Pittsburg State University
Application for Continuing Review of Investigations
Involving the Use of Human Subjects

This application must be completed by the Investigator and sent to the IRB by the 20th day of the month during the Fall and Spring academic semesters to be considered for full review the following month. Expedited or Exempt reviews may be submitted at any time.

☐ This research was exempted under 45 CFR 46.104(d). Please fill out the remainder of this page and a brief description of any changes (even if the only change is to extend the approved deadline for completion or for an annual check-in), skip pages 2-3, and sign on Page 4.

This research qualifies for Expedited review under one of the following criteria specified in *45 CFR 46.110*:

☐ It meets the following Expedited criteria listed on the *Review Criteria Form*: _____

☐ It involves only minor changes in previously approved research which was reviewed and approved within the past year

Continued review is **NOT** required if:

- the approved research has progressed to the point where only data analysis is required **OR**
- the approved research has progressed to the point where only involves accessing follow-up clinical care data (*45 CFR 46.109(f)*)

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

Protocol #: _____

Project Title: _____

Investigator Name(s): _____

☐ Check this box to indicate that all investigators have valid ethics training that will not expire during the duration of this continuation (attach completion certificates)

Department: _____

Local Address: _____

Phone: _____ E-Mail Address: _____

If the PI is a student, complete the following:

Faculty Sponsor: _____

Department: _____

Phone: _____ E-Mail Address: _____

I. Project Status

Original Approval Date: _____ New Expected Completion Date: _____

Current research Procedures involve:

- ☐ Recruiting participants
- ☐ Providing research intervention(s)
- ☐ Ongoing data collection
- ☐ Ongoing analysis of identifiable data
- ☐ Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

If project externally funded, what is Agency and FAR#: _____

Current funding period start date:_____ End date:_____

Attach a copy of final grant application (s) and/or recent report to funding agency.

II. Project Summary

Brief summary of research progress to date. Attach additional sheets as necessary.

Are any of the research procedures or conditions no longer active (i.e. have portions of the study been completed)? If so, please describe. Attach additional sheets as necessary.

List research site(s).

List presentations or publications that have resulted from this research since the last review. Attach additional sheets as necessary.

Participants:

1. How many participants have completed the study since the last report? _____
2. How many total participants have completed this study since initial approval? _____
3. Will more participants be recruited? If so, approximately how many? _____
4. A copy of the approved consent form should have been signed by each participant of the study and retained for your records. Has this requirement been met?
   - ☐ Yes
   - ☐ N/A – Waiver approved
   - ☐ No, explain:

5. Have any potential participants declined to participate or withdrawn from the research? If yes, explain. Attach additional sheets as necessary.

6. Summarize any complaints about the research (and their resolution) since the last review. Attach additional sheets as necessary.
   ☐ Attach a copy of current consent form(s) and any recruitment materials.

III. Risks/Benefits:

According to the US Office for Human Research Protections (hhs.gov):

*Unanticipated problems, in general, include any incident, experience, or outcome that meets **all** of the following criteria:*

1. *unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;*
2. *related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and*
3. *suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.*

An adverse event in general is used very broadly and includes any event meeting the following definition:

> *Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research*

1. Summarize unanticipated problems (even if previously reported) or adverse events that have occurred since the last review. Attach additional sheets as necessary.

2. Has any new information or additional risk(s) been discovered that would affect the risk/benefit ratio for new subjects or those who have currently/previously enrolled? If yes, please explain how this has been/will be addressed for all participants. Attach additional sheets as necessary.

PRINCIPAL INVESTIGATOR ASSURANCE

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects and the ethical conduct of this research for which this application has been submitted.

I agree to comply with all PSU policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Title 45, Part 46 of the Code of Federal Regulations.
- The Belmont Report, *Ethical Principles and Guidelines for the Protection of Human Subjects and Research.*

I also agree that the following criteria will be met:

- The project will be performed by qualified personnel according to the research protocol.
- Copies of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human subjects will be maintained in the respective department.
- Necessary review by the PSU Institutional Review Board will be sought if changes made in the research protocol may result in the research no longer meeting the original approved criteria.
- All study investigators have completed the approved ethics training, and a copy of the valid completion certificate is attached to this application.
- The Principal Investigator has read and understands the PSU Assurance Handbook concerning human subjects research protocols.

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

IRB Use Only

☐ **Continuation Approved**

☐ **Approved, project remains open for:**

- ☐ **Data analysis, including analysis of identifiable private information or specimens, or**
- ☐ **Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care**

_____	_____	_____
Signature of IRB Chair	Name (please print)	Date

Received Date: _____ Review Date: _____ Next Report due: _____