| For Office Use Only: | |
|---------------------------------|--------------------------|
| Date Reviewed: | IRB Case No: |
| IRB Reviewer: | |
| Exempt Expedited Full | Duration of Approval: to |
| Approved Approved with Conditio | ns* Not Approved |
| *Conditions: | |

BLUE MOUNTAIN COMMUNITY COLLEGE INSTITUTIONAL REVIEW BOARD

EXPEDITED AND FULL REVIEW APPLICATION FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS

The Blue Mountain Community College Institutional Review Board (IRB) reviews all requests to conduct research involving human subjects. The principal investigator/ project director is responsible for providing complete information regarding research procedures and the informed consent process. If the principal investigator is a student, the application must be approved and signed by the applicant's faculty or staff sponsor and the department chair.

APPLICATION PROCESS: Complete the application and obtain required signatures, then submit one original of the application and all supporting materials to the IRB Chair, Grants Office, P-107B, BMCC-Pendleton.

The IRB chair will notify each applicant of the IRB's decision. If you have questions, please contact the IRB chair at (541) 278-5838.

The principal investigator/project director must supply the following required documentation:

| A copy of all | questionnaires | s or surv | ev instrumer | nts |
|---------------|----------------|-----------|--------------|-----|
| r oopy of un | quodiorinanoc | | ey motramer | 110 |

A copy of informed consent document(s) or minor assent document(s)

Letters of approval from cooperating institutions (if appropriate)

All required signatures

Please type or print responses.

PROJECT TITLE:

Check here if requesting expedited review, and explain why the project merits expedited review:

1. Principal Investigator's Name

(If more than one principal investigator, provide supplementary page with contact information.)

Department

Phone

Mailing Address

Email

Faculty Sponsor (of student project) Phone

Department
Is this a class project? yes no Other?
2. Project Start Date:
Project End Date:
3. Is a proposal for external support being submitted? yes no Agency or Sponsor:
Deadline:

If yes, you must submit one complete copy of the grant proposal with this application. The BMCC Grants Office must approve all grant applications and the IRB all research protocols before the grant proposal may be submitted to the funding agency.

- 4. Is this a continuation of an approved IRB project? yes no lf yes, previous IRB case number:
- Have the investigators completed human subjects research training through the U.S. Department of Health and Human Service, Office of Human Research Protections? yes date of certification: (attach a copy) no

Note: The college expects researchers to read the human subjects administrative procedure. BMCC generally does not require DHHS human subjects training and certification, though the training is recommended. In some instances. the IRB may require a researcher to complete the DHHS training and to present the certificate before beginning the research project.

5. **PROJECT SUMMARY**: The IRB must have sufficient information about what will happen to the subjects in order to evaluate and to estimate possible risks. Assurance from the investigator, no matter how strong, will not substitute for a description of the transactions between the investigator and subject. Provide a **brief, non-technical summary** of the proposed research: purpose and benefits, targeted participants, data-collection procedures, disposition of and access to data, estimated level of risk, risk management procedures, and informed consent procedures.

6. SUBJECT SELECTION:

a. Will any subjects belong to any of the following categories?

Subjects of research involving deception Subjects under the age of 18 years Subjects exposed to discomfort or harassment beyond levels encountered in daily life

| Yes 🗌 |] No | |
|-------|------|--|
| Yes 🗌 |] No | |
| Yes 🗌 | No | |

Subjects of research involving fetuses, pregnant Yes No women, human in-vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions

If subjects belong to any of the above categories, please address in Question #7 special procedures required for informed consent.

| b. | Anticipated age range of subjects: | From | То | |
|----|-------------------------------------|-------|------|------|
| c. | Will subjects be students at BMCC? | All 🗌 | Some | None |
| d. | How many subjects will participate? | | | |

- e. How will subjects be selected, enlisted, or recruited?
- **7. INFORMED CONSENT PROCESS:** Describe the informed consent process and attach a copy of all consent and/or assent documents.
- **8. PROCEDURES:** *Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure.*
- **9. CONFIDENTIALITY AND ANONYMITY:** How will the research protocol maintain and protect subjects' privacy and confidentiality of information?
- **10. RISKS:** Describe all known and anticipated risks to the subject including side effects, risks of placebo, risks of normal treatment delay, etc.
- **11. BENEFITS**: Describe the anticipated benefits.

12. QUALIFICATIONS OF THE PRINCIPAL INVESTIGATOR AND OTHER KEY

PERSONNEL: Describe the job title, responsibilities, academic background, other professional training, and research experience of each individual listed.

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RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- Submitting any changes in project procedures to the IRB for written approval before implementing such changes.
- Communicating with the IRB Chair any problems connected with the use of human subjects once the project has begun.
- Retaining informed consent documents for a minimum of three years after the project ends.
- Reapplying annually for renewal of IRB approval, if the project is <u>not exempt</u> and is unchanged and ongoing, at least four weeks before the expiration date of the current approval. (Approved <u>exempt</u> projects that are unchanged and ongoing require annual renewal application, at least ten business days before the expiration date, using the Exempt Protocol Application form.)

The principal investigator may not initiate any research involving human subjects until written notification of IRB final approval. If the IRB grants conditional approval, the principal investigator must, before initiating the research project, demonstrate to the IRB's written satisfaction that the project will comply with any and all conditions. *Failure to provide all required information will result in return of your IRB application for correction before the IRB will complete its review.*

SIGNATURES: I certify to the best of my knowledge that the information presented is an accurate reflection of the proposed research project and that I have read and will comply with the letter and spirit of the Blue Mountain Community College Administrative Procedure on Research on Human Subjects and the Role of the Institutional Review Board.

Α.

Principal Investigator

B. Approval by Faculty Sponsor of Student Research Projects:

I confirm the accuracy of this application, and I accept responsibility for the conduct of this research, the supervision of human subjects, and maintenance of informed consent documentation as required by the IRB.

Faculty Sponsor

C. Approval by Department Head or Supervisor:

I confirm the accuracy of the information stated in this application. I am familiar with and approve of the procedures that involve human subjects.

Department Head or Supervisor

Admin Procedure 06-2006-0004 Rev. 07-08

Date

Date

Date