**TEMPLATE INSTRUCTIONS**

This template serves as a starting point for researchers when developing their informed consent materials. Researchers will be responsible for customizing this template to fit the specific needs and requirements of their study to ensure all regulatory and agency specific requirements that may apply are included.

For all non-exempt studies, the general requirements for informed consent must be obtained in accordance with the requirements set forth in [45 CFR 46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116) and documented in accordance with the requirements set forth in [45 CRF 46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117). Projects funded or regulated by certain agencies, may require additional elements to be included. Agency specific requirements include, but are not limited to:

* [DOJ requirements](https://www.ecfr.gov/current/title-28/chapter-V/subchapter-A/part-512/subpart-B/section-512.16)
* [FDA requirements](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent)
* [NIH requirements](https://policymanual.nih.gov/3014-301)
* [NIJ requirements](https://nij.ojp.gov/funding/informed-consent-requirements)

When developing your informed consent materials, the information presented must align across all submission materials (non-exempt application, recruitment materials, data collection materials, etc.).

To facilitate participant understanding, the language utilized in the informed consent materials should be:

* Developmentally appropriate for the study population and aimed at no higher than an 8th grade reading comprehension level for adult participants when possible.
* Free of technical jargon and legalese
* If abbreviations and acronyms are used, spell out the full term and indicate its abbreviation in parenthesis at its first mention.

Additional helpful guidance for developing Informed consent materials can be found under the guidance section of the [WSU IRB Forms webpage](https://irb.wsu.edu/forms/).

When customizing this template:

* Bracketed text in red font indicates instructions and prompts for the researchers.
* Unbracketed text in black font indicates sample starter text based on the basic required elements of informed consent for most studies but will not be comprehensive for all.
* Please ensure that finalized forms are revised so that all brackets are deleted, and that all text font is black.
* Submit only the finalized form, do not include this instruction page in your submission file.

**INFORMED CONSENT FORM**

**[Template For Non-Exempt Research]**

**Research Study Title:** [Study Title as listed on the submitted application]

**WSU IRB #:** [##### to be assigned by the WSU HRPP/IRB after processing of submission]

**Principal Investigator Information:**

[First Last name]

[WSU college/department affiliation]

[WSU Phone number]

[WSU email address]

**Introduction**

You are invited to take part in a research study conducted by [Principal Investigator First and Last name] at Washington State University (WSU). Before deciding to join, it's important to understand why we're doing this research, what participating involves, and what possible risks and benefits there may be. This document is an informed consent form, which gives you information about the study and what it means to participate.

**Key Information**

[For consent forms greater than 2000 words, provide a concise summary of the following key information:

* The fact that consent is being sought for research and that participation is voluntary;
* The purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research;
* The reasonably foreseeable risks or discomforts to the prospective subject;
* The benefits to the prospective subject or to others that may reasonably be expected from the research; and
* Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.]

**Purpose of the Study**

We are conducting this study to learn more about [insert a brief and clear explanation of the research objectives]. Your participation in this study will help us understand [insert potential impact or significance of the study].

**Benefits**

There [are/are no] direct benefits to you for participating in this study. [If there are direct benefits to participants, include a statement as to what the benefit will be].

By participating in this study, you may be contributing to [insert potential benefits to society/participant if applicable].

**[Include if applicable] Disclosure of Alternative Treatments**

Before deciding to participate, it's important to know that there may be alternative procedures or courses of treatment that could be advantageous to you. [Insert a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject]**.**

**Eligibility**

[Number required for more than minimal risk studies only] We plan on enrolling [insert estimated number] eligible participants.

You may be eligible to participate in this study if you are:

* [List eligibility criteria].

**Study Procedures**

If you choose to be in the study, you will be asked to do the following:

* [List and describe each participant-based study procedure such as interviews, surveys, experiments, observations, or interventions. Indicate any procedures that are experimental. Your descriptions should be concise and presented in terminology that your participants will easily understand].

**Length of Participation**

Your involvement in the study will take about [estimated total duration, e.g., minutes, hours, days, weeks, etc.].

**Compensation/Incentives and Costs**

If you choose to participate in this study, you may be eligible to receive [Include disclosure of any compensation/incentives for participation including amount awarded, how and when payment will be issued, and any stipulations that may apply].

It is important to that there could be expenses related to your participation in this study such as [specify any potential costs, such as travel, additional medical tests, etc.].

If you suffer a research related injury (physical, psychological, social, financial, or otherwise) because of your participation in this study [Include an explanation as to whether any voluntary compensation or treatments are available and, if so, what they consist of, or where further information may be obtained].

**Confidentiality**

Your privacy is important to us. Your data will be [Explain level of confidentiality of collected/recorded data and how you will protect participant’s privacy. Include how data will be stored, who it will be shared with and for what reasons].

**Risks**

It's important to know that the following risks may be associated with participating in this study:

* [List all risks associated with participating in the study].

To help reduce these risks, [Include any risk mitigation/management strategies and available resources/referrals that may be offered if applicable].

[Include if applicable] Unexpected risks to you, or to an embryo or fetus if you are or were to become pregnant, may occur due to treatments or procedure involved in this study.

**Voluntary Participation**

Your participation in this study is voluntary. This means that you can choose whether to participate in this research study. You can choose to say no, not answer specific questions, or change your mind about participating at any time without penalty or loss of benefits. We will share any significant new findings which may impact to your willingness to continue participation. If you choose to withdraw your consent, [include statement of the consequences, if any, and the procedures for orderly termination of participation by the subject].

**Questions and Contacts**

If you have any questions about this study, you may contact:

[Researcher’s First Last name]

[Researcher’s role such as Principal investigator, Co-Investigator, research assistant, Research coordinator]

[WSU Phone number/WSU email address]

This study has been approved by the WSU Institutional Review Board (IRB). If you have questions or concerns about your rights as a research participant in this study, you may contact the WSU IRB at irb@wsu.edu.

**Participant’s Indication of Consent**

You will be provided a copy of this signed document for your records.

[ ]  I have read and understood the information in this consent form. I have had the opportunity to ask questions, and any questions I had have been answered to my satisfaction. By signing below, I voluntarily agree to participate in this research study.

[ ]  I do not consent.

Participant's Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant's Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Include the recommended optional elements bellow as needed.]

Researcher's Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher's Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[If the participant is unable to consent, the legally authorized representative (LAR), as defined in [45 CFR 46.102](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102), may consent on their behalf.]

[ ]  I, the undersigned, am the legally authorized representative (LAR) for the participant named below. I have read and understand the information provided in this consent form. By signing below, I consent to the participation of the participant in this research study.

LAR’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

LAR’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant's Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_