

CONSENT FORM TEMPLATE

Instructions for developing a consent document:

This consent form template can be used to submit consent documents to the HSRC. Please follow directions and call the HSRC office (509-963-3115) if you have any questions.

Drafting the Consent Form: The fill-in consent form to be completed by faculty, staff and student researchers is found starting on page 2 of this document. This instructional page, page 1, **should be deleted** before you submit the consent form to HSRC.

Headings: All numbered questions are recommended to be in bold 14 point font size. Depending on the research, questions marked “[*Insert if applicable*]” may be omitted. If questions are omitted, renumber as necessary. Suggestions or tips to be written under each heading are bracketed and typed as bold red text. Edit the black text, as needed.

Protocol Description: The portions of the consent form that are specific to your study must agree with your HSRC application.

Reading Level and Required Font Sizes: The HSRC expects investigators to write consent forms in simple language. The preferred reading level for average educated adults is 8th grade; however, this is dependent upon the age and/or cognition level of subjects. Please use the Spelling and Grammar feature of Microsoft Word to check the Flesch-Kincaid reading level of the text of the document that you write. The text for each section should be in 12-point font.

Pagination: Once the text of the consent document is complete and you have removed this instruction page, the page numbering should self-correct. Please check that this occurs; correct the page numbers, if necessary.

Please Note: This template is designed for a “typical” study. It may be simplified or expanded to meet your particular needs. Use it as a guide for the types of information you may need to include. Format is less important than contents.

Please see sample informed consents, Parent Permissions and Child Assents using this template. These samples are available at [Informed Consent Instructions](#)

CENTRAL WASHINGTON UNIVERSITY

RESEARCH PARTICIPANT INFORMED CONSENT

Study Title:

Principal Investigator: *[Include CWU title, department and contact information]*

Faculty Sponsor: *[Applicable for student research only. Include CWU title, department and contact information]*

1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Ask questions about anything you do not understand now, or when you think of them later.
- You are a volunteer. If you do join the study and change your mind later, you may quit at any time *[If study occurs in one session only, then add, “during or right after testing”.]* without fear of penalty or loss of benefits.
- While you are in this study, the study team will keep you informed of any new information that could affect whether you want to stay in the study. *[Include this bullet only if study will continue over several sessions or a long period of time.]*
- If children may join this study, the word “you” in this consent form will refer to both you and your child. *[If this study does not involve children, you may delete this bullet.]*

2. Why is this research being done?

[Start with an introductory sentence describing the primary purpose of the research as stated in the protocol:] This research is being done to....

[State what the study is designed to discover or establish.]

3. Who can take part in this study?

[Describe the basic eligibility criteria, but DO NOT state that the participant has been “selected for” the study:]

[Give approximate number of participants expected to participate.]

4. What will happen if you join this study?

[Start with the statement:] If you agree to be in this study, we will ask you to do the following things:

[Describe the procedures using lay language, short sentences, and short paragraphs. Define and explain all professional and scientific terms in ordinary language. For example, volumes should be described in terms of teaspoons or tablespoons. Use subheadings and bulleted items for clarity.]

[Specify the assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of procedures, etc.]

[If results are given to participants, detail here.]

5. What are the risks or discomforts of the study?

[Describe any reasonable risks, discomforts, or inconveniences. These may include physiological risks/discomforts, psychological, emotional, financial, social, and legal risks. Explain how these will be managed.]

*[If appropriate to the study, end with the statement: **There may be side effects and discomforts that are not yet known.**]*

6. Are there risks related to pregnancy?

[Insert this heading and section if applicable.]

[Describe foreseeable risks to a fetus. Describe any required pregnancy testing and actions that may be taken if the participant or a participant's partner becomes pregnant. This should also include the requirement of adequate birth control measures for women of childbearing potential and for men (when appropriate to a study).

*[If appropriate to the study, end with the statement: **This research may hurt an embryo or fetus in ways we do not currently know.**]*

7. Are there benefits to being in the study?

*[State the direct benefits, or the possibility of direct benefits, that are likely for research participants. If there are no direct benefits, state: **There is no direct benefit to you from being in this study.**]*

*[Describe the generalizable or societal benefits and use a sentence such as: **If you take part in this study, you may help others in the future.**]*

[Do NOT include financial rewards for participation in the study. Any payment to participants should be included in the "Will you be paid if you join this study" section.]

8. What are your options if you do not want to be in the study?

*[For CWU student participants, use the following statement: **You do not have to join this study. If you do not join, it will not affect your grade in any class or any of your privileges as a CWU student.**]*

*[For other participants, use the following statement: **You do not have to join this study. If you do not join, it will not affect any benefits to which you are entitled.**]*

9. Will it cost you anything to be in this study?

[Insert this heading and section if applicable.]

*[List any costs to participants for the study procedures. List all related costs, such as parking. If none of the costs will be the responsibility of the participant, state: **The study procedures will be provided at no cost to you.**]*

10. Will you be paid if you join this study?

[Insert this heading and section if applicable.]

[State whether the participant will be paid or offered other financial rewards. If not, state so.]

11. Can you leave the study early?

[You can agree to be in the study now and change your mind later. If you wish to stop at any time, please tell us right away. Add the following for student participants: Leaving this study early will not affect your standing at CWU in any way.]

*[If you wish to use partially collected data from a withdrawing subject, add the following: **If you leave the study early, the investigator may use information already collected from you.**]*

12. Why might we take you out of the study early?

[Insert this heading and section if applicable.]

[If appropriate to the study, add some or all of the following statements:

You may be taken out of the study if:

- 1. Staying in the study would be harmful.**
- 2. You fail to follow instructions.**
- 3. You become pregnant.**
- 4. The study is cancelled.**
- 5. There may be other reasons that we don't know at this time to take you out of the study.]**

13. What information about you will be kept private and what information may be given out?

[Describe in appropriate detail the measures you will take to assure confidentiality (or anonymity). Include information on security of data storage, when data will be destroyed or if it will be kept for use in future research.]

14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by the CWU Human Subject Review Council. HSRC is made up of faculty from many different departments, ethicists, nurses, scientists, non-scientists and people from the local community. The HSRC's purpose is to review human research studies and to protect the rights and welfare of the people participating in those studies. You may contact the HSRC if you have questions about your rights as a participant or if you think you have not been treated fairly. The HSRC office number is (509) 963-3115.

b. What do you do if you have questions about the study?

Call the principal investigator, _____, at *[insert telephone number.]**[For student researchers, you may want to include the name and phone number of faculty sponsor.]*

- c. **What should you do if you are injured, ill or emotionally upset as a result of being in this study?** *[May not be applicable for low risk studies. Call HSRC office with questions.]*
If you think you are injured or ill as a result of being in this study, call the principal investigator, *[insert name]*, at *[insert telephone number]*.

[Use the text below for CWU student subjects only; for other subjects, edit appropriately]
If you have an urgent problem related to your participation in this study, call the Student Medical and Counseling Clinic at *[insert one or both, as appropriate: 963-1881 (medical) or 963-1391 (counseling).]*

This study is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research. However, the services at the Student Medical and Counseling Clinic will be open to you as they are to all students.

15. What does your signature on this consent form mean?

By signing this consent form, you are not giving up any legal rights. Your signature means that you understand the study plan, have been able to ask questions about the information given to you in this form, and you are willing to participate under the conditions we have described.

A copy of the form will be given to you.

Participant's Name (print): _____

Participant's Signature: _____ Date: _____

Signature of Investigator: _____ Date: _____