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

For IRB Use Only
Date Received: _____
Application #: _____

The application must be typed (not hand-written) and all attachments included as a single PDF document. Submit documents based on the schedule posted on the IRB page on the PSU website. When submitting the forms, allow sufficient time for the appropriate level of review before the planned start date. Attach additional sheets as necessary.

For questions about the review process contact Cindy Johnson at 620-235-4175 or at irb@pittstate.edu. Consult HHS.gov for guidance on Human Subjects Research.

Contact information is required to ensure that research subjects can contact the investigator(s)

Investigator(s) Name(s): _____

☐ Check this box to indicate that all investigators have completed approved ethics training. Attach valid completion certificates to the completed application. Student projects: include all committee members.

Department: _____

Local Address: _____

Phone: _____ E-Mail Address: _____

Project Title: _____

Expected Starting Date: _____ Expected Completion Date: _____

Application review type. Use *Review Criteria Form* to determine appropriate category. When multiple categories apply, applications will be evaluated on the ***most restrictive*** of categories.

☐ Full Review. Category:_____

☐ Expedited Review. Category:_____

☐ Exempt Review. Category:_____

☐ **This research is also being submitted to an external IRB.** A full copy of that application or letter of support is attached, along with a completed External IRB Collaboration Form.

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

Name of agency: _____

If the PI is a student, complete the following:

Faculty Sponsor: _____

Department: _____

Phone: _____ E-Mail Address: _____

Committee Members: _____

I. Description of the Subjects

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 (explain): _____

C. For projects conducted in schools or school settings, written approval from the School Administrator must be obtained. Please attach to end of this application.

Location: _____

Name of School: _____

What grade are the students in? _____ Approximate Age of Students? _____

How many classes involved? _____ What subject: (secondary)? _____

D. Does this research require participation from an organization other than PSU? If Yes, please attach a letter of support/understanding or documentation from that organization demonstrating approval or willingness to participate.

E. 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: Summarize the strategies used to collect data and protect participants. Discuss what will be the purpose of collecting the data (e.g. is the data for an improvement project, is the data solely for a peer-reviewed publication, is it a pilot for a larger study, etc.). Attach additional sheets as necessary.

III. Procedure: Activities Involving Human Subjects. Attach additional sheets as 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 recruit participants into the study? If advertising for subjects, include a copy of the proposed advertisement.

2. What precisely will be done to the subjects? State instructions given to the subjects and activities in which they will engage. If you are using questionnaires or handouts, please include a copy as an attachment to this application.

3. If any of the subjects are minors or "vulnerable" (e.g. 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 below in Section IV.A)

☐ Interviews (Submit sample questions)

☐ Standardized tests (list names; attach a copy if possible)

☐ Test (Submit a copy)

☐ Task(s) (briefly explain below in Section IV.A)

☐ Video or Audio Recordings, Still Images

☐ Computer Entries (explain below in Section IV.A)

☐ Other _____

A. Explain the procedures for collecting, recording, and storing that data during the study. Attach additional sheets as necessary. If using an online survey tool (e.g. SurveyMonkey, Qualtrics, etc.), include a screen shot of the survey's settings.

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. Students should include faculty advisors/committee members.

C. Federal regulations require that data be kept for at least three years after completion of the research (*45 CFR 46.115(b)*). PSU Policy requires that all study data be maintained on university-owned SharePoint/Teams (or equivalent) that is managed by the Office of Research Administration and Compliance.

☐ Check this box to indicate that all study data will be solely kept on PSU-controlled storage, and that any users accessing the data on machines other than those maintained by PSU are following the guidelines in the Handbook.

☐ Check this box if data is to be submitted to a 3rd Party Site (e.g. to abide by an Open Source policy required by some publications). Below, provide the name of the site, rationale for the submission to the 3rd party site, and include (as a separate attachment if necessary) the privacy policy of that site.

D. Explain the level of confidentiality you are guaranteeing the participants. Include data privacy policies for all external tools being used.

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, what specifically will be offered, and how will it be dispersed?

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

☐ Employability
☐ Deception (benevolent misdirection)
☐ Financial or personal reputation
☐ Embarrassment
☐ Emotional stress or discomfort
☐ Psychological stress or discomfort
☐ Loss of confidentiality
☐ Criminal or civil liability
☐ Physical stress or discomfort
☐ Other (explain): _____

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.*" (*45 CFR 46.102(j)*) Please explain.

VI. Informed Consent

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. For studies involving minors or others incapable of providing their own legal consent, in addition to consent of the subject's representative, informed ***ASSENT*** should be obtained from study participants in a manner appropriate to the study population unless otherwise waived by the IRB (e.g. plain language, provisions for non-English speakers, provisions for minors or those incapable of providing consent).

For further information about informed consent processes review the information provided by the Department of Health and Human Services.

<u>Exemption, Waiver, Alteration of Informed Consent or Documentation of Consent</u>

If applying for research that will not include Informed Consent, check any that apply and attach appropriate documentation to this application. All other research must contain appropriate Informed Consent/Assent.

- ☐ This study is ***Eligible for Exemption***, so Informed Consent is not required; however, investigators should include in the instructions to participants that participation is voluntary, may be discontinued at any time, and that withdrawing or not participating will not result in negative consequences.
- ☐ ***Passive Parental Consent*** (a.k.a. Opt-Out consent) is requested because the research meets the minimum elements of Passive Parental Consent as described in the *PSU Policy Assurance Handbook*, **AND** parents will have no less than 14 calendar days to opt their student out of the study, **AND** the notification document will be sent directly to the parents.
- ☐ ***Waiver or Alteration*** of Informed consent is requested because the research involves public benefit/service programs **AND** that the research could not otherwise be carried out without waiver or alteration of Informed Consent (*45 CFR 46.116(e)*). Include *Informed Consent Waiver or Alteration Form*.
- ☐ ***Waiver or Alteration*** of Informed consent is requested because the research involves no more than minimal risk to the subjects **AND** could not otherwise be carried out without the requested waiver or alteration **AND** could not otherwise be carried out without using private information or biospecimens (if required) in an identifiable format **AND** the waiver or alteration will not adversely affect the rights and welfare of the subjects **AND** whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. (*45 CFR 46.116(f)*). Include *Informed Consent Waiver or Alteration Form*.
- ☐ ***Waiver of documentation*** of informed consent is requested because the only record linking the subject to the research would be the Informed Consent form **AND** the principal risk would be loss of confidentiality (*45 CFR 46.117(c)(i)*).
- ☐ ***Waiver of documentation*** of informed consent is requested because the research presents no more than minimal risk **AND** does not involve procedures requiring written consent outside a research setting (*45 CFR 46.117(c)(ii)*).
- ☐ ***Waiver of documentation*** of informed consent is requested because the subject is a member of a cultural group or community that does not normally sign forms **AND** there is no more than minimal risk **AND** there is an alternative method for documentation of consent (*45 CFR 46.117(c)(iii)*)
- ☐ ***Exception from informed consent requirements*** is requested for emergency research purposes. Provide documentation of requirements of *21 CFR 50.24* as outlined in the *Policy Assurance Handbook* as an attachment to this application.

<u>Informed Consent Contents and Process</u>

A. Explain the procedures that will be used to obtain consent/assent. Attach additional sheets as necessary.

B. Federal regulations (*45 CFR 46.116*) state that the following elements should be provided to each subject in a manner that they can understand with key information at the beginning of the document. Place a check mark before each component included in your consent document. Attach a copy of the document to this application.

- ☐ A statement that the study involves research
- ☐ An explanation of the purposes of the research
- ☐ The expected duration of the subject's participation
- ☐ A description of the procedures to be followed
- ☐ Identification of any procedures which are experimental
- ☐ A description of any reasonably foreseeable risks or discomforts to the subject
- ☐ A description of any benefits to the subject or to others which may reasonably be expected from the research
- ☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- ☐ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- ☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
  - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- ☐ For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- ☐ Research, Rights or Injury: An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- ☐ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

<u>Additional Elements as Appropriate</u>

- ☐ A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- ☐ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- ☐ Any additional costs to the subject that may result from participation in the research
- ☐ The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- ☐ A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- ☐ The approximate number of subjects involved in the study
- ☐ If the research involves biospecimens, if the study will/might include whole genome sequencing

<u>Documentation of Assent</u>

- ☐ When studying minors or others incapable of giving legal consent, assent forms must also be provided (unless waived by the IRB). Assent forms should contain the same information as above, but the language and delivery method should be appropriate for the subject population. Attach a copy of all assent documents that will be used to this application (including *Informed Consent Waiver or Alteration* form if applicable).

VII. Certification and Approval

Verification of Assurance

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 a) changes are made in the research protocol which may result in the research no longer meeting the original approved criteria, or b) Continued Review at the appropriate time.
- 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 and all research personnel have read and understand the PSU Assurance Handbook concerning human subjects research protocols.

Principal Investigator Signature	Name (please print)	Date

Faculty Sponsor: If the Investigator is a student, the Faculty Sponsor (e.g. thesis director, research supervisor, etc.) 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.

Faculty Sponsor Signature	Name (please print)	Date

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

Department Reviewer Signature	Name (please print)	Date

IRB USE ONLY

_____	_____	_____
Signature of IRB Chair (not required for Exempt Review)	Name (please print)	Date

Meeting Date of Full Board Review: _____

Review Date of Expedited Review: _____
Attach correspondence to this application.

Continuing Review Date:

☐ 1 year from last business day of month of initial approval: _____

☐ Otherwise specified by board: _____