Pittsburg State University
Protocol Amendment for Investigations
Involving the Use of Human Subjects

This application must be completed by the Investigator and sent to the IRB prior to implementing changes. This form should not be used in place of a Continuation for research that is set to expire.

Examples of changes requiring IRB review include but are not limited to changes in:

- investigators or research team members
- purpose/scope of research
- recruitment procedures
- compensation strategy
- participant population
- research setting
- interventions involving participants
- data collection procedures, surveys, measures, or other data forms

For questions about the review process contact Cindy Johnson at 620-235-4175 or at irb@pittstate.edu.

Protocol Information

Protocol #: _____

Project Title: _____

Initial Review Type: ☐Exempt Category: _____

☐ Expedited Category: _____

☐ Full Category: _____

Investigator Name(s): _____

☐ Check this box to indicate that all investigators (including those being added on this amendment) have completed approved ethics training (attach valid completion certificates)

Principal Investigator (PI) Contact information

Department: _____

Local Address: _____

Phone: _____ E-Mail Address: _____

If the PI is a student, complete the following:

Faculty Sponsor: _____

Department: _____

Phone: _____ E-Mail Address: _____

Description of Proposed Changes

Draw attention to changes/additions in a previously approved protocol by using highlighting, colored text, etc. in the relevant locations and attach a copy of the revised protocol with this submission. If the changes are limited to addition/change in research team members, research sites, etc. a revised protocol form is not needed.

1. Date of proposed implementation of change(s): _____
   Cannot be implemented prior to IRB approval unless the IRB Chair has determined that the change is necessary to eliminate apparent immediate hazards to participants
2. Describe the proposed change(s), including justification:

3. Will the change(s) increase existing risks or present new risks to participants? If yes, describe the risks and how they will be minimized.
   ☐ Yes ☐ No

4. Will the change(s) involve the addition of a vulnerable group of participants? If Yes, provide additional information.
   ☐ Yes ☐ No

5. Does the proposed change involve a waiver or alteration of some or all the elements of informed consent or the documentation of consent? If Yes, attach the updated Informed Consent and describe the rationale for the changes.
   ☐ Yes ☐ No

6. Does the proposed change involve a new research site? If yes, describe new location.
   ☐ Yes ☐ No

Impact for Participants (future, current, or prior):

1. Will the change(s) alter information on previously approved versions of the recruitment materials, informed consent, or other documents, or will the change(s) require new documents? If yes, attach revised/new document(s), highlighting changes.
   ☐ Yes ☐ No

2. Could the change(s) affect the willingness of currently enrolled participants to continue in the research? If yes, describe procedures that will be used to inform current participants, and re-consent, if necessary.
   ☐ Yes ☐ No

3. Will the change(s) have any impact to previously enrolled participants? If yes, describe impact, and any procedures that will be taken to protect the rights and welfare of participants.
   ☐ Yes ☐ No

_____	_____	_____
Signature of Investigator	Name (please print)	Date

IRB USE ONLY

Changes: _____ Approved

_____Not Approved

_____	_____	_____
Signature of IRB Chair (Sufficient for Exempt initial review)	Name (please print)	Date

Completion Date of Expedited Review of revision(s): _____
Attach correspondence to this application.

Meeting Date of Full Board Review of revision(s): _____
Attach correspondence if approved electronically in lieu of convened meeting