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

UC IRB – APPLICATION FOR EXEMPT REVIEW

TO: IRB CHAIR, UNIVERSITY OF CHARLESTON Date: _____

Primary Investigator: _____ Email: _____

Other Investigators: _____ Email: _____

_____ Email: _____

Department: _____ Degree / Program: _____

Project Title: _____

_____

Funding Agency: _____

TYPE OF EXEMPTION

Check the type of exemption you are claiming:

A. Exemptions:

Research in which the only involvement of human participants is in one of the following categories is exempt from full review by the IRB, provided that the researcher submits and obtains Committee approval of an Application for Exemption from IRB Review. No research is exempt if any of the targeted populations for this research consists of persons who are:

- legally incompetent;
- significantly mentally ill or impaired; or
- vulnerable to extraordinary institutional coercion, such as prisoners, residents of 24-hour skilled nursing facilities, or anyone who is involuntarily confined.

B. Categories:

☐ **1. Educational Practices:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

☐ **2. Educational Tests, Surveys, Interviews, Observation of Public Behavior:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) is exempt, if:

1. the information obtained is not identifiable;
2. the information, if disclosed outside the research, could not reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.
3. the information in the researcher's private data (including field notes) as well as in any published material, information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Note: This exemption does not apply if the participants are minor children. "Minor children" are persons who have not attained the legal age for consent under the applicable jurisdiction in which the research will be conducted. In the United States, this age is 18 years.

☐ **3. Benign Behavioral Interventions in Conjunction with the Collection of Information from Adult Subjects:** Benign behavioral interventions are defined as "brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing"

Note: Research using deception is not eligible for exemption in this category unless the subjects prospectively agree that they will be unaware of or misled regarding the nature and purpose of the research.

☐ **4. Secondary Research for Which Consent is Not Required:** This category covers secondary research uses of identifiable private information or identifiable biospecimens. Informed consent is not required if at least one of the criteria listed below is met:

1. Use of publicly available identifiable private information or identifiable biospecimens.
2. Information recorded by the investigator in such a way that the identity of the subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify subjects.

3. Research use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or public health activities and purposes as those terms are defined in HIPAA.
4. Analysis of data on behalf of a federal agency or department – as opposed to an investigator-initiated analysis of federally supplied data – if the requirements of certain federal laws are met.

☐ **5. Research and Demonstration Projects that Are Conducted or Supported by a Federal Department or Agency**: This category covers research and demonstration projects that will serve as a public benefit and service and must meet the following criteria:

1. The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
2. The research or demonstration project must be conducted pursuant to specific federal statutory authority.
3. There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).
4. The project must not involve significant physical invasions or intrusions upon the privacy of participants

☐ **6. Taste and food quality evaluation and consumer acceptance studies**: Research in this category must meet the following criteria:

1. Wholesome foods without additives are consumed, or
2. Food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ **7. Storage or maintenance for secondary research for which broad consent is required**: This category is for the storage of identifiable biospecimens and identifiable private information, prior to secondary analysis. The storage and maintenance may be exempt if the IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and if broad consent is obtained.

☐ **8. Secondary Research for Which Broad Consent is Required:** This category allows the secondary analysis of existing private identifiable data and identifiable biospecimens provided broad consent was secured and the documentation of consent was either secured or waived. The IRB must also conduct a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and that the use is within the scope of the broad consent. Category 8 also requires that the investigator does not include returning individual research results to subjects as part of the study plan; however, the exemption does not prevent investigators from returning results if required by law.

NOTE: all procedures for all participants in a project must be exempt in order for the project to be exempt from Committee review.

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 or Administrator 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, listed 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.

☐ Check the Type of Exemption that you are claiming.

☐ Attach a **short (maximum of two pages) research proposal summary** that describes your project, clearly shows how the participants and procedures in your project fit the requirements for exemption in the category you have 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 your survey instrument**.

☐ Attach a current NIH or CITI Certificate for each Investigator on this project (Primary Investigator and Other Investigator). All Investigators are required to have NIH or CITI Training within three years.

☐ 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 (Can not be one of the Investigators)

If you have questions, please direct them to the Chair of University of Charleston's Institutional Review Board.

Rebecca Linger, IRB Chair, 304-357-4998,
UC-Charleston, Pharmacy Room 304G, rebeccalinger@ucwv.edu or irb@ucwv.edu

Please submit your completed application to:

Electronic Copy: irb@ucwv.edu

Printed Copy: UC – Campus Mail
John Adkins, IRB Coordinator -- Library

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 Federal and State regulations. 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.

Signature of Principal Investigator (Faculty Member or Administrator)	Principal Investigator's Email Address and Phone
Signature of Other / Student Investigator (Only one required)	Other / Student Investigator's Email Address
Signature of Principal Investigator's Supervisor (Not an Investigator on this project)	Supervisor's Email Address

Do Not Write Below – For IRB Use Only

Reviewer's Comments:

☐ The project is exempt from Committee review.

☐ The project must be reviewed. Please complete **The IRB Application for Expedited or Full Review**.

Signature of Reviewer	Date
Print Name of Reviewer	

Short-Form Consent

You are invited to participate in a research study conducted by , from the University of Charleston *affiliation*. I hope to learn . You were selected as a possible participant in this study because .

If you decide to participate, .

Risks associated with participation . However, I cannot guarantee that you personally will receive any benefits from this research. *Describe any compensation*.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Subject identities will be kept confidential by *describe methods of confidentiality*.

Your participation is voluntary. Your decision whether or not to participate will not affect your relationship with *type of entity*. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without penalty.

If you have any questions, please feel free to contact *primary investigator name, email, and phone number*. If you have questions regarding your rights as a research subject, contact Dr. Rebecca Linger, Chair University of Charleston, Institutional Review Board [phone: 304-357-4998, email: rebeccalinger@ucwv.edu]. You will be given a copy of this form to keep.

Your signature indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation without penalty, that you will receive a copy of this form, and that you are not waiving any legal claims.

Signature: _____

Print Name: _____ Date: _____