



Research Protocol Amendment Form

Instructions: Federal regulation requires that changes to approved protocols be submitted to the IRB for review and approval prior to the implementation of these changes.

Section I: General Study Information

Title of Study	
IRB Protocol #	
Approval Date	
Name of Primary Investigator (PI)	
PI Email	
PI Phone number	

Section II: Amendment Information

Indicate the type of amendment you are requesting (select all that apply)

- Change in protocol (design, methods, procedures, etc.)*
- Change in number of participants and/or selection criteria*
- Change in recruitment materials (flyers, emails, compensation, etc.)*
- Change in study materials (forms, questionnaires, etc.)*
- Change in consent form*
- Change in research personnel
- Other changes

**Please attach all revised/new documents with the changes highlighted.*

For each item selected above, describe the changes being made and the justification for each change.

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Do the requested changes increase the risks to participants? YES NO

If yes, please explain:

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Are any of the changes the result of an unanticipated problem or adverse event? YES NO

If yes, please explain:

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If yes, did you previously report these events to the IRB with an Adverse Event Form? YES NO
If no, you must also submit an Adverse Event Form to the IRB along with the Amendment form.

Are the changes expected to affect the participants' willingness to participate in the research study?
 YES NO

If yes, please explain:

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Section III: Certification

I hereby certify that the information provided entirely and accurately described the proposed changes to the research protocol. I agree not to make any changes to the project during the approval process until the IRB approval for these changes has been obtained, except in the case of immediate harm to participants.

PI Name	
PI Signature	
Date	
Supervisor Name (if applicable)	
Supervisor Signature (if applicable)	
Date	

Completed IRB Forms and supporting documentation should be submitted to (OIRE@nwfsc.edu) in one communication.