

Western Washington University

Human Subjects Review Committee

Human Subjects Continuing Review Form

The Human Subjects Review Committee (HSRC) generally approves human subject protocols for a twelve-month period. Federal regulations also require a continuing review for ongoing projects no less than annually. Please complete and return this form to the Office of Research and Sponsored Programs, Old Main 530, Mail Stop 9038, prior to the current expiration date.

Principal Investigator(s): _____ **Department(s):** _____

Title: _____ **Mail Stop:** _____

E-mail: _____ **Phone:** _____ **Source of Funding:** _____

Original Approval Date: _____ **Last Continuation Approval** _____ **Current Expiration:** _____

Check if you do not intend to renew this protocol.

Number of subjects approved for inclusion in the study: min _____ max _____ total _____

Total number of subjects enrolled to date: min _____ max _____ total _____

Do you plan to enroll additional subjects? yes _____ if yes - how many? _____ no _____

Total number of subjects withdrawn: adult _____ minor _____

Total number of subjects excluded: adult _____ minor _____

CONTINUING REVIEW:

- 1 Have the risks and/or benefits to the subjects changed from those originally anticipated? Yes No
- 2 Did any adverse events or unanticipated problems involving risks to the subjects or others occur? Yes No
- 3 Have any subjects withdrawn or have you excluded anyone from the study? Yes No
- 4 Have any subjects expressed discomfort or concerns or complained about the research? Yes No
- 5 Since the last HSRC review, have there been any findings, publications, or other relevant information that relate to risks associated with the research? Yes No
- 6 Are any subjects participating in the study who have not signed a consent (and/or assent) form? Yes No

If you answered —“YES“ to any of the above questions, please attach a detailed explanation, including actions taken to reduce the risks or discomforts to subjects and/or to communicate new findings or knowledge to subjects. If you are still enrolling subjects in this study, please attach a copy of the current HSRC-approved consent form.

CERTIFICATIONS: I certify that the above information and attachments adequately and accurately updates all aspects of the human subjects protocol. I accept responsibility that all personnel working on the project will adhere to WWU’s policies for research involving human subjects. I will obtain approval from the HSRC prior to instituting any significant changes in the project. I understand that HSRC approval is not final until I receive notification of such in writing and that the HSRC can require changes to the protocol. I understand that approval of projects is for a maximum of one year and I will apply for a renewal. I will maintain documentation of consent forms and other research notes for at least three years after completion of the research.

Signatures:

Responsible Investigator: _____ **Date:** _____

Faculty Advisor (student research): _____ **Date:** _____

For RSP use only: **Date Received:** _____ **Expedited:** Yes No

RSP/HSRC Signature: _____ **Date Reviewed:** _____