MOUNT WACHUSETT COMMUNITY COLLEGE
IRB APPROVAL FORM

☐ Exempt Review ☐ Expedited Review ☐ Full Review

Name of principal investigator: _____ Phone: _____

Principal investigator status: ☐ MWCC Staff ☐ MWCC Student ☐ Other

If other, institutional affiliation: _____

Project title: _____

_____

Proposed Project Dates: from_____ to_____

The above project meets the following criteria (please check the appropriate criteria):

☐ Does not involve human subjects who are members of a special population, such as children, prisoners, pregnant women, mentally challenged persons, and economically or educationally disadvantaged persons

☐ Does not involve sensitive topics

☐ Does not involve deception

☐ Does not involve more than minimal risk to subject

Action taken:

☐ Approved as submitted

☐ Approved pending submission of revision and/or additional information

☐ Received _____(date)

☐ Disapproved

_____ _____

IRB Chair (or designee's) Signature Date

APPLICATION FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS

1. Based on Institutional Review Board Policies, indicate level of review:

   ☐ **Exempt**
   ☐ **Expedited**
   ☐ **Full**

2. PI's Mailing Address: _____
   Email: _____

3. Faculty sponsor (if other than PI): _____ Advisor's phone: _____
   *Required for student research

4. Funding source (including pending) _____
   *Please provide a copy of the grant application if the project is externally funded

5. Research site(s) _____

6. In order for the IRB to evaluate your application, the following required information must be provided:

   ☐ A copy of all questionnaires or survey instruments
   ☐ Informed consent document(s) or minor assent document(s)
   ☐ Letters of approval from cooperating institutions (if appropriate)
   ☐ All required signatures

   Failure to provide all required information will result in return of your application for correction prior to IRB approval.

In the space provided below, or in a separate attachment that clearly addresses each of the items below, provide complete answers to the following questions:

7. **Project Description:** Provide a brief summary of the proposed research. Include the specific aims of the research. Include a description of hypotheses or questions to be answered.

8. **Procedures:** A detailed description of all procedures to be performed on human subjects for the purposes of research must be included. Observational or interview studies should indicate the type of contacts and interactions with subjects and the means of observation to be used. Frequency, duration, and location of interviews, surveys, or observations should be indicated.

9. **Data analysis:** Explain how you are going to answer your study question using the data that you will collect (e.g., statistical tests).

10. **Subject Selection:** Describe the characteristics of the subjects, such as age range, gender, and ethnic background. How will subjects be identified for inclusion in the study? How will they be recruited? Describe any special feature(s) of the study population. Explain the rationale for the involvement of subjects who are likely to be vulnerable to coercion or undue influence, such as children or minors, elderly persons, prisoners, pregnant women, or persons with impaired decision-making ability. If any payments or incentives, financial or non-financial, are offered, describe and justify the nature and amount of the compensation.

Will subjects be less than 18 years of age?	Yes ☐ No ☐
Age range of subjects:	From _____ To _____
Will subjects be students MWCC?	Yes ☐ No ☐
How many subjects will participate?	_____

11. Risks to subjects and steps taken to minimize risks: If the study involves more than minimal risk and/or includes vulnerable populations, describe any potential risks to subjects (including physical, psychological, social, legal, economic, or other) and assess their likelihood and seriousness. Describe the procedure for protecting against or minimizing any potential risks, and steps that will be taken in the event that a subject does experience them.

12. Benefits of the proposed study: This section must present a justification for the proposed study. The discussion should focus on the significance of the new knowledge that is being sought and an evaluation of the potential benefits to individuals and/or society.

13. **Informed Consent Process:** Describe the informed consent process and attach a copy of all consent and/or assent documents. If the study includes a survey, please include a consent statement at the beginning of the survey instrument.

14. **Confidentiality and Anonymity:** How will subjects' privacy and confidentiality be maintained? Please check one of the following options.

☐ Anonymous (direct identifiers, such as names of subjects, or indirect identifiers, such as codes, are never recorded with the research data and therefore cannot be linked to the subjects). Describe how the information will be recorded anonymously.

☐ Confidential (coding or security measures are in place to protect the privacy of individual subjects). Describe the steps you will take to maintain confidentiality, including the identity of the subjects, their responses, and any data that you obtain from private records and/or capture on audiotape or videotape. If audio or video taping subjects, describe the disposition of the data and/or the tapes once the study has been completed.

15. Data security: Please describe how data will be secured. Generally at least two of the following safeguards should be included. If you are using both electronic data and hardcopy data, you will need two safeguards for each type.

Electronic Data: (mark at least two that apply or select "not applicable")

- ☐ Secure network (e.g. firewall)
- ☐ Password access
- ☐ Data recorded anonymously
- ☐ Coded responses, with master list kept as a hardcopy or on a secure network (confidential)
- ☐ Not applicable
- ☐ Other (please specify):

Hardcopy Data: (mark at least two that apply or select "not applicable")

- ☐ Locked office
- ☐ Locked file cabinet
- ☐ Data recorded anonymously
- ☐ Data coded by PI or research team with a master list secured and kept separately (confidential)
- ☐ Not applicable
- ☐ Other (please specify):

16. **Responsibilities of the Principal Investigator:** Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being put into practice. Any problems connected with the use of human subjects once the project has begun, must be brought to the attention of the IRB Chair. The principal investigator and his or her designee are responsible for retaining Informed Consent Documents for a period of three years after completion of the project.

17. **Proof of ethics training:** the principal investigator must provide proof of completed ethics training; please attach.

18. **Signatures:** In preparing this IRB application, I certify that I have read and understand the Procedures and Guidelines of the IRB, and that I intend to comply with the letter and the spirit of the college's policy. I certify to the best of my knowledge the information presented herein is an accurate reflection of the proposed research project.

A. Signature of Principal Investigator

_____ _____

Principal Investigator Date

*If additional co-investigators are involved in the study, use the Researcher Assurance Form for additional signatures.

B. Approval by Faculty Sponsor (required for all students)

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 Date

NOTE: Do not begin collection of data (including pilot studies) until you receive notification that your application has been approved by the IRB/DRB.

MOUNT WACHUSETT COMMUNITY COLLEGE

RESEARCHER ASSURANCE STATEMENT

I have read and understand MWCC's Policies and Procedures concerning research involving the use of human subjects and agree:

1. To accept responsibility for the ethical conduct of this research project.
2. To obtain approval from the college's IRB prior to instituting any change in the research project.
3. To report to the College's IRB serious adverse reactions or unexpected effects on subjects.
4. To submit to the IRB an End of Project Report at the completion of the research project.

a. _____ _____
Researcher's printed name Department/Program

_____ _____
Researcher's signature Date

b. _____ _____
Researcher's printed name Department/Program

_____ _____
Researcher's signature Date

c. _____ _____
Researcher's printed name Department/Program

_____ _____
Researcher's signature Date

d. _____ _____
Researcher's printed name Department/Program

_____ _____
Researcher's signature Date

e. _____ _____
Researcher's printed name Department/Program

_____ _____
Researcher's signature Date

For student research:

I have approved the procedures of the research project described in the attached application. I agree to assist the student with the policies for conducting research involving human subjects.

_____ _____
Faculty research advisor's printed name Department/Program

_____ _____
Faculty research advisor's signature Date