**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.

While exempt studies are not held to the full requirements for consent set forth in set forth in 45 CFR 46.116 there must be a consent process that includes the basic elements of consent to ensure participants have sufficient information to make an informed decision about participation. Projects funded or regulated by certain agencies, may require additional elements to be included.

When developing your informed consent materials, the information presented must align across all submission materials (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 parentheses at its first mention.

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 FOR RESEARCH**

**[Template For Exempt Research]**

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

**Introduction**

You are invited to take part in a research study conducted by **[Principal Investigator First and Last name]** at Pacific Northwest University of Health Sciences (PNWU). 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.

**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]**.

**Eligibility**

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

* **[List eligibility criteria]**.

**Study Activities**

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. If applicable, identify procedures that may be 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.]**.

**Audio / Video Recording [If applicable]**

The study will be **[audio recorded, video-recorded, etc.]** If you do not wish to be recorded, you should not participate in the study. **OR** The study will be **[audio recorded, video-recorded, etc.]** If you do not wish to be recorded, please let the study team know. We will record your information via **[describe alternative recording method, e.g. hand-written notes]**.

**Deception or Incomplete Disclosure [If applicable]**

You will be unaware of or misled regarding the nature or purposes of this research study in order to get your unbiased response. The purpose of the research will be shared with you after you complete the study.

**Allergies [If applicable]**

This study involves **[eating/tasting/smelling/drinking/touching]** **[name food/beverage/or ingredients]**. Individuals with allergies to **[food/beverage/ingredients]** should not participate in this 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]**.

**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]**.

**Compensation/Incentives**

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]**.

**Confidentiality**

We will protect the information you share by **[details: e.g., will not collect identifiers, will de-identify the data, will keep identifiers separate from responses, encryption, etc.]**. Only members of the study team will have access to your research data.

**[If study involves focus group]** We will ask members of the focus group to maintain the confidentiality of comments made during the discussion. However, there is still a risk that comments you make during the discussion may be shared outside of the group.

Research information you provide as part of this study will be kept for **[how long]** and **[may/will not]** be used for future research.

**Voluntary Participation**

You do not have to be in the study if you do not want to. You may choose not to **[e.g., answer any survey question, continue with the interview, etc.]** for any reason. You can also decide to be in the study now and change your mind later **[delete if participation is anonymous or explain when withdrawing is no longer possible]**.

**Questions and Contacts**

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

**[name of PI and contact information]**

The PNWU Human Research Protection Program (HRPP) has determined that this study is exempt. If you have concerns about your rights as a research participant their office can be reached by email at research@pnwu.edu.

**Consent to Participate [No signature]**

By **[selecting yes below, continuing with the research activities, etc.]**:

* I acknowledge that I am at least 18 years old, **[If applicable]**
* I have read the above information, and
* I voluntarily agree to participate.

**[When developing procedures for obtaining participants’ indication of consent it is important that the researchers understand that signed written consent is not a requirement for studies verified as exempt. Researchers should customize how they are recording indication of consent to best support their study design and are urged to not include fields where identifiers are collected unless necessary. For studies that will utilize a signed written consent procedure, include the optional recommended elements below as needed.]**

**Consent to Participate [Signature]**

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.

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

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

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 legally authorized representative (LAR) for the participant, I have read and understand the information provided in this consent form. I consent to the participation of the participant in this research study.

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

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

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