

Slippery Rock University Institutional Review Board (IRB)
Change to Protocol Form

Principal Investigator:

Protocol Number:

Protocol Title:

Current Approval Expires:

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. SRU's IRB may re-evaluate its continuing review or no continuing review decision depending on the type of change(s) proposed. **This form should not be used to report violations and deviations.**

Incomplete applications will be returned.

For information or help, contact the IRB Office

Phone: 724-738-4846 e-mail: irb@sru.edu

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**.

Section A: Change of Principal Investigator (PI)

Name of Current Principal Investigator:

Name of New Principal Investigator:

Qualifications 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(s) and/or Research Assistant(s)

My signature indicates that the PI listed on this research study shared with me the list of assurances on page 2 of this previously approved protocol. I have read, understand, and agree to conduct this research project in accordance with these assurances.

Name(s) of Co-Investigator(s):	Signature(s):	Date Signed:	CITI Completion Date:
Name(s) of Research Assistant(s):	Signature(s):	Date Signed:	CITI Completion Date:

Qualifications of Co-Investigator(s) and/or Research Assistant(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/assistants. 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(s) and/or Research Assistant(s)

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

For Office Use Only:

- ☐ This change to protocol reveals new findings that require additional oversight
- ☐ This change to protocol does not reveal new findings that require additional oversight.

Jeremy Lynch, IRB Chair

Date