-Medical Informed Consent for 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 Project 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 muli-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 (or research) activities in lay language with appropriate detail> and will take approximately <state how long it will take to participate in the study.>

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

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

An explanation of other research activities must be included. Attach interviews or questionnaires that may be conducted or other forms of data collection in addition to the research 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. Also, inform the participant that they can skip any questions that they do not wish to answer and that they may discontinue at any time.

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

## What are the possible risks and discomforts?

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

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, if applicable.

## 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 to participating in the research that could be considered include:

Indicate appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.

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

Describe benefits related to the purpose of the research.

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 for participation is not considered a benefit and should be addressed in the “Will you receive any payment…” section of this document.**

## What will it cost you to participate? (Remove this section if not applicable.)

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

Use one of the following two options:

The research Sponsor, <insert sponsor name>, will pay for <insert the procedures the Sponsor will pay for>.

OR

Any expense associated with current therapy or treatment of side effects will be billed to you or your insurance company.

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

Use one of the following 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 or awarded a National Institutes of Health (NIH) Certificate of Confidentiality, you may be asked to provide your 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 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.

If you are targeting WVU employees or WVU study employees are research subjects, please include the following language: If you are a WVU employee or a WVU student-employee, you are required to report the total amount of compensation received for your participation in a research study to the WVU Tax Services Office upon receipt of payment.

(Include regardless of the option chosen above) Your data, research results, or any other information related to this research or used in this research study may contribute to a discovery. In some instances, your data, your research results, the discoveries, or any other information related to this research study (even if identifiers are removed) may be of commercial value. The information 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 information as confidential as possible. However, if the law requires that we disclose your confidential information, every effort will be made to limit the use and disclosure of the information. Your name will not be used in the publication of information about the research.

Your research records could be subpoenaed by court order or may be inspected by the Sponsor (if applicable) 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 could include the 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 the sponsor, mandatory reporting, and any possibility of loss of confidentiality due to media attention.)

Include this sentence if applicable:

Audiotapes or videotapes will be stored in a secure location and will be destroyed as soon as possible after the research is complete.

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.

Add the following if using WVU cell phone/email to communicate with participants during the course of the study:

The researchers will send <text/email>messages during the study for <scheduling visits, surveys, instructions, and payment information>. Please note that <text/email> messages may not be secure, and there could be unintended disclosure if received or viewed by an unintended person(s). While messages will be sent using WVU-owned cellular phones and WVU email accounts, we cannot guarantee the security and privacy of information in <text/email> messages.

<Text/Email> messaging will not be used to discuss healthcare information; if the participant uses <text/email> messaging to ask a healthcare-related question, the researcher will call the participant and will not respond using a <text/email> message.

[ ]  I agree to receive <text/email> messages during the study.

**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 collected as part of this research. The information could be used for future research or distributed to another Principal Investigator for future research without obtaining additional informed consent.

**OR**

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

## 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.>

**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, provide information regarding the treatment and how to obtain additional information.

In some circumstances, Only Minimal Risk studies may be required to include injury language. Examples include invasive procedures, studies involving FDA-regulated drugs or devices, exercise (i.e. performance/physical procedures that are outside of daily experience), and other circumstances as determined by the IRB.

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 as a result of 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.

**Who should you contact if you have questions or concerns?**

**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 not 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 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 may be 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.

[ ]  No, I **do not** want to be contacted.

**Signatures**

**Participant Signature Section**

I willingly consent to participate in this research. Upon signing this form, you will receive a copy.

Printed Name:

Signature:

Date:

**Legally Authorized Representative Signature Section (delete this section if not applicable)**

The participant is unable to give informed consent. I, as the legally authorized representative of the participant, give consent for their participation in this study.

Printed Name:

Signature:

Date:

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

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

Printed Name:

Signature:

Date: