EAST
STROUDSBURG
UNIVERSITY

East Stroudsburg University Institutional Review Board (IRB)
Change to Protocol Form

This application is to request a change to a currently approved study. Any proposed changes to approved research must be reviewed and approved by the IRB ***prior*** to implementation. This includes changes to study, inclusion or exclusion criteria, recruitment methods, research personnel, *any* new or revised study materials, changes in investigators, etc. Approval is required for all changes whether initiated by investigator or external sponsor. **This form should not be used to report violations and deviations.** Incomplete applications will be returned.

If you are requesting a change in Principal Investigator, complete **section A.**
If you are requesting an addition of a Co-Investigator(s) or Research Assistant(s), complete **section B.**
If you are requesting a removal of an Investigator(s)/Assistant(s), complete **section C.**
If you are requesting a change to the protocol, complete **section D.**

Principal Investigator: Protocol Number:
Protocol Title:
Current Approval Expires:

Section A: Change of Principal Investigator (PI)

Name of Current Principal Investigator:
Name of New Principal Investigator:

Statement of Current PI: I agree to the transfer of responsibilities of PI to the above-named investigator. (Note: If the PI will remain on the study as a Co-Investigator, complete Section B. If not, complete Section C.

_____ _____
Signature of Current PI Date

Statement of New PI: I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subject research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in the IRB Application Form. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations and comply with federal regulations.

Does the new PI have a relationship with the sponsor of the study or the company of the product, as defined in the conflict of interest policy? ☐ Yes ☐ No
***If yes, include a statement in the Informed Consent regarding the investigator's relationship with the sponsor**

_____ _____
Signature of New PI Date

All consent forms need to be updated to reflect the change in PI. Submit two copies of each consent document, one with the changes highlighted and the other a clean copy to be stamped.

Section B: Addition of Co-Investigator

Name(s) of Co-Investigator(s):	Signature(s):	Date:

Name(s) of Research Assistant:	Signature(s):	

Does the above-named co-investigator(s) and/or research assistant(s) have a relationship with the sponsor of the study or the company of the product, as defined in the conflict of interest policy? ☐ Yes ☐ No

***If yes, include a statement in the Informed Consent regarding the co-investigator's and/or research assistant's relationship with the sponsor.**

Statement of PI: I authorize the addition of the above investigator(s)/assistant(s).

_____ _____

Signature of PI Date

All consent forms need to be updated to reflect changes to the investigators/assitants. Submit two copies of each consent document, one with the changes highlighted and the other a clean copy to be stamped.

Section C: Removal of an Investigator/assistant

Name(s) of Investigator(s)/Assistant(s):	Signature(s):	Date:

Statement of the PI: I authorize the removal of the above investigator(s)/assistant(s).

_____ _____

Signature of PI Date

All consent forms need to be updated to reflect changes to the investigator(s)/assistant(s). Submit two copies of each consent document, one with changes highlighted and the other a clean copy to be stamped.

Section D: Change to Protocol

List and describe each proposed change

Describe any risks that may arise from the proposed changes

Was a consent form or cover letter required as a part of the original approval? ☐ Yes ☐ No (if yes, Submit two copies of each consent document, one with changes highlighted and the other a clean copy to be stamped)

Is this change being submitted in response to an unanticipated problem/adverse event or new findings? ☐ Yes ☐ No (if yes, complete the Adverse Event Form. It is the responsibility of the Principal Investigator to inform the IRB Office of all adverse events in a timely manner.)

Attach new or revised consent forms, questionnaires, surveys, recruitment materials, advertisement, sponsor's document describing the changes (if applicable), etc. Two copies of the forms must be submitted, one with the changes highlighted and the other, a clean copy.

_____ _____

Signature of PI Date