UNIVERSITY OF CHARLESTON

_____ **Application No.**
This Number is assigned by the IRB upon approval.

UC IRB - APPLICATION FOR EXPEDITED OR FULL REVIEW
FOR USE OF HUMAN PARTICIPANTS IN RESEARCH

TO: IRB CHAIR, UNIVERSITY OF CHARLESTON Date: _____

Primary Investigator: Must Be a Faculty Member Email: _____

Other Investigators: _____ Email: _____

_____ Email: _____

Department: _____ Degree / Program: _____

Project Title: _____

_____

Funding Agency: _____

Check the most appropriate answer for each question. Do not leave any questions unanswered.

1. The investigator(s) request the following type of review:	☐EXPEDITED	☐FULL	
2. Will human participants be participating in:			
a. biomedical procedures	☐YES	☐NO	
b. procedures to elicit information (personality tests, questionnaires, inventories, surveys, feelings, or other aspects of the behavior of participants?	☐YES	☐NO	
c. procedures specifically designed to directly modify the knowledge, thinking, attitudes, feelings, or other aspects of the behavior of participants?	☐YES	☐NO	
3. If biomedical procedures are involved:			
a. are provisions for emergency medical care necessary? (If yes, give details on the Informational Survey #8 & 9)	☐YES	☐NO	☐N/A
b. has a qualified MD participated in the planning of the project?	☐YES	☐NO	☐N/A
c. will this study involve drugs or chemical agents (dosages), ionizing radiation, non-ionizing radiation (microwaves, lasers), or high intensity sound?	☐YES	☐NO	☐N/A
4. Does this study involve giving false or misleading information to participants or withholding information from them such that their "informed consent" is in question? (If yes, give details on the Informational Survey; deception method on #5 and debriefing method on #11)	☐YES	☐NO	
5. Are procedures to be used new or innovative (not established and accepted)? (If yes, give details on the Informational Survey # 8&9.)	☐YES	☐NO	
6. Will the procedures:			
a. cause any degree of discomfort, harassment, invasion of privacy, risk of physical injury, or threat to the dignity of participants, or be otherwise potentially harmful to participants?	☐YES	☐NO	
b. if answer to 6a is yes, have specific provisions been made to correct any harmful or adverse conditions that may arise? (Give details on the Informational Survey #10)	☐YES	☐NO	☐N/A
7. Can the potential benefits to participants from the conduct of this study be considered to outweigh the risks to participants? (If yes, explain on the Informational Survey)	☐YES	☐NO	

8. Can the potential benefits to society from the conduct of this study be considered to outweigh the risks to participants? (If yes, explain on the Informational Survey)	☐YES	☐NO	
9. Will participants come in direct contact with any type of electrically powered equipment? (If yes, detail on the Informational Survey #6, the name and qualifications of the individual who will check for electrical safety and attach a signed letter from that person which indicates his/her level of involvement with the project.)	☐YES	☐NO	
10. Is the project specifically designed to involve participants who are:			
a. minors (less than 18 years of age)?	☐YES	☐NO	
b. pregnant women?	☐YES	☐NO	
c. prisoners?	☐YES	☐NO	
d. developmentally intellectually disabled?	☐YES	☐NO	
e. mentally disabled (brain-injured, psychiatric patients, etc.)	☐YES	☐NO	
f. physically disabled	☐YES	☐NO	
g. institutionalized?	☐YES	☐NO	
11. Will participants receive any payment for participating (money, course credit, etc.)?	☐YES	☐NO	
12. Are procedures for maintaining confidentiality of all participants' data fully described?	☐YES	☐NO	
13. Will survey software be used?	☐YES	☐NO	
If yes, please list the company or educational facility.	_____		
Is it secured with a single user logon and password?	☐YES	☐NO	
14. Do procedures include obtaining parental/guardian consent and/or institutional authorization for access to participants if minor, mentally disabled or institutionalized participants?	☐YES	☐NO	☐N/A
15. Are procedures for obtaining informed consent fully described?	☐YES	☐NO	
16. Will a copy of the informed consent document and explanation of the study be provided to each participant?	☐YES	☐NO	
17. Have copies of informed consent documentation been submitted along with the protocol (ie: signature document with explanation of study, transmittal letter, debriefing statement or other)?	☐YES	☐NO	
18. Will any non-University of Charleston site(s) be included in data collection?	☐YES	☐NO	
19. If an educational facility, please list the grade of any students involved	Click here to enter text.		
20. Fill in the estimates below:	Click here to enter text.		
Average amount of time required for participation (in hours).	Click here to enter text.		
If questionnaires or tests are involved, the total number of items.	Click here to enter text.		
Number of volunteers (participants) to be involved in this study.	Click here to enter text.		
21. Beginning date (pending approval)	Click here to enter text.		
22. Ending date of involvement.	Click here to enter text.		

INSTRUCTIONS TO INVESTIGATORS

This application must be completed in its entirety with all required attachments to be considered for review. Please check to ensure that you have all of the following attached before submitting:

☐ List a UC Faculty Member as the Primary Investigator.

☐ List Students, Non-UC Faculty/Administrators, and additional investigators as Other Investigators.

☐ List the Department your program falls under if academic, list your actual department if employment or grant related.

☐ List the Degree and Program you are conducting this research for, if applicable.

☐ List the Title of Your Project.

☐ List any Funding Agency, if applicable.

☐ Attach a **short (maximum of two pages) research proposal summary** that fully describes your project, clearly shows how the participants and procedures in your project fit requirements for the expedited category (if selected), describes how you will be protecting the privacy of the participants; how you will be maintaining the confidentiality of data collected; and where the research will be performed. If you are surveying your subjects, **please include the survey instrument**.

☐ Attach a current Human Research Subjects Training Certificate for each Investigator on this project (Primary Investigator and Other Investigator). All Investigators are required to complete this training within 3 years of this proposal submission.

☐ Consent Form that you plan to use with your participants, if applicable.

☐ Organization Permission Letter to conduct research on non-UC premises. Letter must be on the organization's letterhead and signed by an officer of the organization. If the organization is an educational facility, it must be signed by a President, Vice President, Provost, Principal, or Vice Principal.

☐ Attach a copy of your survey, questionnaire, or interview questions as you plan to deliver them to the participants.

☐ Attach a copy of any other method of data collection, if not from survey, questionnaire, or interview.

☐ Attach a copy of the Consent to Audio Tape / Video Tape, if applicable.

☐ Attach any other pertinent documentation. Please specify: _____

☐ Have ALL Required Persons Signed this application?

(Your application will not be reviewed, if it is not signed and submitted with ALL required documentation. Acceptable forms of signature: Scanned, Faxed, or Adobe Digital Signature. Typed names are not considered signatures.)

1) Principal Investigator (Faculty Member or Administrator)

2) Other Investigator (Student doing project)

3) School or Division Chair (Cannot be one of the Investigators)

All applications must be completed in its entirety and contain all required signatures and documents or they will not be processed but will be returned to the Principal Investigator. Please submit your completed application using one of the following methods:

1) Electronically to irb@ucwv.edu (Save the entire application packet as one single PDF file and send as an attachment. Please no links)

2) Paper application to Institutional Review Board, UC-Charleston, Box 9 (Do not send to individual IRB members.)

If you have questions or need to report problems with your project, please direct them to the Chair of UC-IRB:

Rebecca Linger, IRB Chair..... 304-357-4998

UC-Charleston, Pharmacy Room 304G..... rebeccalinger@ucwv.edu or irb@ucwv.edu

UC IRB Information Survey

APPLICATION FOR EXPEDITED OR FULL REVIEW
REGARDING USE OF HUMAN PARTICIPANTS IN RESEARCH

Respond to each of the following items or questions. Provide enough detail so the reviewers will be able to judge how well your study protects human participants. Your responses must be preceded by the exact question and typed in the original order. Normally, your response will not exceed five pages.

1. Provide a brief description of the proposed study (purpose, problem to be investigated).
Click here to enter text.

2. What are your qualifications for conducting the study? (What is your experience with the procedures and instrumentation to be used in this study? If a student, what is your status and which faculty member will supervise your research and what are his/her qualifications?)
Click here to enter text.

3. What are the requirements for and characteristics of the participant population? (What gender, age range, health or medical status, prisoners, institutionalized, adults, mentally disabled, etc.?)
Click here to enter text.

4. How will participants be sampled, recruited or otherwise enlist as participants in the study?
Click here to enter text.

5. Describe in detail the methodology of your study (how will the study be conducted from start to finish as far as human participants are concerned? Be specific about the methods, instrumentation, types of data collected, any incentives or compensation, etc.)
Click here to enter text.

6. Describe the personnel, materials/equipment, or other resource requirements for your study. (Identify all personnel involved in the study, their role, their qualifications and their access to the data.)
Click here to enter text.

7. How will you obtain the informed consent of the participants? (How, where, and when will the study be explained to participants? How will participants indicate their consent?)
Click here to enter text.

8. What are the potential risks to the participants and what is the likelihood and seriousness of these risks? Risks could be physical, psychological, social, legal, etc. and may result from your experimental procedures, medical treatment, or your methods of obtaining, handling, or reporting data, and compensation. (Studies with greater than minimal risk will require annual review by the IRB.)
Click here to enter text.

9. As applicable, for each risk identified in #8, describe other methods that were considered that would reduce or eliminate these risks, and explain why they will not be used.
Click here to enter text.

10. What are the potential benefits to the individual participants and/or society as a result of the proposed research?
Click here to enter text.

11. As applicable, describe how you will minimize or protect against potential risks to participants throughout the study. (Describe emergency procedures, confidentiality safeguards, deception involved and the debriefing procedures, security measures for storing and accessing data, etc.)
Click here to enter text.

12. As applicable, provide the names and addresses of experts in your field (not including the investigator) with whom the committee members could communicate to discuss the potential risks of your procedures.
Click here to enter text.

13. If appropriate, provide references to any published materials that would help the committee make a judgement regarding your procedures for safeguarding the rights and safety of your participants.
Click here to enter text.

EXPLANATORY NOTE: If any of the items listed above is not applicable to your study, type N/A after the question instead of leaving the question blank.

UC Institutional Review Board
Informed Consent
Type Title of Project Here

Introduction	NAME OF PRINCIPAL INVESTIGATOR AND OTHER INVESTIGATORS, in the NAME OF DEPARMENT Department at the University of Charleston, is conducting a research study to examine PROJECT PURPOSE. By signing below, you have volunteered to take part in the study because you EXPLAIN SUBJECT CRITERIA.
Procedures	BRIEFLY EXPLAIN PROCEDURES IN LAY TERMS.
New Findings	If new information is found during the course of this study, your consent to continue to participate in this study will be re-obtained. If you are interested in the results of this study, you can request the results at the completion of the study. EXPLAIN WHAT RESULTS WILL BE AVAILABLE. FULL STUDY, INDIVIDUAL, ETC.
Risks	Participation in this study will not include any risks beyond EXPLAIN RISKS..
Care if Harmed	If you are injured as a direct result of participation in this study, you must immediately contact the Primary Investigator PRIMARY INVESTIGATOR and the Chair of the UC-IRB, Dr. Rebecca Linger (304) 357-4998. FOR RESEARCH INVOLVING MORE THAN MINIMAL RISK, INCLUDE 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.
Benefits	There may or may not be any direct benefit to participants from these procedures. EXPLAIN ANY BENEFITS TO THE PARTICIPANTS
Explanation & Offer to Answer Questions	PRINCIPAL INVESTIGATOR has explained the study to you and answered your questions. If you have other questions or research-related problems, you may reach PRINCIPAL INVESTIGATOR at PHONE NUMBER . If you have questions about your rights as a research participant, please contact Dr. Rebecca Linger, Chair, Institutional Review Board at (304) 357-4998.
Right to Withdraw Without Consequences	Participation in this research is entirely voluntary. You may refuse to participate or withdraw at any time without consequence or loss of benefits. Whether or not you participate and/or withdraw in this study will in no way affect your relationship to the University of Charleston. You may be withdrawn from this study without your consent by the investigator. DESCRIBE ANY MISUSE IF APPLICABLE.
Confidentiality	Research records will be kept confidential to be consistent with federal and state regulations. Only the investigators will have access to the data and it will be kept in a locked file cabinet in a secure room. Videotape records (if used) will be kept for five years and then destroyed. The results of the study may be presented at professional meetings and published in professional journals but you will be asked permission before your image may be used in these settings.
IRB Approval Statement	The Institutional Review Board for the Protection of Human Participants at the University of Charleston has reviewed and approved this research project.
Copy of Consent	You have been given two copies of this Informed Consent. Please sign both copies and retain one copy for your files.
Investigator Statement	I certify that the research study has been explained to the above individual, by my research staff and that the individual understands the nature and purpose, the possible risks and benefits associated with taking part in this research study. Any questions that have been raised have been answered.

Signature of PI & Student Investigator

_____ _____

Signature of Primary Investigator Signature of Student Investigator

I agree to participate in this study

_____ _____

Signature of Participant Date

Certification of Application

I certify that all research conducted pursuant to this application will be conducted in compliance with all applicable University of Charleston policies and the institutional assurance with the U.S. Department of Health and Human Services regarding the use of human participants. University review and approval is requested. Major additions to or changes in procedures involving human participants that occur after review of the application will be brought to the attention of the review committee by the investigator. In addition, the committee will be notified of any unanticipated events that do or could affect the safety and wellbeing of participants. Student projects must be supervised by a full-time University of Charleston faculty member. In addition, only the faculty advisor may be the Principal Investigator. Although non-University of Charleston investigators may be involved in a project in any capacity, all projects must be sponsored by a full-time University of Charleston member who is ultimately responsible for the safe conduct of the study.

I agree to abide by all policies as set forth by the UC-IRB regarding human subjects in research and to file all reports as required and in a timely manner. I understand that I am the responsible party in this application and it is my duty to oversee this project and all reporting. I understand that I must maintain all records on file for a period of three years from the latter date of completion or publication.

Click here to enter text.	Click here to enter text.		
Name: Principal Investigator (UC Faculty Member)	Email Address	Phone	Signature

I agree to abide by all policies as set forth by the UC-IRB regarding human subjects in research and to report any issues promptly to the Principal Investigator and the IRB.

Click here to enter text.	Click here to enter text.		
Name: Other Investigator	Email Address	Phone	Signature

I have read and approve of this application. I understand that, in the event the Principal Investigator is no longer with the University, the records and reporting will fall to me as the School/Department Chair.

Click here to enter text.	Click here to enter text.		
Name: Primary Investigator's Supervisor (May NOT be an investigator on this project)	Email Address	Phone	Signature