Please note:
Do not staple.
Handwritten forms are not accepted.

IRB Number_____

FAIRMONT STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD (IRB)
RESEARCH PROJECT OUTLINE FORM

Proposal Title	

1. Study Personnel

a. Primary Investigator Name

First		Middle		Last	
Department					
Address					

(If not a Fairmont State University campus address, please include city, state and zip code)

Email		Phone	
Attach required CITI training completion report with submission.			

Undergraduate Student ____ Graduate Student ____ Faculty ____ Staff ____

b. Co-investigators

Name		Department	
Address			
Email		Phone	
Attach required CITI training completion report with submission.			

Undergraduate Student ____ Graduate Student ____ Faculty ____ Staff ____

Name		Department	
Address			
Email		Phone	
Attach required CITI training completion report with submission.			

Undergraduate Student ____ Graduate Student ____ Faculty ____ Staff ____

Name		Department	
Address			
Email		Phone	
Attach required CITI training completion report with submission.			

Undergraduate Student ____ Graduate Student ____ Faculty ____ Staff ____

c. Advisor Information (if applicable)

Name		Department	
Address			
Email		Phone	
Attach required CITI training completion report with submission.			

d. Research Assistants

Name		Department	
Attach required CITI training completion report with submission.			

Name		Department	
Attach required CITI training completion report with submission.			

Name		Department	
Attach required CITI training completion report with submission.			

Name		Department	
Attach required CITI training completion report with submission.			

e. If anyone else will be assisting with components of this research, please list their role(s). Outside parties may require additional coordination and approvals. Non-Fairmont State Collaborators: It is critical that you identify non-FSC collaborators, and initiate any coordination and/or approval process early, to minimize delays caused by administrative requirements.

i. Does your non-Fairmont State collaborator's organization have an Assurance with OHRP? (For Federalwide Assurance and Multiple Project Assurance (MPA) listings of other institutions, please reference the OHRP website under Assurance Information at: http://ohrp.osophs.dhhs.gov/polasur.htm). If yes, please enter your collaborator's MPA number.

2. Study Timeline

a. **Anticipated Starting Date** (Study, including recruitment, **cannot** begin prior to IRB approval. This date should **never** precede the submission date.)					
b. Duration of Study	Years		Months		

3. Funding Status

a. Is the researcher receiving support or applying for funding (e.g. grant funding)? *Make sure to contact the grant office at Fairmont State*	Yes		No	

If **YES**

List Source	
Describe any consulting or other relationships with this sponsor.	

Optional: Funding will be used for:

☐	Paying Participants (provide further details in the compensation section, as needed)
☐	Researcher Expenses (postage, equipment, travel, etc.)
☐	Other _____

4. Health and Safety Information

Does your protocol require work with human blood, human tissue, cell cultures derived from human cell lines, or virus/bacteria that is classified as bio risk II or above by the CDC or Canada Public Health?	Yes		No	

5. Review Level

Based on the available definitions, please choose the review level and category you believe to be appropriate for this study. (More than one category may apply.) If you believe that your project qualifies for exemption, please indicate which exemption category applies. Please remember that only the IRB can make the final determination whether a project is exempt from IRB review, or not. This category should not apply to protocols being prepared for expedited or quorum review.

☐	Exempt Review – See description of categories at: http://www.fairmontstate.edu/files/u2/irb-fsu-policy.pdf	Category	
☐	Expedited Review – See description of categories at: http://www.hhs.gov/ohrp/policy/expedited98.html	Category	
☐	Full Board Review		

6. Recruitment/Selection of Participants

a. What is the **maximum** number of participants to be enrolled? If screening occurs, include the number of participants that will need to be screened in order to get the number necessary for statistical significance. Please note that once the protocol is approved this number must not be exceeded.	

b. Characteristics of participants (check as many boxes as appropriate)

	Minors		Disabled (Physically or Mentally)		Elementary School Students
	Adults		Legally Incompetent		Middle School Students
	Prisoners		Cognitively Impaired		High School Students
	Pregnant		Non-English Speaking		University Students

c. Briefly describe the criteria for selection of participants (inclusion/exclusion). Include such information as age range, health status, etc. Attach additional pages if necessary.

d. Describe how you will identify and recruit prospective participants.

e. Records

Are you accessing existing records for this study?	Yes		No	

If **YES**, describe the records and attach a letter of support from the holder or custodian of the records (e.g.., primary physician, therapist, public school official.)

f. Please describe your relationship to the potential participants (e.g., instructor of class, co-worker). If no relationship, state no relationship.

Attach copies of all recruitment tools (advertisements, posters, etc.) labeled as **Appendix A**.

g. Performance Sites/Location of Research

- ☐ Fairmont State University Facility
- ☐ Other – Describe below and provide a letter of support

7. Project Description

2. a. Provide a **brief** summary of this project, using non-technical terms that would be understood by a non-scientific reader. This description must be in enough detail so that the IRB members can make an informed decision about the proposal.

b. Describe the specific scientific objectives or aims of this research and any previous relevant research.

c. Methodology: Sequentially describe the procedure(s) that will be performed/followed with human participants.

d. Describe any potential risk(s) or discomfort(s) of participation and the steps that will be taken to minimize them. In your opinion, does the proposed research involve more than **minimal risk** to participants? ("Minimal risk" means that "the risk 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 physical or psychological examinations or tests.)

e. Describe the anticipated benefit(s) to the individual participants. If none, state that. (Note that compensation is **not** a benefit, but should be listed in the compensation section.)

f. Describe the anticipated benefit(s) to society and/or the scientific community in lay language. There must be some benefit to justify the use of human participants.

8. Confidentiality

a. Check all that apply

☐	Data is collected anonymously, with no face-to-face contact with participants
☐	Data is not collected anonymously, but will be recorded without identifiers (e.g., name, SSN)
☐	Data will be recorded with a code replacing identifiers and a master list connecting the code and the identifier will be used.
☐	Data will be recorded with identifiers (e.g., name, SSN)
☐	The nature of the data makes it potentially identifiable (e.g., audio or video recordings, photographs)

b. If a master code list will be used (option number 3, above) please provide details, such as how/where the code list will be securely stored, and the approximate month and year it will be destroyed, etc.

c. If data is stored with identifiers, please provide details of how the data will be stored securely (e.g., locked cabinet, password protected) as well as the approximate month and year that the data will be de-identified.

d. Data Sharing

Will **identifiable** data be shared with anyone outside the immediate research team?	Yes		No	

If **YES**, please describe.

e. Recording

Will participants be Audio recorded?	Yes		No	
Video recorded?	Yes		No	

If **YES**, please describe how/where recordings will be stored, who will have access to them, and provide an approximate month and year that they will be destroyed.

f. Additional Details (if needed)

9. Compensation

a. Will participants receive a gift or token of appreciation?	Yes		No	

If **YES**, list the item and its approximate value.

b. Will participants receive services, treatment or supplies that have a monetary value?	Yes		No	

If **YES**, please describe and provide the approximate value.

c. Will participants receive course credit?	Yes		No	

If **YES**, please describe non-research alternatives to earn the credit, the number of points to be awarded, and what percentage of the total points for the course it represents. If you are using the Psychology Pool, which has established guidelines that provide these details to the IRB, simply write Psych Pool.

d. Will participants receive monetary compensation (including gift cards)?	Yes		No	

If **YES**, please detail the amount per session and total compensation possible. Additionally, describe what compensation amount is paid to participants who discontinue participation prior to completion.

e. Will University funds be used to pay or otherwise compensate participants?	Yes		No	

If **YES**, please consult with the Fairmont Finance Office, then list what participant information you need to provide to the Finance Office to document payment in the consent form.

10. Instruments

List all questionnaires, instruments, and standardized tests to be used, and provide a brief description of each. Copies of each item must be provided and labeled as **Appendix B**.

11. Data Analysis

How will the data be analyzed? What statistical procedure(s) will be used to test the hypotheses? If qualitative, how will the data be coded, etc.?

12. Informed Consent Process

a. Select one of the following options

	I am obtaining signed consent for this study.
	I am obtaining consent without signature. (Choose rationale below) ☐ Exempt study ☐ To protect the privacy of participants ☐ Needed due to cultural norms ☐ Not practical (online or phone study) ☐ Other
	I do not plan to obtain consent.

Provide additional information, if needed.

Please go to http://www.fairmontstate.edu/irb and select the appropriate consent form template(s). Use of a template is strongly recommended because they include required elements. Attach a copy of each consent document or text and label it as **Appendix C**.

b. How and where will the consent process occur? Will participants have an opportunity to ask questions and have them answered? What steps will be taken to avoid coercion or undue influence? Do you preserve the anonymity of participants? (An anonymous participant is one whose identity is unknown, even to the researcher.) If "no" explain why and describe how you will protect the identity of participants.

c. Will all adult participants have the legal/cognitive capability to give informed consent?	Yes		No	

If **NO**, explain the procedures to be followed to obtain informed consent for these individuals.

d. Will any participants be minors?	Yes		No	

If **YES**, you must obtain both parental consent and minor assent. Please describe the procedure below and attach consent and assent documents as Appendix C.

e. Will participants be deceived or incompletely informed regarding any aspect of the study?	Yes		No	

If **YES**, provide rationale and justification for the use of deception.

If **YES**, attach a copy of the post-study debriefing information and label as **Appendix D**. Additionally, complete the questions related to a consent form waiver or alteration in section 12.

Primary Investigator Assurance

I certify that the information provided in this outline form is complete and correct.

I understand that as an investigator, I have responsibility for the protection of the rights and welfare of human participants, conduct of the study, and the ethical performance of the project.

I agree to comply with Fairmont State University policies on research and investigation involving human participants, as well as with all applicable federal, state and local laws regarding the protection of human participants in research.

Additionally, I agree to the following:

- I have not started the study and will not begin until approval has been obtained.
- I will ensure the project will be performed by qualified personnel, according to the Fairmont State approved protocol. : I assure that all personnel working with human participants described in this protocol are technically competent and have completed training in the treatment of human participants.
- I will not implement any changes to the study until approved by the Fairmont State IRB.
- I will obtain legally effective informed consent from human participants if applicable, and documentation of informed consent will be retained, in a secure environment, for three years after termination of the project.
- I will report adverse/unexpected events to the Fairmont State IRB promptly.
- I will stop the study upon attaining the expiration date (unless determined to be exempt).
- If funded by an extramural source, I assure that this application accurately reflects all procedures involving human participants as described in the grant/contract proposal to the funding agency. I also assure that I will notify the IRB, and the funding/contract entity if there are modifications or changes made to the protocol after the initial submission to the funding agency.

Investigator Signature_____**Date** _____

(Please print name) _____

Investigator Signature_____**Date** _____

(Please print name) _____

Please note: If you are submitting this signature page separate from the rest of the IRB submission, include the title of the study on this page.

Faculty Advisor/Sponsor Assurance

By my signature below, I agree to the following:

As sponsor on this research application, I certify that the student(s) or guest investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular study in accordance with the approved protocol.

Additionally, I agree to the following:

- I am the responsible party for the legal and ethical performance of the project.
- The proposed research has not started and will not begin until approval is obtained.
- The investigator(s) is knowledgeable about the regulations and policies governing research with human participants.
- The investigator(s) has sufficient training and experience to conduce this particular study in accordance with the approved protocol.
- I will meet with the investigator(s) on a regular basis to monitor study progress.
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in resolving them.
- I assure that the investigator will promptly report adverse/unexpected events to the IRB in writing.
- If I will be unavailable, as when on sabbatical or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence.

Faculty Advisor Signature_____**Date** _____

(Please print name) _____

*The faculty advisor must be a member of the Fairmont State faculty.

Please note: If you are submitting this signature page separate from the rest of the IRB submission, include the title of the study on this page.

Checklist:

- ☐ Completed and Signed Project Outline Form (this form)
- ☐ Required CITI training completion reports for each investigator
- ☐ Appendix A – A copy of any recruitment tools (advertisements, posters, etc.
- ☐ Appendix B – A copy of all instruments (surveys, standardized tests, questionnaires, interview topics, etc.)
- ☐ Appendix C – A copy of all consent documents (in 12 pt. Font) including
  - ___ Informed Consent to Participate in Research (adult participants)
  - ___ Parental Permission/Informed Consent (parents of participants who are minors)
  - ___ Assent to Participate in Research (used when participants are minors)
- ☐ Appendix D – A copy of the debriefing text
- ☐ Appendix E – A copy of the approval from other IRBs, School District, Corporation, etc.
- ☐ Appendix F – A copy of Human Participants Research Training Certificates
- ☐ Appendix G – Any additional materials that will assist the IRB in completing its review

All fields on the form must be completed, regardless of review level. If a field is not applicable, indicate by inserting N/A. Incomplete forms will result in delayed processing.

Please submit the completed project outline form, appendices, and scanned signature pages, preferably by email, to jsmallridge@fairmontstate.edu or in person to:

Dr. Joshua Lee Smallridge Associate
Professor of Criminal Justice
110 Hardway Hall
Fairmont State University
Fairmont, WV 26554

If you have questions, call 304-367-4740, visit the website at http://www.fairmontstate.edu/irb or email jsmallridge@fairmontstate.edu.