SUNY OLD WESTBURY

IRB 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. Minor changes do not need approval; please see the IRB website for more information.

Section I General Study Information

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

Section II Amendment Information

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

- ☐ **Change in protocol (design, methods, procedures, etc.)***
- ☐ **Change to number of participants and/or selection criteria**
- ☐ **Change in recruitment materials (flyers, emails, compensation, etc.)***
- ☐ **Change in study materials (surveys, 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 rationale for the proposed changes.

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Do the requested changes increase the risks to participants?

☐ **Yes** ☐ **No**

If yes, please explain:

Are any of the changes the result of an unexpected or adverse event?

☐ **Yes** ☐ **No**

If yes, please explain:

If yes, did you promptly report these events to the IRB via the Adverse Event Report Form?

☐ **Yes** ☐ **No**

If no, you must submit an Adverse Event Report Form to the IRB along with the IRB Amendment Form.

Are the changes expected to affect participants' willingness to participate in the research?

☐ **Yes** ☐ **No**

If yes, please explain:

Section III CERTIFICATION

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

PI name:

PI signature: **Date:**

Please submit this form and any changed documents to PACS.