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

This application must be completed by the Investigator and sent to the Office of Graduate and Continuing Studies by the first Tuesday of the month during the fall and spring academic semesters to be considered for full review on the second Tuesday of the month.

Expedited and exempt reviews can be turned in any time. For questions about the review process contact Brian Peery in Russ Hall, #112, Ext. 4175.

1. Investigator(s) Name(s): _____

2. Department: _____

3. Local Address: _____

4. Phone: _____

5. E-mail Address: _____

6. Project Title: _____

7. Expected Completion Date: _____

8. Expected Starting Date _____

9. Is this project (check all that apply): Use review criteria in Form CR-1 to determine which category of review applies.

☐ Application for Full Review ☐ Protocol Change ☐ Thesis/Special Investigation

☐ Being submitted for external support ☐ Continued Review ☐ Application for Expedited Review

☐ Being conducted in a foreign country ☐ Faculty Research ☐ Application for Exempt Review

☐ Publishable research ☐ A Class Project

10. If notification of human subject approval is required give date required: _____

Name of agency: _____

11. If you are a student, complete the following:

Faculty Sponsor: _____

Department: _____

Phone: _____

**** If submitted externally, a complete copy of the proposal must be submitted to the IRB.****

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CERTIFICATION AND APPROVAL

Certification by Investigator: I certify that (a) the information presented in this application is accurate, (b)only the procedures approved by the IRB will be used in this project, (c)modifications to this project will be submitted for approval prior to use, and that all guidelines outlined in the PSU Policy and Assurance Handbook for the Protection of Human Research Subjects will be followed as well as all applicable federal, state and local laws regarding the protection of human subjects in research as outlined in Form VA-1.

_____

Signature of Investigator Date

Faculty Sponsor: If the Investigator is a student, his/her Faculty Sponsor must approve this application. I certify that this project is under my direct supervision and that I accept the responsibility for ensuring that all provisions of approval are met by the investigator.

_____ _____

Signature of Faculty Sponsor Date

Department Review Committee Chair: I acknowledge that this research is in keeping with the standards set by our department, university, state and federal agencies and I assure that the student principal investigator has met all departmental requirements for review and approval of this research.

_____ _____

Signature of Department Review committee Chairperson Date

_____ _____

CPHRS Chairperson Date

I. Description of the Subjects (If advertising for subjects, include a copy of the proposed advertisement.)

A. How many subjects will be involved? _____

B. Subject Population (check all that apply) _____

☐ Adults ☐ Prisoners ☐ Minors ☐ Intellectual Disability

☐ Physically Ill ☐ Disabled ☐ Special Education ☐ Other

C. For projects conducted in schools or school settings:
(Written approval from the Building Administrator must be obtained)

What grade are the students in? _____

Approximate Age of Students? _____

How many classes involved? _____

What subject: (secondary)? _____

Location: _____

Name of School: _____

D. What criteria will be used to select subjects AND/OR what criteria will be used to exclude individuals? (e.g., age, sex, race, ethnic origin, religion, or any social or economic qualifications)? State why the selection will be made on the basis or bases given.

II. Abstract: Describe the purpose of the research and summarize the strategies used to collect data and protect participants.

III. Procedure: Activities Involving Human Subjects (Attach additional sheet if needed)

A. Give a brief description or outline of your research procedures as they relate to the use of human subjects.

1. Who will be the subjects? How will you enlist their participation?

2. What precisely will be done to the subjects? State instructions given to the subjects, activities in which they will engage, tests and questionnaires (if you are using questionnaires or handouts, please include a copy with this application.)

3. If any of the subjects are minors or "vulnerable" (children, prisoners, mentally or physically disabled, pregnant women), discuss how their special condition will be handled. 4. How will subjects be informed of research findings?

IV. Confidentiality and Anonymity

How will the data be collected? (Check all that apply)

- ☐ Questionnaires (Submit a copy)
- ☐ Observations (describe how they will be conducted)
- ☐ Interviews (Submit sample questions)
- ☐ Standardized tests (attach a copy if possible; list names
- ☐ Test (Submit a copy if possible)
- ☐ Task(s) (briefly explain)
- ☐ Video or Audio Tapes
- ☐ Computer Entries (explain)
- ☐ Other in description of above:

A. Explain the procedures for collecting, recording and storing that data during the study.

B. Who will have access to the data during the study? (Access should be limited to protect anonymity of subjects and confidentiality of subject responses)

C. Explain what will happen to the data once the study is completed. Is there a need to keep the data or will it be destroyed? If kept, how long and where will it be stored, how will confidentiality be ensured, who will have access to it?

D. Explain the level of confidentiality you are guaranteeing the participants.

V. Benefits, Risks, and Costs of this Study

A. What are the potential benefits to the subjects, to the field or discipline, or to the University?

B. Will compensation (money, extra credit, etc.) be offered to the subjects? If so, how will it be dispersed?

C. What risks or discomforts are most likely to be encountered by the subjects? Please consider carefully.

- ☐ Employability
- ☐ financial or personal reputation
- ☐ emotional stress or discomfort
- ☐ loss of confidentiality
- ☐ physical stress or discomfort
- ☐ deception (benevolent misdirection)
- ☐ embarrassment
- ☐ psychological stress or discomfort
- ☐ criminal or civil liability
- ☐ other (explain below)

D. What safeguards will you use to eliminate or minimize these risks? If there is the possibility of adverse reactions by the subjects, explain where the subjects can receive help.

E. In your opinion, does the research involve **more than minimal risk** to subjects? ("Minimal risk" means "the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine or psychological examinations or tests.")

VI. Additional Information or Completion of a Previous Section:

VII. Informed Consent: (Not needed for exempt review)

Unless authorized by the IRB, no investigator may involve a human being as a subject in research under the auspices of the University unless the investigator has obtained the informed consent of the subject or the subject's legally authorized representative.

Attach a copy of all consent documents that will be used to this application.

For further information about informed consent processes review the information on Continuing and Graduate Studies web page in the Forms for Research Involving Human subjects.

A. Explain the procedures that will be used to obtain consent:

B. Federal regulations state that the following elements of information should be provided to each subject. (Place a check mark before each component included in your consent document.)

☐ An explanation of the purpose of the project and the expected duration of the subject's participation.

☐ An explanation of the activities or procedures to be followed.

☐ A description of any risks or discomforts to the subject.

☐ A description of any benefits of the project to the subject or to others.

☐ A statement that participation in this project is voluntary and the subject may withdraw at any time.

☐ A statement describing the extent to which confidentiality of records identifying the subject will be maintained.

☐ An explanation of whom to contact with questions regarding the study.

1. Explain request for waiver of any component listed above or other special conditions related to informed consent.

PITTSBURG STATE UNIVERSITY

COMMITTEE FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS (CPHRS)

Verification of Assurance Form

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 application.

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*
- The project will be performed by qualified personnel according to the research protocol
- Maintaining a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human subjects in the respective department
- Necessary review by the PSU IRB (The Committee for the Protection of Human Research Subjects –CPHRS) will be sought if changes made in the research protocol may result in the research no longer meeting the original approved criteria.
- The Principal Investigator has completed the NIH Protection of Human Research Subjects On-Line Training Program.
- The Principal Investigator has read and understands the PSU Assurance Handbook concerning human subjects research protocols.