Mount Wachusett Community College

Institutional Review Board

Policies and Procedures on Human Subjects Research
Revised April 2020

Background

The Mount Wachusett Community College Institutional Review Board is responsible for safeguarding the rights of people who participate in research conducted by members of the college community or others on our campus. This document identifies guidelines and procedures for anyone associated with Mount Wachusett Community College who is conducting research involving human subjects. Any research conducted by MWCC faculty, staff, or students, or sponsored in whole or in part by MWCC must be reviewed and approved prior to the start of the project. Mount Wachusett Community College has established an Institutional Review Board (IRB) to ensure that the College is meeting the objectives of protecting people's privacy, health and safety, and people's ability to participate voluntarily in human subject research and meeting the federal regulations.

Human Subject Research

Research involving human subjects is governed by federal regulations and Mount Wachusett Community College policy. The college assures that it will comply with the Office of Human Research Protection regulations for the Protection of Human Research Subjects.

The United States Department of Health and Human Services defines a human subject as "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 [45 CFR 46.102 (f)]." Research, also defined in 45 CFR 46.102 (d), "means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Journalistic or historical activities that focus on individuals do not meet the definition of research that requires IRB approval.

The Public Health Service Act (Title IV, Part G, Section 491a) required the Department of Health and Human Services (DHHS) to issue regulations for the protection of human subjects of research and to implement a program of instruction and guidance in ethical issues associated with such research. The regulations are codified as Title 45 Part 46 of the Code of Federal Regulations, Protection of Human Subjects (CFR 45.46), issued on

June 18, 1991 and updated on July 14, 2009. These regulations apply to all research involving human participants that is conducted or supported in foreign or domestic settings.

Ethics in Human Research

Mount Wachusett Community College is committed to the ethical guidelines set forth in the federal regulations regarding any human subjects research. The College assures that all activities related to human subjects research, regardless of the source of support, will be guided by the ethical principles as stated in the Belmont Report (located at hhs.gov). These principles include the following important considerations:

Informed Consent*:* Any research that takes place under the College's auspices must have respect for persons as autonomous agents. Therefore, all subjects must be informed about what participation in the project entails. It is important that the researchers ensure that the potential participants understand what is required of them as research subjects. An informed consent form signed by individuals participating in the study is a good way to document agreement. Federal law requires that only individuals that are 18 years or older are capable of giving informed consent. Subjects under 18 years of age may participate in the research project only with the consent of the parent or legal guardian. If children are selected as participants, the research must be explained to them by their parent or guardian in language that they can understand, and they must assent to participate.

The IRB may *waive the requirement for the researcher to obtain a signed consent form* for participants [under Title 45 CFR Part 46.117 (c)] providing the only record linking the subject to the research is the consent form and there will be little potential harm as the result of a breach of confidentiality, *or* if the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required. The waiver will be determined by the IRB.

Voluntary Participation*:* Human subject participation in the research project must be voluntary; it must occur as the result of free choice; it cannot be based on compulsion or obligation. The disclosure of relevant information must be presented to the individual in a manner that is clear, concise and readily understandable. The subject cannot be made to feel they are being coerced.

Inducement to participate: There are times when students may be selected to participate in research. Oftentimes a faculty member may use an inducement to students to participate such as offering extra credit. Caution should be exercised to insure that the inducement is not so large to cloud the student's judgment about what is in his or her best interest. In addition, if extra credit is made available to student participants there must be a procedure in place whereby students not participating may also earn extra credit. Furthermore, students should not be recruited in the classroom as that may compromise the student's confidentiality.

***Identification and minimizing of risks**:* Just about all research involves some risk. It may be physical, social, economic, or psychological in nature. In approving the project, the IRB will make a determination on the risks involved. It will also assess if the risks have been minimized as much as possible without compromising the validity of the research. The IRB will also analyze the benefits of the research, whether the risk is reasonable in relation to its benefits, whether the selection of the subjects is equitable, how informed consent will be sought, and if there are adequate provisions in place to protect the confidentiality of the subjects.

***Research involving deception**:* There may be times when it is necessary to withhold some pertinent information from the subjects when disclosure of this information would likely impair the validity of the study. In such cases, subjects should be told that they are being invited to participate in research in which some features will not be disclosed until their participation has ended or the research has concluded, whichever is more feasible. However, researchers are not to deceive subjects if the research involves physical harm, discomfort or unpleasant emotional experiences all of which, if disclosed, would affect their decision to participate.

***Confidentiality and anonymity**:* It is important that all research involving human subjects maintain their confidentiality. This is especially important if the research involves asking the participants questions regarding their personal life or other information that the individual may not want to be made public. A policy of total anonymity is preferred whenever possible. The researcher must tell the individual who will have access to the data, the purpose of the data, and how the information thus gathered will remain confidential.

Institutional Review Board (IRB)

The goal of the IRB is to protect the rights and welfare of those individuals who agree to participate in research. The review and approval of proposals and activities by the IRB are meant to assist the researchers by having a review that will objectively analyze the potential risk involved to research participants, as well as ways to minimize that risk. As part of the process, the College IRB will evaluate the aforementioned ethical practices in determining risk.

Membership of the IRB consists of **at least** five members. The members will have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members and their diversity, including race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. One of the five members **must be** an individual with no connections to the College.

The MWCC IRB members will include the Vice President of Academic and Student Affairs or their designee, at least one faculty member, at least one representative from the

Office of Student Affairs, at least one representative from the office of Planning, Development, and Institutional Research, and the Chair of the Institutional Research Board and one community member not otherwise affiliated with MWCC either directly or through an immediate family member. At least one (1) member will be a non-scientist and at least one (1) member shall be a scientist. IRB members are approved by the federal Office of Human Research Protections (OHRP) for three years. A list of current board members will be posted on the College website.

The MWCC IRB will meet at least once per year and additionally as needed to review plans for research by members of the institution and those associated with the College who are conducting human subject research. Review of research applications by the IRB can occur electronically. All MWCC personnel will receive notice of the existing Human Subjects Research Guidelines annually.

The responsibility is with the researcher(s) to refer projects to the IRB whenever human subjects are used in research, even if they do not think that the subjects are at a high risk level. Federal legislation places the burden of liability for negligence and harm directly on the researcher and the College. If it is not clear whether the research involves human subjects or whether the activity requires IRB, review, the researcher must seek assistance from the College's IRB in making the determination.

IRB approval must be obtained **prior** to conducting the research; this includes the IRB approval that the research meets exemption status.

Types of Review

There are three types of review conducted by the IRB: ***Exempt Status, Expedited Review, and Full Board Review***. If a researcher or faculty sponsor is not sure which category their proposed research may fall, he/she is encouraged to contact the IRB chair for guidance.

Exempt Status **-** Certain research activities may be exempt from review by the IRB, if approved by the IRB chairperson and confirmed in writing to the principal investigator(s). *Exempt Status* requires review by one member of the Board, preferably its Chairperson, or by one or more of the experienced IRB members so designated by the Chairperson to conduct the review. The determination as to whether a project is exempt from IRB review cannot be made by the principal investigators themselves. Research may be exempt when the only involvement of human subjects falls into one or more of the following categories.

The six federally-approved categories of exemption under 45 CFR 46.101(b) are as follows:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact

students' opportunity to learn required educational content or the assessment of educators who provide instruction. This may include (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, if at least one of the following criteria is met: (i) information obtained is recorded in such a manner that human subjects cannot readily be identified, directly or through identifiers linked to the subjects; (ii) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, educational advancement, employability, or reputation; or, (iii) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make required determinations. In the case of (iii), the IRB conducts a limited review to determine that there are adequate privacy safeguards in place.

3. Research involving behavioral interventions with adults who prospectively agree to the research, when the information collected is limited to verbal or written responses, including data entry or audiovisual recordings. Kinds of behavioral interventions are limited to (1) communication or interpersonal contact with the participant; (2) performance of a cognitive, intellectual, educational, or behavioral task; (3) manipulation of the subject's physical, sensory, social, or emotional environment. Physical exercise, range of motion activities, or other physical tasks are not included under this exemption. The behavioral intervention must be brief in duration, harmless, painless, unlikely to have adverse affects on the participant, and unlikely to cause emotional discomfort, offense, or embarrassment.

   The criteria for when Exemption 3 applies to such research is the same as for Exemption 2, in summary: (1) the information recorded cannot be readily linked back to the subjects in such a manner that subjects' identity can be readily ascertained, directly or through identifiers linked to the subjects; or (2) any disclosure of this information would not place the subjects at risk of certain harms, or (3) the information is recorded in an identifiable manner, even if sensitive, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study.

   Exemption 3 applies to behavioral interventions only. It is not applicable to biomedical research. Additionally, it applies only to research with adults; it is not applicable to research with children.

4. Secondary research involving the use of existing data, documents, records, pathological specimens, or diagnostic specimens, including identifiable private information if at least one of the following criteria is met: (i) the identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not have contact with the subjects, and the investigator will not re-identify subjects; or (iii) the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a 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.

Exemptions 1 and 3-6 are applicable to research studies that use children as subjects. Exemption 2 regarding educational tests is also applicable to research involving children as subjects. However, exemption 2 for research involving survey or interview procedures or observations of public behavior does not apply to research involving children as subjects, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed (45 CFR 46.401 (b)).

Following review of Exempt Status notification, the IRB may request additional information. Once a decision is made to approve or disapprove a project's ***Exempt Status,*** the researcher will be notified on a very timely basis. Proposals and activities that do not meet ***Exempt Status*** may be re-submitted upon making the necessary changes to meet ***Exempt Status*** or to move to an Expedited Review, or they may be withdrawn.

Exempt studies do not require continued IRB monitoring. However, any revisions made to exempt research must be approved by the IRB before their implementation. The principal investigator may not begin the research study until he/she receives written confirmation that the research meets exemption criteria.

The following research activities do **not** qualify for exempt status:

- Surveys or interviews of children or minors (subjects under the age of 18).
- Research studies that use prisoners, pregnant women, the cognitively or mentally impaired, or other "vulnerable" subjects.
- Recorded audio or taped data that presents potential harm to subjects if revealed.
- Studies in which data, documents, or records are labeled in such a manner that subjects can be identified, directly or indirectly, through identifying links (e.g., codes).
- Research studies that involve more than minimal risk to subjects.
- Surveys or interviews collecting sensitive data such as illegal activities, sexual orientation or behavior, memories of abuse, etc., that may be painful or embarrassing to reveal.
- Studies involving deception where an investigator does not disclose the true purpose of the research.
- Observational studies involving sensitive aspects of subjects' behavior or in settings where subjects have a reasonable expectation of privacy.

Expedited Review - Some research projects may be eligible for review through an expedited procedure. Studies which involve no more than minimal risk to the participants may be eligible for an expedited review process. Minimal risk means "that 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" (45 CFR 46.102 (i)).

Expedited Review requires review by one member of the Board, preferably its Chairperson, and by one or more of the IRB members so designated by the Chairperson to conduct the review. Reviewing IRB members will be selected based upon the type of human subject involved.

Expedited review procedures will be used when research involves:

- Students of a special population such as children, pregnant women, prisoners, or mentally challenged persons.
- Sensitive topics.
- Deception.
- More than minimal risk to subjects.

Research that involves human subjects as part of an ***Expedited Review*** must maintain an adequate standard of informed consent as well as confidential data. Any information that is gathered on the subjects must be safeguarded so as to ensure that the data cannot be linked either directly or indirectly to the subject.

The list of categories of research that may be reviewed by the IRB through an *expedited review* involves but is not limited to the following:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part

312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (*NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt*.)

8. Continuing review of research previously approved by the IRB as follows: (a) where (1) the research is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research-related interventions; and (3) the research remains active only for long-term follow-up of subjects; or (b) where the remaining research activities are limited to data analysis; or (c) where no subjects have been enrolled and no additional risks have been identified.

Once a decision is made to approve or disapprove a project the researcher will be notified on a very timely basis. Proposals that are not approved may be re-submitted upon making the necessary changes, be submitted for a different status, or be withdrawn.

Full Board Reviews examine research that involves special populations, sensitive behavioral research, research involving deception, or research that has the potential to harm the subjects. A *Full Board Review* requires a meeting involving a quorum of the IRB members.

Federal regulations **require** that an Institutional Review Board give special consideration to protecting the welfare of special populations, such as children, prisoners, pregnant women, or mentally challenged persons. (It is understood that in some cases, the condition or status of the human subject may not be known prior to the research or the human subject may not self-identify to the research at the time of the research. For example, the researcher may not know the pregnancy status of a woman and the woman may not self-identify such status.) Research involving special populations, sensitive behavioral research, research involving deception, or research that has the potential to harm subjects automatically require a *Full Board Review*. Such a review will require the approval of a majority of members of the IRB.

Once a decision is made to approve or disapprove a project the researcher will be notified on a timely basis. Proposals that are not approved may be re-submitted upon making the necessary changes.

Research Guidelines

If MWCC is the primary institutional affiliation, researchers are responsible for notifying the IRB of human subjects research. All human subjects research conducted by MWCC affiliated investigators must be submitted to the MWCC IRB for review. All researchers must complete a MWCC application for human subjects research and submit to the college Institutional Review Board.

All grants received by the College must be reviewed at the time of award to ensure compliance with the regulations described in these guidelines. This will be done by the Mount Wachusett Community College Office of Planning, Development, and Institutional Research, in conjunction with the principal investigator and overseeing administrator of the grant.

Most educational projects do not require an IRB review under federal law. If there is any possibility that the information obtained through a human subjects research project will be shared with entities outside of the college such as at conference or to publish the results either in print or in an electronic format, the proposed research may require IRB review.

Generally, classroom activities do not require an IRB review if the activity meets ***all*** the following criteria:

- part of pedagogy
- participants are only students and the instructor(s) enrolled in the class
- results are shared only with students and the instructor(s) enrolled in the class
- risk to students is minimal
- members of special populations are not participants (children under 18 years, pregnant women, prisoners, or cognitively impaired subjects)

Faculty and/or staff associated with students who are conducting research are responsible for disseminating the guidelines to those students.

Cooperative Research with Another Institution / Single IRB Policy

There may be times when the College engages in cooperative research with another institution. In such circumstances, one institution may agree to delegate responsibility for initial and continuing review of all or portions of the research activity to the other institution's IRB (45 CFR 46.114). For any portion of the research that the College's researchers do not delegate to another IRB, the researchers remain responsible to complying with MWCC's policies and procedures. The agreement for IRB review of cooperative research must be documented **in writing** with copies furnished to all

involved with the agreement and those ensuring compliance with IRB policies and procedures. Irrespective of the agreement, **each** institution is responsible for safeguarding the right, welfare and confidentiality of the human subjects.

Research being carried out at MWCC may be approved by another institution's IRB. This may happen if (a) the primary researcher is affiliated with another college or university, and has applied to that IRB for oversight; (b) research is being conducted at multiple sites, and IRB approval has been or will be obtained through another affiliated college or university.

In such as case, please note the following:

- If the researcher's primary institution needs verification from MWCC's IRB that it will defer oversight, please contact MWCC's IRB chair.
- Once IRB approval has been obtained from the primary site, the researcher must provide a copy of that IRB approval to the MWCC IRB chair.
- The form for approval of cooperative research must be completed and submitted before research begins.

Ethics Training

MWCC recommends that all researchers involved in human subjects research review guidelines and training materials such as those listed below.

The Office of Human Research Protections (OHRP) offers Educational Resources for Investigators on their website at https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html/assurance-training. This site includes video tutorials.

IRB Records

The IRB will keep adequate documentation of IRB activities including the following:

A. Copies of all research applications reviewed, approved sample consent forms, and reports of any injuries to subjects.
B. Minutes of all IRB meetings to include the names of people attending the meetings, actions taken by the IRB, the vote taken on those actions including who voted for the action, who voted against and who abstained from voting, the reasons for any requested change in the project or project disapproval, a written summary of the discussion of controversial issues and their resolutions, and any dissenting reports or opinions. If a member of the IRB has a conflict of interest in the project, he/she must abstain from a vote on that project.
C. Records of any continuing reviews of project activity.
D. Copies of all correspondence between the IRB and the researchers.
E. A list of all IRB members as required by 45 CFR 46.103 (b) (3).
F. Written procedures for the IRB as required by 45 CFR 46.103 (b) (4).

G. Statements of significant new findings provided to subjects as required by 45 CFR 46.116 (b) (5).

The IRB will provide for the maintenance of records relating to a specific research activity for at least three years after termination of the last IRB. In turn, IRB records will be available for inspection and copying by authorized representatives of the federal Office of Human Research Protection (OHRP) at reasonable times and in a reasonable manner or the requested records will be copied and forwarded to OHRP when requested by an authorized Department of Health and Human Services representative which is the parent agency for OHRP.

As required by 45 CFR 46.103 (b) (3) the IRB records will include a list of the IRB members by name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, etc. sufficient to describe each member's chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant.

The IRB must also have written procedures for (i) conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the College; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than investigators that no material changes have occurred since the previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject 45 CFR 46.103 (b) (4).

Student Research

The Guidelines for Compliance with Federal Regulations for Human Subjects Research apply to student research. Faculty who are overseeing a student who is conducting research involving human subjects are responsible for informing the student about the guidelines and for disseminating the guidelines to the student. Submission of an application to the IRB and approval of the IRB prior to starting the research is required. Research projects that are totally self-contained within the course and among students enrolled in the course only, that do not put the participants at risk, and that will not be shared with entities outside the class do need to submit an IRB application.

Appeals

If the application is denied, the researcher has a right to appeal to the IRB. The researcher should submit a letter to the IRB Chairperson requesting another review and provide an appropriate rationale. An attempt will be made to resolve the problem(s) identified with the proposal. The IRB is the final authority over whether the proposal is approved.

Instructions for Application for IRB Review of Human Subject Research

Before submitting an application to the Institutional Review Board, ensure that you review the College's Guidelines for Compliance with Federal Regulations on Human Subjects Research

The Application for IRB Review of Human Subjects Research is available from the Office of Academic Affairs, and online at mwcc.edu/about-mwcc/offices/academic-affairs/institutional-research-board/

A. Application Submission

Submit **one** copy of the application to the IRB chairperson. Please allow at least **one month for review of the application**, **prior** to the start of the project. Research **may not start** until the project has been approved by the IRB.

Submit application and all supporting documentation via email to the committee chair or by mail to:

IRB Chairperson
Office of Academic Affairs
Mount Wachusett Community College
444 Green Street
Gardner, MA. 01440

An exempt review will be conducted by the IRB chairperson. If necessary, the IRB Chairperson will solicit input from the appropriate member(s) of the IRB or the full IRB.

The IRB will make one of the following decisions:

- The application is approved as submitted
- Approval is granted pending application revisions or the submission of additional materials
- Application is denied approval

B. Application Instructions

Although the IRB is composed of individuals with an academic background, they come from different disciplines. Therefore, the application should be written so that it can be understood by a non-specialist. If the application includes technical terminology, the terminology should be explained.

To facilitate the review of the application, respond to each statement and do not refer the reviewers to information in a previous or later response.

Attach all relevant materials (including copies of all questionnaires or survey instruments, informed consent document templates, letters of approval from cooperating institutions).

Sign the Researcher Assurance Statement/Supervisor Approval portion of the application. If the researcher is a student, then the student and the faculty supervisor must sign.

C. Continuing Review and Submission of the Annual Update

For research that requires full board review that continues beyond one year, it is the responsibility of the researcher to submit a request for Annual Update to the IRB. The first update must be received by the IRB within twelve months following the application approval date. If the IRB determines that a project requires review more often than annually, the researcher will be notified. Projects can be updated annually for a maximum of five years. Continuation of projects beyond five years requires resubmission of the application.

Continuing review is not required for exempt or expedited research, research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable, or research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

D. Reporting Changes in Research Protocol

Any change in an activity that affects the human subjects must be approved by the IRB prior to implementation, except where an immediate change is necessary to eliminate a hazard to the subjects. Researchers should submit a request for approval of a change in the activity and identifying the change in activity to the IRB. If the change in the activity requires a change in the consent form, attach a new consent form to the request for change.

E. Reporting End of Project

When the project is completed, the researcher must send an End of Project report to the IRB. Include the end date of the project.

F. Submission of a Report of Injury

If a subject sustains an injury during the study, the researcher must take immediate action to assist the subject according to the safety policy of Mount Wachusett Community College and notify the IRB within 24 hours of the injury.

G. Reporting Non-Compliance with IRB Policies and Procedures

Any incident of noncompliance with IRB policies and procedures should be reported immediately to the IRB.

H. Record Keeping

The principal investigator, project director, or researcher must retain the approved application and signed consent forms for a minimum of three years following the completion of the project, or longer if required by the IRB. They should be stored in a

secure location to ensure privacy. For student research, the faculty supervisor must retain these documents. The IRB may request copies of these forms. Government funding agencies often require that all documents associated with research be retained for three years following the completion of the project or grant.

I. Forms - Copies of these materials and forms may be made as needed.

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.