

Western Washington University

Human Subjects Review Committee

Human Subjects Protocol Modification Form

The Human Subjects Review Committee (HSRC) generally approves human subject protocols for a twelve-month period. The responsible Principal Investigator (PI) is required to report all proposed modifications to the protocol and/or the informed consent form to the HSRC during the approval period, and the HSRC must approve these modifications prior to their implementation. If modifications are significant, the PI may be asked to submit a new protocol. Please complete and return this form to the Office of Research and Sponsored Programs, Old Main 530, Mail Stop 9038.

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

Title: _____ **Mail Stop:** _____

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

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

Attach a statement (maximum of 2 pages) which addresses the following as appropriate:

- 1 Description of MINOR CHANGES proposed: includes changes in project title, principal investigator(s), co investigator(s), location of the study, and data analysis and/or reporting procedures.
- 2 Description of MAJOR CHANGES proposed: includes changes in purpose of the study, duration of the study, subject population, subject recruitment procedures, number of subjects (including controls), costs and/or compensation to subjects, voluntary participation, experimental procedures, alternate procedures, procedures for maintaining confidentiality, and/or consent procedures (including changes to the consent form).
- 3 Discussion of unanticipated risks or new information that may affect the risk/benefit assessment, if applicable.
- 4 Brief discussion of the implications of the proposed changes on the likelihood of increased or decreased risks and/or benefits to the study participants.
- 5 If the consent form(s) will be modified, please **attach** a copy of the new consent form(s) for HSRC approval.

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:** _____