EAST STROUDSBURG UNIVERSITY INSTITUTIONAL REVIEW BOARD for RESEARCH INVOLVING HUMAN SUBJECTS

RESEARCH PROTOCOL REVIEW FORM

For information or help contact Dr. Shala Davis: Koehler Field House, East Stroudsburg University
Phone: 570-422-3336 **e-mail: sdavis@esu.edu**

1. PROPOSED START DATE of STUDY: _____ IRB number: _____
PROPOSED REVIEW CATEGORY (Check one): ☐ **Full Board** ☐ **Expedited** ☐ **Exempt**
2. PROJECT TITLE: _____
_____

3. _____ _____ _____ _____ _____
PRINCIPAL INVESTIGATOR **TITLE** **DEPT** **PHONE** **ESU E-MAIL**

_____ _____ _____
MAILING ADDRESS **FAX** **ALTERNATE E-MAIL**

4. SOURCE OF FUNDING SUPPORT: ☐ **Not Applicable** ☐ **Internal** ☐ **External Agency:** _____ ☐**Pending** ☐**Received**

5. LIST ANY CONTRACTORS, SUB-CONTRACTORS, OTHER ENTITIES OR IRBs ASSOCIATED WITH THIS PROJECT:

6. **GENERAL RESEARCH PROJECT CHARACTERISTICS**

6A. Mandatory CITI Training

Names of key personnel who have completed CITI tutorial:

_____ _____
_____ _____
_____ _____
_____ _____

Note: Prior to submission to IRB, non-campus personnel must seek approval from Chief Academic Officer.

Letter from Provost's Office dated _____

Attach to Research Application.

6B. Research Methodology

Please check all descriptors that best apply to the research methodology.

Data Source(s): ☐ New Data ☐ Existing Data

Will data be recorded so that participants can be directly or indirectly identified? ☐ Yes ☐ No

Data collection will involve the use of:

☐ Educational Tests (cognitive diagnostic, aptitude, etc.)
☐ Surveys/Questionnaires
☐ Internet/electronic
☐ Audio/Video/Photos
☐ Interview/Observation
☐ Physical/Physiological Measures or Specimens
☐ Private records or files
☐

6C. Participant Information

Please check all descriptors that apply to the participant population.
☐ Males ☐ Females ☐ ESU students

Vulnerable Populations
☐ Pregnant Women/Fetuses ☐ Children and/or Adolescents (under age 19 in AL)
☐ Prisoners

Persons with:
☐ Economic Disadvantages ☐ Physical Disabilities
☐ Educational Disadvantages ☐ Intellectual Disabilities

Do you plan to compensate your participants? ☐ Yes ☐ No

6D. Risks to Participants

Please identify all risks that participants might encounter in this research.

☐ Breach of Confidentiality
☐ Deception
☐ Psychological
☐ None
☐ Coercion
☐ Physical
☐ Social
☐ Other _____
_____
_____
_____

*Note that if the investigator is using or accessing confidential or identifiable data, breach of confidentiality is always a risk.

FOR IRB OFFICE USE ONLY

DATE RECEIVED: _____ BY _____ **PROTOCOL # _____**
DATE OF IRB REVIEW: _____ BY _____ **APPROVAL CATEGORY:_____**
DATE OF IRB APPROVAL: _____ BY _____ **INTERVAL FOR CONTINUING REVIEW:_____**
COMMENTS:_____

7. PROJECT ASSURANCES
PROJECT TITLE:_____

_____

A. PRINCIPAL INVESTIGATOR'S ASSURANCES

1. I certify that all information provided in this application is complete and correct.
2. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the East Stroudsburg University IRB.
3. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities and are in compliance with East Stroudsburg University policies regarding the collection and analysis of the research data.
4. I agree to comply with all East Stroudsburg policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
    a. Conducting the project by qualified personnel according to the approved protocol
    b. Implementing no changes in the approved protocol or consent form without prior approval from the IRB
    c. Obtaining the legally effective informed consent from each participant or their legally responsible representative prior to their participation in this project using only the currently approved, stamped consent form
    d. Promptly reporting significant adverse events and/or effects to the IRB in writing within 5 working days of the occurrence.
5. If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct responsibility in my absence. This person has been named as co-investigator in this application, or I will advise the IRB, by letter, in advance of such arrangements.
6. I agree to conduct this study only during the period approved by East Stroudsburg University IRB.
7. I will prepare and submit a renewal request and supply all supporting documents to the IRB before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the East Stroudsburg University IRB.
8. I will prepare and submit a final report upon completion of this research project.

My signature indicates that I have read, understand and agree to conduct this research project in accordance with the assurances listed above.

_____	_____	_____
Printed name of Principal Investigator	**Principal Investigator's Signature**	**Date**

B. FACULTY ADVISOR/SPONSOR'S ASSURANCES

1. By my signature as faculty advisor/sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.
2. I certify that the project will be performed by qualified personnel according to the approved protocol using conventional or experimental methodology.
3. I agree to meet with the investigator on a regular basis to monitor study progress.
4. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
5. I assure that the investigator will promptly report significant adverse events and/or effects to the IRB in writing within 5 working days of the occurrence.
6. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the IRB by letter of such arrangements. If the investigator is unable to fulfill requirements for submission of renewals, modifications or the final report, I will assume that responsibility.
7. I have read the protocol submitted for this project of content, clarity, and methodology.

_____	_____	_____
Printed name of Faculty Advisor/Sponsor	**Signature**	**Date**

C. DEPARTMENT HEAD'S ASSURANCE

By my signature as department head, I certify that I will cooperate with the administration in the application and enforcement of all East Stroudsburg University policies and procedures, as well as all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants by researchers in my department.

_____	_____	_____
Printed name of Department Head	**Signature**	**Date**

8. PROJECT OVERVIEW: Prepare an abstract that includes:
(400 word maximum, in language understandable to someone who is not familiar with your area of study):

I.) A summary of relevant research findings leading to this research proposal, (*Cite sources; include a "Reference List" as Appendix A.)*
II.) A brief description of the methodology,
III.) Expected and/or possible outcomes, and,
IV.) A statement regarding the potential significance of this research project.

9. PURPOSE.

a. Clearly state all of the objectives, goals, or aims of this project.

b. How will the results of this project be used? (e.g., Presentation? Publication? Thesis? Dissertation?)

10. KEY PERSONNEL. Describe responsibilities. Include information on research training or certifications related to this project CITI **required. Be as specific as possible**. (Attach extra page if needed.) *All non ESU-affiliated key personnel must attach **CITI certificates of completion.***

Principal Investigator_____Title:_____E-mail address_____
Dept/ Affiliation: _____

Roles / Responsibilties:

Individual: _____ Title:_____ E-mail address_____
Dept / Affilitaion: _____

Roles / Responsibilties:

Individual: _____ Title:_____ E-mail address_____
Dept / Affilitaion: _____

Roles / Responsibilties:

Individual: _____ Title:_____ E-mail address_____
Dept / Affilitaion: _____

Roles / Responsibilties:

11. **LOCATION OF RESEARCH. List all locations where data collection will take place. (**School systems, organizations, businesses, buildings and room numbers, servers for web surveys, etc.) **Be as specific as possible. Attach permission letters.**

12. **PARTICIPANTS.**
    a. **Describe the participant population you have chosen for this project.**
    (If data are existing, check here ☐ and describe the population from whom data were collected.)

    b. **Describe why is this participant population is appropriate for inclusion in this research project.** (Include criteria for selection.)

    c. **Describe, step-by-step, all procedures you will use to recruit participants.** *Include a copy of all e-mails, flyers, advertisements, recruiting scripts, invitations, etc., that will be used to invite people to participate.*

    What is the minimum number of participants you need to validate the study?_____
    Is there a limit on the number of participants you will recruit? ☐**No** ☐ **Yes- the number is_____**
    Is there a limit on the number of participants you will include in the study? ☐**No** ☐**Yes-the number is _____**

    d. **Describe the type, amount and method of compensation and/or incentives for participants.**
    (If no compensation will be given, check here ☐.)

    Select the type of compensation: ☐Monetary ☐Incentives

- ☐ Raffle or Drawing incentive (Include the chances of winning.)
- ☐ Extra Credit (State the value)
- ☐ Other

Description:

13. PROJECT DESIGN & METHODS.

a. Describe, step-by-step, all procedures and methods that will be used to consent participants.

☐ Check here if this is "not applicable"; you are using existing data.

b. Describe the procedures you will use in order to address your purpose. Provide a step-by-step description of how you will carry out this research project. Include specific information about the participants' time and effort commitment. (NOTE: Use language that would be understandable to someone who is not familiar with your area of study. Without a complete description of all procedures, the East Stroudsburg University IRB will not be able to review this protocol. If additional space is needed for this section, save the information as a PDF file and insert after page 6 of this form.)

c. **List all data collection instruments used in this project.** (e.g. surveys and questionnaires in the format that will be presented to participants, educational tests, data collection sheets, interview questions, audio/video taping methods etc.)

d. Data analysis: Explain how the data will be analyzed.

14. **RISKS & DISCOMFORTS: List and describe all of the risks that participants might encounter in this research.** ***If you are using deception in this study, please justify the use of deception and be sure to attach a copy of the debriefing form you plan to use .***

15. PRECAUTIONS. Identify and describe all precautions you have taken to eliminate or reduce risks as listed in #14. If the participants can be classified as a "vulnerable" population, please describe additional safeguards that ou will use to assure the ethical treatment of these individuals.

If using the Internet to collect data, what confidentiality or security precautions are in place to protect (or not collect) identifiable data? Include protections used during both the collection and transfer of data.
(These are likely listed on the server's website.)

16. BENEFITS.

a. List all realistic direct benefits participants can expect by participating in this specific study.
(Do not include "compensation" listed in #12e.) Check here if there are no direct benefits to participants. ☐

b. List all realistic benefits for the general population that may be generated from this study.

17. PROTECTION OF DATA.

a. Will data be collected as anonymous? ☐**Yes** ☐ **No** **If "YES", skip to part "g".**
("Anonymous" means that you will not collect any identifiable data.)

b. Will data be collected as confidential? ☐**Yes** ☐ **No**
("Confidential" means that you will collect and protect identifiable data)

c. If data are collected as confidential, will the participants' data be coded or linked to identifying information?
☐**Yes (If so, describe how linked.)** ☐ **No**

d. Justify your need to code participants' data or link the data with identifying information.

e. Where will code lists be stored? (Building, room number?)

f. Will data collected as "confidential" be recorded and analyzed as "anonymous"? ☐Yes ☐ No
(If you will maintain identifiable data, protections should have been described in #15.)

g. Describe how and where the data will be stored (e.g. hard copy, audio cassette, electronic data, etc.), **and how the location where data is stored will be secured in your absence. For electronic data, describe security. If applicable, state specifically where any IRB-approved and participant-signed consent documents will be kept on campus for 3 years after the study ends.**

h. Who will have access to participants' data?
(*The faculty advisor should have full access and be able to produce the data in the case of a federal or institutional audit.)*

i. When is the latest date that <u>confidential</u> data will be retained? (Check here if only anonymous data will be retained ☐)

j. How will the <u>confidential</u> data be destroyed?(NOTE: Data recorded and analyzed as "anonymous" may be retained indefinitely.)

All protocols must include the following items:

1. ☐ Research Protocol Review Form (All signatures included and all sections completed)

FROM THIS SECTION ON, FOR FULL BOARD REVIEW,
PLEASE NUMBER YOUR APPENDICES FROM THIS PAGE ON, BEGINNING WITH PAGE 11.

2. ☐ **Consent Form or Information Letter** and any Releases (audio, video or photo) that the participant will sign.

3. ☐ **Appendix A,** "Reference List"

4. ☐ **Appendix B** if e-mails, flyers, advertisements, generalized announcements or scripts, etc., are used to recruit participants.

5. ☐ **Appendix C** if data collection sheets, surveys, tests, other recording instruments, interview scripts, etc. will be used for data collection. Be sure to attach them in the order in which they are listed in #13c.

6. ☐ **Appendix D** if you will be using a debriefing form or include emergency plans/procedures and medical referral lists (A referral list may be attached to the consent document).

7. ☐ **Appendix E** if research is being conducted at sites other than East Stroudsburg University or in cooperation with other entities. A **permission letter** from the site / program director must be included indicating their cooperation or involvement in the project.
   NOTE: If the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of **IRB approval** from each entity is required prior to initiating the project.

8. ☐ **Appendix F –** Written evidence of acceptance by the host country if research is conducted outside the United States