For Office Use Only:
Date Reviewed:_____ **IRB Case No:**_____
☐**Approved as Exempt** ☐**Approved as Exempt with Conditions*** **Duration of Approval:** _____ **to** _____
***Conditions:** _____
☐**Not Exempt: Referred for** ☐ **Expedited Review** ☐**Full Review** **IRB Reviewer:**_____

BLUE MOUNTAIN COMMUNITY COLLEGE INSTITUTIONAL REVIEW BOARD
EXEMPT PROTOCOL PETITION

Research activities are exempt from IRB review only when the involvement of human subjects falls into one or more of the categories defined under 45 CFR 46.101(b), listed on the following page. Even if your study may qualify as exempt, you must complete and submit this petition form to the office of the IRB. The IRB or its designee, not the researcher, makes the final determination of exemption. Exempt studies do not require continued IRB monitoring; however, the project director must: (a) request IRB approval of any changes made to the approved exempt research **before the changes can be implemented, and (b) submit** annual renewal applications **to reconfirm the exempt status of ongoing projects that remain unchanged.**

Principal Investigator/Project Director**:** _____Date Submitted: _____

Title of Research Project: _____

Projected Duration of Research Project: _____ months Projected Start Date: _____

Proposed Exemption Category (refer to the following page): 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐

TO COMPLETE THE PETITION:

1. Attach the following documents:
   a. A brief summary of the project (purpose and benefits, participants, data-collection procedures, disposition of/access to data, estimated level of risk, risk management procedures, need for informed consent).
   b. A copy of the informed consent form or statement, if applicable.
   c. A copy of the measure(s) or instrument(s) to be used in the project
2. Answer questions A through I (below).
3. Sign the acknowledgement on page 2.

Please answer all of the questions on this page. If the question does not apply, mark 'no.' If you answer 'yes' to any of the questions below, your study will not qualify as exempt research and you must complete the full IRB application.

For research involving special populations, interventions, or manipulations:	**Y**	**N**
A. Does your study involve deception of subjects?	☐	☐
B. Does your research involve survey or interview procedures with children (under the age of eighteen) as subjects?	☐	☐
C. Does your research expose subjects to discomfort or harassment beyond levels encountered in daily life?	☐	☐
D. Does your research involve fetuses, pregnant women, human in-vitro fertilization, or children or other individuals involuntarily confined or detained in penal institutions?	☐	☐

For research using survey procedures, interview procedures or observational procedures (NOTE: Surveys or interviews with children as subjects are not exempt.):	**Y**	**N**
E. If the data are to be recorded by audiotape or videotape, and were the information to be revealed or disclosed, could this place subjects at risk (note: risks may be psychological, social, physical, economic, or legal)?	☐	☐
F. Are subjects identifiable (e.g., by name or through demographic data), and will collection of information include sensitive data (e.g., illegal activities or sensitive issues such as sexual orientation, sexual behavior, undesirable work behavior, or other potentially embarrassing information)?	☐	☐
G. If subjects are identifiable (see F. above), are there potential risks to them if the information is revealed or disclosed?	☐	☐

For research using existing or archived* data, documents, records, or specimens:	**Y**	**N**
** "Existing or achived" means collected (i.e., on the shelf) prior to the research for a purpose other than the proposed research. It includes data or specimens collected in research and nonresearch activities.*		
H. Will any data, documents, records, or specimens be collected from subjects after the IRB approves the research?	☐	☐
I. If the existing data, documents, records, or specimens are originally labeled with identifiers and are not publicly available, is the investigator recording the data in such a manner that subjects can be identified, directly or indirectly, through identifying links (e.g., demographic information that might reasonably lead to the identification of individual subjects – name, phone number, medical record number, audio or video tape, social security number, or any code number that can be used to link the investigator's data to the source record)?	☐	☐

ACTIVITIES EXEMPT FROM IRB REVIEW

Research activities involving human subjects in the following categories may be exempt from review by Blue Mountain Community College's Institutional Review Board (IRB). The principal investigator/project director is authorized to make the first, unofficial determination of eligibility for exemption; however, the college bears the responsibility for concurring in that determination based on information provided by the principal investigator/project director to the IRB.

*The following exemptions do **NOT** apply when (a) **deception** of subjects may be an element of the research; (b) subjects are **under the age of eighteen**; (c) the activity may **expose the subject to discomfort or harassment** beyond levels encountered in daily life; or (d) **fetuses, pregnant women, human in-vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions** are subjects of the activity.*

EXCEPT FOR THE ABOVE EXCLUSIONS, the federally approved categories of exemption are:

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

8. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement); survey procedures; interview procedures or observations of public behavior, **unless**: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or indirectly, through identifiers linked to the subjects AND (b) any disclosure of the human subjects' responses outside the research reasonably would place the subjects at risk of criminal or civil liability or would be damaging to the subjects' financial standing, employability, or reputation.

9. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 **if**: (a) the human subjects are elected or appointed public officials or candidates for public office, or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

10. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

11. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

12. Taste and food-quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed, or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or if it contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the U.S. Food and Drug Administration or approved by the U.S Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempting an activity from review does not absolve the investigator(s) of the activity from ensuring that the welfare of the subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

The principal investigator is responsible for:

a. Submitting any changes in project procedures to the IRB for written approval before implementing such changes.
b. Communicating with the IRB Chair any problems concerning human subjects once the project has begun.
c. Retaining informed consent documents for a minimum of three years after the project ends.
d. Reapplying annually for renewal of exempt status, if the project is unchanged and ongoing, at least 10 business days before the expiration date of the current approval.

ACKNOWLEDGEMENT: The statements and information provided in this application are true and accurate. I have read BMCC's Administrative Procedure on Research Involving Human Subjects and the Role of the Institutional Review Board and will comply with all college and federal requirements and regulations governing human subjects research.

Principal Investigator (PI)/Project Director Signature: _____ **Date:** _____

Instructor or Faculty Advisor Signature (for Student PIs): _____ **Date:** _____

Department Head Signature (for Student PIs): _____ **Date:** _____