MOUNT WACHUSETT COMMUNITY COLLEGE
IRB APPROVAL FORM

Type 1 Review

Name of contact person: ___________________________ Phone: ___________________________

Faculty research advisor: ___________________________ Advisor’s phone: ___________________________
(for student research)

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 subjects

Research requiring Type 1 review
Action taken:
☐ approved as submitted
☐ approved pending submission of revision and/or additional information
☐ received ___________ (date)
☐ requires Type 2 review

__________________________________________ IRB Chair (or designee’s) Signature ______________________ Date

☐ disapproved

Research requiring Type 2 review
Action taken:
☐ approved as submitted
☐ approved pending submission of revision and/or additional information
☐ received ___________ (date)

☐ disapproved

__________________________________________ IRB Chair (or designee’s) signature ______________________ Date

Action taken:
APPLICATION FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS

The College’s IRB reviews all requests to conduct research involving human subjects. In completing the IRB application, be advised that persons reviewing it may be entirely unfamiliar with the field of study involved. Present the information in non-technical terms. It is the investigator’s responsibility to provide information in typewritten form regarding the procedures, the informed consent process, and supply the required documentation listed at the bottom of this page.

1. Based on Institutional Review Board Policies, indicate which level of review is appropriate for this project:

☐ Type 1 Review: class research projects involving the use of human subjects who are not students in the class and who are not considered to be members of a special population, such as children, prisoners, pregnant women, mentally challenged persons, and economically or educationally disadvantaged persons. Projects involving special populations, sensitive behavioral research, research involving deception, and research that is harmful to the subjects automatically require a Type 3 review.

☐ Type 2 Review: minor changes in previously approved research (within one year), or research activities involving no more than minimal risk and which only include involvement of human subjects in one or more of the categories detailed in the Institutional Review Board Policies.

PROJECT TITLE: ____________________________________________________________

2. Principle Investigator’s Name ________________________________________________

Department _______________ Phone _______________ Mailing Address _______________

Faculty Sponsor _______________ Phone _______________
(required if principle investigator is a student)

3. Project Start Date: _______________ Project End Date: _______________

4. Is a proposal for external support being submitted? Yes__ No__

Agency or Sponsor: ___________________________________ Deadline: _______________
If yes, you must submit one complete copy of the proposal with this application.

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

☐ A copy of all questionnaires or survey instruments

1 Adapted from materials created by the IRB of Fitchburg State College.
☐ 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, provide complete answers to the following questions:

6. **Project Description:** Provide a brief summary of the proposed research. The IRB must have sufficient information about what will happen to the subjects to evaluate and estimate possible risks. Assurance from the investigator, no matter how strong, will not substitute for a description of transactions between the investigator and subject.

7. **Subject Selection:**

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? _____
How will subjects be selected, enlisted or recruited?

8. **Informed Consent Process:** Describe the informed consent process and attach a copy of all consent and/or assent documents.
9. **Procedures**: Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure.

10. **Confidentiality and Anonymity**: How will subjects’ privacy be maintained and confidentiality be guaranteed?

11. **Risks**: Describe all known and anticipated risks to the subject including side effects, risks of placebo, risks of normal treatment delay, etc.

12. **Benefits**: Describe the anticipated benefits.
13. **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.

14. **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

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.

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**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.

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MOUNT WACHUSETT COMMUNITY COLLEGE
REQUEST FOR ANNUAL UPDATE FOR
RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS

Name of contact person: ___________________________ Dept./Program: ____________

Address: ______________________________________ Phone: ________________

Faculty research advisor: _________________________ Advisor’s phone: __________
(for student research)

Project title: ________________________________________________________________

________________________________________________________________________

Project dates: from __/__/____ to __/__/____

Number of subjects who completed the study ______

Number of subjects who are currently involved in the study ______

Number of subjects to be enrolled in the study in the next 12 months ______

Number of subjects who voluntarily withdrew from the study ______

Number of subjects experiencing adverse reactions, complications, or injuries resulting from participation in the study ______

Attach a one page description of the known reasons for voluntary withdrawal of subjects from the study and the adverse reactions, complications, or injuries resulting from the study. Include a brief summary of progress on the project and preliminary results.

______________________________ ____________________________
Primary researcher’s printed name Department/Program

____________________________
Primary researcher’s signature

Date

For Student Research:

______________________________ ____________________________
Faculty research advisor’s printed name Department/Program

____________________________
Faculty research advisor’s signature

Date

______________________________
Committee use only: Date of first IRB approval: __________ IRB project number: __________

Date received by IRB: __________________________ Date approved by IRB: __________
MOUNT WACHUSETT COMMUNITY COLLEGE
REQUEST FOR CHANGE IN PROTOCOL FOR
RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS

Name of contact person: ___________________________ Dept./Program: ___________________________

Address: ______________________________________ Phone: ___________________________

Project title: ____________________________________

Project dates: from ___/___/___ to ___/___/___

Description of proposed changes (Attach additional pages and revised consent forms if needed.):


Justification for proposed changes (Attach additional pages if needed):


Primary researcher's printed name ___________________________ Department/Program ___________________________

Primary researcher's signature ___________________________ Date ___________________________

For Student Research:

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

Faculty research advisor's signature ___________________________ Date ___________________________

Committee use only: IRB project number: ___________________________

Date received by IRB: ___________________________ Date approved by IRB: ___________________________
Complete the following information and submit one copy to the IRB chairperson.

Project title: ____________________________

Name of contact person: __________________ Dept./Program: ______________

Address: ____________________________ Phone: __________________

Project dates: from ___/___/___ to ___/___/___

This is to verify that the above named research involving the use of human subjects was performed according to the procedures approved by the IRB. The research project is now complete.

A total of ______ subjects participated in this research project. ______ subjects voluntarily withdrew from the research project. ______ subjects experienced complications, adverse reactions, or injuries resulting from participation in the research project. All records for this project will be maintained for 3 years by the researcher or faculty research advisor and will be accessible if review of the data is necessary. If the faculty member is no longer at FSC, the Department/Program will maintain the records.

Primary researcher's printed name ____________________________

Department/Program ____________________________

Primary researcher's signature ____________________________

Date ____________________________

For Student Research:

Faculty research advisor's printed name ____________________________

Department/Program ____________________________

Faculty research advisor's signature ____________________________

Date ____________________________

Committee use only:

Date received by IRB: ____________________________ IRB project number: ____________________________
GLOSSARY

ASSENT: Agreement by an individual not competent to give legally valid informed consent (e.g., child or cognitively impaired individual). Failure to object cannot be construed as assent.

ASSURANCE: A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

BELMONT REPORT: A report prepared in 1976 for the National Institute of Health outlining the ethical principles and guidelines to be followed for the protection of Human Subjects of Research. The commission preparing the Belmont Report was authorized by the National Research Act of 1974 (Pub. L. 93-348).

CONFIDENTIALITY: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

DEBRIEFING: Giving subjects previously undisclosed information about the research project following completion of their participation in research. This usage departs from standard English, in which debriefing is getting rather than imparting information.

GUARDIAN: See legally authorized representative.

HUMAN SUBJECT: A living individual about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual; or 2) identifiable private information.

INFORMED CONSENT: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic therapeutic or preventive procedure.

LEGALLY AUTHORIZED REPRESENTATIVE: An individual or judicial or other body who is authorized under applicable state or local law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in research.

MINIMAL RISK: The probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

MINOR: Any person under the age of 18 years.

PARENT: A child's biological or adoptive parent.
PREGNANCY: The period of time from confirmation of implantation of a fertilized egg, through any of the presumptive signs of pregnancy, such as missed menses or by medically acceptable pregnancy tests, until expulsion or extraction of the fetus.

PRINCIPAL INVESTIGATOR OR PRINCIPAL RESEARCHER: The scientist or scholar with primary responsibility for the design and conduct of a research project.

PRISONER: An individual involuntarily confined or detained in a penal institution or an alternative facility including those detained pending arraignment, trial, or sentencing.

PRIVACY: Control over the extent, timing, and circumstances of sharing oneself (intellectually, physically, behaviorally) with others.

PRIVATE INFORMATION: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical records).

PROJECT DIRECTOR: the individual who has been selected to supervise the grant and oversee the daily operations of the grant.

RESEARCH PROTOCOL: The formal design or plan of an experiment or research activity; specifically, the plan submitted to the IRB or designated representative for review and to an agency for research support.

VOLUNTARY: A subject's decision to participate (or to continue to participate) in a research activity that is made free of coercion, duress, or undue inducement.

Note: the design of the forms and the glossary is based on information provided by Fitchburg State College