IRB Policy and Procedures

Institutional Review Board Members

- William Dixon, Ed.D. (Chair), Institutional Research
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Mission Statement

Monroe Community College's Institutional Review Board (IRB) provides a focus and guiding set of principles to assure the safety of participants in research projects, the provision of full and informed consent by participants, and guidelines for researchers as to the ethical conduct of research.

Purpose

Monroe Community College's Institutional Review Board is a standing committee. Its purpose is to review, approve or disapprove, and to conduct continuing review of research involving human participants. The primary purpose of such review is to assure the protection of the rights and welfare of human participants. Monroe Community College's IRB board meets as needed. An IRB should be properly composed and function according to the Code of Federal Regulations, Title 21, Part 56 and Title 45 part 46. This document will highlight major requirements of both titles as well as local requirements.

Research involving human participants may not be conducted within MCC without prior approval from the IRB.

Membership

An IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at MCC. The IRB shall be qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

In addition to possessing the professional competence necessary to review specific research activities, the IRB shall determine the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

The IRB may not consist entirely of men, or entirely of women, or entirely of members of one profession.

The IRB shall include at least one member whose primary concerns are in nonscientific areas.

The IRB shall include at least one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

Each member of the IRB will be required to complete the Human Subject Protection Program. In addition, attendance at meetings and number of protocols reviewed by scientific members will be reported annually to the Provost.

The IRB shall meet the quorum requirements of one half the boards plus one. This must include the presence of at least one member whose primary concerns are in nonscientific areas.

No member of the IRB may participate in the initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the board.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the board.

The IRB may be called into an interim review session by the Chairperson at the request of any IRB member or institutional official to consider any matter concerned with the rights and welfare of any research participant.

An Acting Chairperson will serve in the Chairperson's absence. In the event that the Chairperson submits a protocol for consideration by a board, or has a potential conflict of interest, an Acting Chairperson must substitute for evaluation of that protocol.

Alternate IRB Members

The IRB can approve the membership of alternate board members. The alternates possess qualifications comparable to the primary board member. Alternates have the same responsibilities as board members and follow the same guidelines. IRB minutes will document when an alternate replaces a board member.

Informational packets to review and meeting agendas will be sent only to primary board members. It is the responsibility of the primary board member to forward the information to their alternate if they are unable to attend a meeting.

The Chairman's alternate is a voting member. A designated member of the IRB will be Acting Chairman in the Chairman's absence.

Qualifications of Investigators

The IRB will consider protocols submitted by qualified investigators. For the purposes of the IRB, all faculty, managers, and administrators could be considered qualified primary investigators.

All investigators who are considering research projects that **involve greater than minimal risk** for participants are required to complete training in Human Participants Protection (see below).

Investigators from outside MCC must obtain approval from the MCC's IRB even for exempt activities.

Definitions

Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Principal Investigator Training in Human Participants Protection for projects that involve greater than minimal risk.

A. Purpose

This policy is intended to assure that all Principal Investigators (PI), Co-Investigators conducting human research that **involve greater than minimal risk**, as defined by regulatory authorities and approved by Monroe Community College's Institutional Review Board have completed adequate training in the protection of human participants.

B. Applicability

This policy applies to all researchers and research staff involved with a project requesting the approval by Monroe Community College's Institutional Review Board.

C. Requirements

- Principal Investigators and Co-Investigators conducting greater than minimal risk studies must provide documentation to the IRB of completion of an acceptable training program in human participant protection before their protocol will be reviewed.
- The recommended training program is Collaborative Institutional Training Initiative (CITI) (www.CITIprogram.org).
- Alternative training programs will be considered acceptable substitutes if they provide a similar depth and breadth of information. The acceptance of alternative programs will be at the discretion of the Chairman of the IRB.
- Documentation of completion of training in human participant's protection will be kept on file by the IRB. The investigator is not required to include this documentation with each protocol submission, but should indicate that documentation is on file.
- Principal Investigators who are not an employee of MCC must sign a Confidentiality Agreement in order to access any information related to a protocol conducted at this site.
- Investigators must be sufficiently qualified by education, training and experience that is appropriate to their role in the research to assume responsibility for the proper conduct of human subject research.
- Investigators should have sufficient time and resources to properly conduct or supervise the research for which they are responsible.
- Investigators are responsible for the safe and secure storage of research data in both paper and electronic formats and protecting the confidentiality of the data.
- Investigators are responsible for the accuracy and completeness of the data recorded and reported in research and in publications about the research.
- Investigators must maintain records appropriate to the research (e.g. the study plan, consent forms, and correspondence from the IRB) and permit inspection of the research records.
- Investigators must maintain records for at least three years after the research ends or for the length of time specified in applicable regulations or applicable institutional or sponsor requirements, whichever is longer, and should take measures to prevent accidental or premature destruction of these documents.

IRB Review

All protocols sent to Monroe Community College's Institutional Review Board will be sent to the chairperson for initial review. The chairperson will determine, based on degree of risk to participants, whether assessment falls under Full-Board Review, Expedited Review or Exempt Category.

Full IRB Review (Research that involves greater than minimal risk)

Monroe Community College's Institutional Review Board have authority to approve, require modification (to secure approval), or disapprove all research activities which come under the jurisdiction of the IRB.

A protocol submitted for consideration by full board review must include all of the elements detailed on the application. Any protocol submission that does not contain all of the required elements as detailed on the application will not be forwarded to the Board for review. The submission will be returned to the investigator for completion.

The IRB shall notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

The IRB's written notification of approval shall include the following specific elements: (1) title of research protocol; (2) name of investigator(s); (3) dates for the submission of progress reports; (4) the requirement to report any increased risk to participants; (5) the requirement that any change in protocol may not be implemented without prior IRB approval; (6) that failure to comply with any of the above requirements will result in the suspension or revocation of the IRB's approval.

Primary Reviewer System

Monroe Community College's Institutional Review Board uses a primary reviewer system. A Primary Reviewer (PR) from the board is identified and receives a complete copy of the IRB protocol submission and has access to all relevant documents for the study. The Primary Reviewer is responsible for reading the protocol in a detailed manner and contacting the Investigator with any questions. The IRB chairperson is also responsible for reviewing all protocols. At the board meeting it will be the responsibility of the Primary Reviewer to present the protocol. Investigators or designee will be required to attend the board meeting to answer questions. If a representative is not present the study may be tabled until the next meeting until a meeting can be scheduled. The IRB Administrator will also have a copy of the protocol and all related study documents.

Each protocol shall be specific regarding the details of the purpose of the study, procedures how the results will be analyzed and interpreted, the risks involved and the monitoring procedures. When applicable, each protocol submission must be accompanied by an informed consent form that meets all requirements (see requirements below).

Expedited Review

The research must involve no more than minimal risk and fall into one of the following categories may receive an expedited review by MCC's Institutional Review Board.

*The following does **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 Expedited Review qualifications are research activities that must incur no more than minimal risk for participants or represent a minor change in previously approved research that involves no additional risks to research participants, in accordance with HHS regulations 45 CFR 46.100. Examples of research activities reviewed on an expedited basis include:

1. Research on educational curricula or teaching methods involving normal educational practices.
2. Research involving the use of educational records if information taken from these resources is provided to the researcher in such a manner that participants cannot be identified.
3. Research on individual or group characteristics or behavior (18 years of age or older) here there is no psychological intervention or deception (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.
4. Collection of data from voice, video, digital, or image recordings made for research purposes.
5. Interviews and interactive surveys on non-sensitive topics.
6. Continuations of approval for previously approved no-risk research with no more than minor changes in procedures.

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

Questions about whether a research activity may be expedited can be directed to the Chair of the Institutional Review Board or the Acting Chair in the chair's absence.

The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. A minor change in protocol or consent form meets the criteria for expedited review.

Under the expedited review procedure, the review will be carried out by the IRB Chairperson and one more reviewer designated by the Chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after full IRB review.

Examples of approval are: recognition packets for participants, formatting changes to the consent form, advertising, formatting changes to advertisements, and administrative changes to a protocol.

The Chairperson of the IRB shall keep all members of the IRB advised of research proposals which have been approved under the expedited review procedure.

Continuing Review

The designated board of the IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less often than once per year.

In conducting continuing review, the responsible board is required to review:

- Number of participants accrued
- Summary of adverse events
- Unanticipated problems involving risk to participants
- Withdrawal of participants
- Complaints
- Summary of any relevant recent literature, interim findings
- Amendments or modifications since last review
- Copy of last signed informed consent if a patient has been enrolled since the last review and any new revisions to the consent document
- If there are no changes in the Informed Consent document the version date on the ICF submitted for renewal should not be revised.
- If there are changes to the Informed Consent Form document, a highlighted copy of the document noting the changes must accompany a cover letter requesting review and approval of the highlighted changes

The above information is listed on the Application for Continuing Review form which must be filled out in its entirety by the investigator. If supplemental information is needed to explain any responses on the Application for Continuing Review, the investigator must forward this information to the IRB. Applications for Continuing Review that are not fully completed including, as appropriate, the provision of supplementary information will be returned to the investigator. This will potentially result in a delay in the board's continuing review and re-approval. If the study is to be terminated, the Principal Investigator is to notify the IRB as soon as possible and submit a completed continuing review form indicating termination.

An expedited continuing review from the Chairperson of the IRB or a designated member of the board is permissible when:

- The protocol is permanently closed to the enrollment of new participants,
- All participants have completed all protocol-related interventions, and
- The protocol remains active only for long-term follow-up of participants.

Or:

- The study was originally approved by expedited review

Exempt Activities

Research activities free of risk will not require IRB review. Research activities involving human subjects in the following categories may be exempt from review by MCC's Institutional Review Board. **The principal investigator/project director is authorized to make the first determination of eligibility for exemption**; however, the IRB bears the responsibility for concurring in that determination based on notice provided by the principal investigator to the Institutional Review Board.

*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:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as: (a) research on regular and special education instructional strategies; (b) 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, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** (b) any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. 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.
4. 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.
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: (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.
6. 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 or 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 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 subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

Questions about whether a research activity may be exempt from human subjects review can be directed to the Chair of the Institutional Review Board or Acting Chair in the chair's absence.

Annual Report

Annually, in June, the IRB Administrator and Chair of the IRB shall prepare a report reviewing the status of protocols that have been considered by the IRB in the past year. A copy of this report will be sent to the IRB members and Provost.

Full Board Review: Primary Reviewer Form

If a Primary Reviewer (PR) feels that an item "needs discussion" or has a specific issue related to their review (other than minor typographical errors), these items must be brought to the attention of the IRB during the review. If these issues are not presented to the IRB, the Principal Investigator (PI) cannot be requested to address the issue or make changes to the consent/protocol.

If there is discovery of a significant issue requiring re-review and vote by the IRB, the PI would be required to address the issue prior to final approval. If this occurs, the three-month window for completing requested changes would start from the latest review.

Requested changes or notes made by the PR directly pertaining to the review, including any typographical errors for formatting modifications should be noted by the PR and given the administrator of the IRB for reference and filing.

Criteria for Approval

The IRB shall determine that all of the following requirements are satisfied before approval of a research protocol is granted.

A. Risks to participants are minimized: (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (b) whenever appropriate by using procedures already being performed on the participants.
B. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits the IRB should consider only those risks and benefits that may result from the research. The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
C. Selection of participants is equitable. In making this assessment, the IRB shall take into account the purposes of the research and the setting in which the research will be conducted.
D. Informed consent will be sought and documented from each prospective participant or the participant's legally authorized representative using a document meeting the informed consent requirements detailed below.
E. A signed copy of the informed consent will be provided to the person signing the form.
F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the participant.
G. Where appropriate, there are adequate provisions to protect the privacy of the participant and to maintain the confidentiality of data.
H. Where some or all of the participants **are likely** to be vulnerable to coercion or undue influence, such as **students, employees, faculty** or persons who are economically or educationally disadvantaged, appropriate additional safeguards shall be included in the study to protect the rights and welfare of these participants.
I. An assessment is made on whether there is an alternative research design or interventions that should be recommended to the investigator to reduce risks associated with the study.

Informed Consent

Basic Elements of Informed Consent

Informed consent document must meet all of the requirements detailed in CFR Title 21, Part 50 as well as Monroe Community College's IRB local requirements detailed below.

1. The first page of the consent form must be printed on Monroe Community College letterhead of the principal investigator's department.
2. The local number of participants anticipated to be enrolled in the study must be listed in consent form**.**
3. The informed consent document must be written at an educational level that is reasonably expected to be understood by the participant ~ 8th grade.
4. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and the identification of any procedures which are experimental.
5. Conflict of Interest Statement – Investigator should state whether he/she is receiving payment for conducting this research.
6. A description of any reasonably foreseeable risks or discomforts to the participant.
7. A description of any benefits to the participant or to others which may reasonably be expected from the research.
8. A disclosure of appropriate alternative procedures, if any, that might be advantageous to the participant.
9. Confidentiality of Records.
10. For research involving more than minimal risk, an explanation as to whether any treatments are available if injury occurs, and, if so, what they consist of, or where further information may be obtained.
11. An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and whom to contact in the event of a research-related injury to the participant.

    Contact Persons

    The consent form must address three (3) areas for participant's questions namely, questions about the research itself, questions about research related injury and questions about the participant's rights. Examples of acceptable wording for this section:

    - "For more information concerning this research you should contact (specify name) at (telephone number) (Note: this person is usually the principal investigator)."
    - "If you believe that you may have suffered a research related injury, contact (specify name) at (telephone number) who will give you further instructions.
    - "If you have any questions about your rights as a research participant, you may email the IRB chairperson at Monroe Community College, William Dixon (wdixon5@monroecc.edu), or call (585) 292-3031."
12. A statement that participation is voluntary, that refusal to participate will involve no penalty to the participant and that the participant may discontinue participation at any time without penalty.
13. The following formatting requirements for consent forms must be met: (a) except for the first page, each page of the consent form must contain a header that includes the title

(complete or abbreviated) of the study; and; (b) each page of the document must include a "page of pages" number style and version date in the footer.

14. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the subject's consent. A statement that the investigator, Monroe Community College or Monroe Community College IRB have the right to terminate the protocol.
15. Any additional costs to the participant that may result from participation in the research.
16. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
17. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the participant.

Signature Page Requirements

Monroe Community College's Institutional Review Board requires that a consent form provide a place for the printed name and signature of the person obtaining consent, the participant, and a witness (if the research is greater than minimal risk). The requirement of a witness is not required by federal regulations; however, Monroe Community College's Institutional Review Board requires this signature for all research with greater than minimal risk to study participants. The intent of the witness is to acknowledge that the participant is giving their consent freely and without reservation, the witness does not need to be present for the entire informed consent process. The witness must be an individual not directly involved in the conduct of the study.

(See "**Sample of a Consent Form**" in the Appendix.)

Waiver of Informed Consent Requirements

The IRB may approve a waiver of some or all of the consent requirements provided that:

- The research involves no more than minimal risk to the participant;
- The waiver will not adversely affect the rights and welfare of the participant;
- The research could not practically be carried out without the waiver; and
- Whenever appropriate, the participant will be debriefed - provided with additional pertinent information after they have participated in the study

The IRB may waive the requirement for written documentation of consent in cases where:

- The principal risks are those associated with a breach of confidentiality concerning the participant's participation in the research, and
- The consent document is the only record linking the participant with the research,

OR

- The research presents no more than minimal risk, and
- The research involves procedures that do not require written consent when performed outside of a research setting.

Adverse Event Reporting

All adverse events which occur during participation in a study protocol under the approval of Monroe Community College's Institutional Review Board (i.e. local adverse events), are to be reported to the IRB.

Administrative Review

Research that has been approved by the IRB may be subject to review by Administration or the Board of Directors. Although these administrative bodies may disapprove a research protocol, these bodies may not approve the research if an IRB board has not approved it.

Suspension of Research

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, the sponsor if applicable, and any regulatory agency such as NSF Administration.

Records

The records of the IRB shall be retained for at least 3 years following completion of the research. Records shall be accessible to authorized representatives including, regulatory agency(s), MCC IRB, department chairman, dean, manager(s) or administrator(s) of the investigator(s) at reasonable times in a reasonable manner.

The Research Office shall prepare and maintain the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants.
2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings, actions taken by the IRB, the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the Investigator.
5. A list of IRB members identified 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.
6. Statements of significant new findings provided to participants.

Conflict of Interest

Any IRB member with a real or potential conflict of interest relative to any business being considered by the IRB must make this conflict of interest immediately known and abstain from the final discussion and voting. The member may provide information requested by the IRB, but may not attempt to influence or otherwise affect the IRB's final deliberations or decision. A conflict of interest may include, but is not limited to the member being an investigator, co-investigator, study coordinator, supervisor or family member of staff conducting a study, or having a direct financial interest in the performance of the study. The financial interest includes equity interests, consulting fees/salary support or intellectual property rights.

This conflict of interest policy extends to all IRB business including board meetings, IRB study audits and inquiries or investigations of misconduct in science.

It is the responsibility of the IRB member to bring any conflict of interest to the immediate attention of the IRB Chairman or Acting Chairman before or during the progress of any board meeting, audit, inquiry or investigation.

Assurance of Member/Alternate Status

The IRB Administrator shall assure that each individual voting on IRB business is either a full board member or an alternate member attending in place of a full member. This will be accomplished by bringing the IRB roster to each board meeting to verify the status of each attendee.

Approvals Pending Revisions

This policy describes the procedures to be followed for verifying that all revisions and additional information requested by the IRB are submitted by the investigator prior to the issuance of a final approval. This policy applies to studies which receive board approval pending revisions.

The IRB Administrator or MCC Chairman will assure all revisions to study submissions have been complied with prior to granting final approval. This assurance shall be documented by the reviewer enumerating items required in the approval letter. The copy of the letter shall be retained in the study file.

Once a Protocol has been given "pending approval", the PI/Research Staff has three (3) months' time to complete the requested changes, unless the IRB Administrator has granted an extension to this time in writing.

If the requested changes cannot be completed within the specified time frame the PI/Research Staff should contact the Research Protections Office for guidance, (most protocols will be required to be resubmitted as new protocols and will be subject to re-review).

Annual Review of MCC Guidelines

The IRB Administrator and MCC Chairman shall complete an annual review of the MCC Policy and Procedure Guidelines during June each year. The guidelines shall be updated to reflect any changes or modifications in policies and procedures or regulations since the last review and approval. A revised copy of the guidelines shall be discussed and approved by the MCC Membership at an annual meeting. If no revisions to the guidelines are indicated, this shall be reported to the MCC and approved by a vote of the members. The guidelines may be revised as needed by a vote of the members at any time between Annual Reviews.

Annual Report

Annually, in June of each year, the IRB Chair and Administrator shall prepare a report reviewing the status of protocols that have been considered by the IRB in the past year. A copy of this report will be sent to the IRB members and Provost.

Quality Assurance Audit

The IRB may routinely audit investigators and studies being conducted under the approval and oversight of the IRB. The Audit process is intended to evaluate the compliance of the investigator and other applicable regulations governing the conduct of the research project. This is also intended to provide investigators with feedback concerning their compliance so that identified deficiencies can be corrected and the investigator achieve voluntary compliance with the requirements of the IRB.

Audit Inspection

Monroe Community College's Institutional Review Board requires that research investigators provide the IRB with a copy of any audit or inspection reports of findings issued to them by regulatory agencies, cooperative groups, the sponsor or the funding agency.

Consent Monitors

Where appropriate, the IRB may require the use of consent monitors. This may include the use of IRB staff or a third party to observe the consent process and the research for protocols approved by the IRB.

Investigator Appeals

Appeals regarding IRB decisions can be submitted, in writing to the IRB by a principal investigator. This process allows the investigator to bring concerns about their individual protocol review to the IRB for reconsideration without compromising the integrity of the IRB review process. If the investigator is not satisfied with the re-review of the IRB an ad-hoc IRB may be assembled. A copy of the appeal will be given to the Provost who can choose the members to conduct the review. The outcomes of the appeals are reported to the appealing investigator. If the investigator appealing is not satisfied with this outcome, he/she can submit a further appeal to Administration (Provost). Administration may not approve research that has not been approved by the IRB.

Guidance on Recruitment of Human Participants Through Advertising

Direct advertising for research participants, i.e. advertising that is intended to be seen or heard by prospective participants, are considered part of the informed consent and subject selection process. The aim of Monroe Community College's Institutional Review Board is to ensure that the information is not misleading to participants. This is especially important when a study may involve participants who are likely to be vulnerable to undue influence, for example students.

When direct advertising is to be used, Monroe Community College's Institutional Review Board must review both the information contained in the advertisement and the mode of its communication. This is to determine that the procedure for recruiting participants is not coercive and that the recruitment material does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

Advertising for recruitment into investigational studies should not use terms such as "new treatment" or "new methods" without explaining that the test is investigational. A phrase such as "you will receive new method" incorrectly implies that all study participants will be receiving newly approved products of a proven worth. Advertisements should not promise "free", when the intent is only to say participants will not be charged for taking part in the investigation.

If an investigator decides to begin advertising for participants after the study has received Monroe Community College's Institutional Review Board approval, the advertising may be considered as an amendment to the ongoing study. When such advertisements are easily compared to the consent, Monroe Community College's Institutional Review Board will review and approve the advertisement using expedited procedures. When the comparison is not obvious or other complicating issues are involved, the advertisement will be reviewed at a convened meeting.

Generally, advertisements should be limited to the information the prospective participants need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements.

- The name and address of the investigator and/or department and the person or office to contact for further information;
- The purpose of the research (e.g. the condition under study or goal of the project);
- In summary form, the criteria that will be used to determine eligibility for the study;
- The time or other commitments required of the participants; and
- A brief list of participation benefits, if any (e.g. a no-cost). Note, payments to participants for participation are not benefits, they are inducements. Advertisements may state that participants will be paid, but they should not emphasize the payment or the amount to be paid.

Data Safety and Monitoring Plan

Given the diversity of research protocols conducted at MCC, it is recognized that a Data Safety Monitoring Plan (DSMP) may not be applicable to some studies. The DSMP submitted with appropriate protocols will be written by the investigator and must answer the following questions:

1. What procedures will you use to monitor the participant's safety throughout the study?
   - Specify whether or not your study involves vulnerable participants
   - Specify the name and contact information of the individual responsible for monitoring the safety environment of the participant
   - List the screening and interim procedures, tests, exams, questionnaires, etc. that will be used to screen out ineligible participants and/or monitor performance.
2. What are your methods of data collection and storage?
   - Indicate who is responsible for the collection and storage of data, where it will be stored, and any security measures needed to properly protect data from inadvertent loss or inappropriate use.
   - Describe the informed consent process and measures to ensure the privacy and confidentiality of study participants
3. Who will verify data accuracy and compliance with the protocol and how often will it be done?
4. Who will monitor the occurrence of adverse events and where will they be documented?
   - Indicate the name and contact information of the individual responsible for monitoring the occurrence of adverse events throughout the study, whether they are anticipated, unanticipated, or serious.
5. To whom and with what frequency will adverse events be reported?
6. What are the criteria for stopping the study all together?
   - specify any conditions that would necessitate early termination
   - indicate who will perform aggregate analyses

Monroe Community College IRB Human Research Protection Program Website

Internet access to Monroe Community College's Institutional Review Board website is www.monroecc.edu/depts/grants/institutional-review-board/.

Specific content on the website includes:

- IRB Application Form
- IRB Guidelines for Submitting an Application
- Exempt Form
- Expedited Form
- Consent Form Checklist
- Student Consent Form
- General (Non-Student) Consent Form
- Policy and Procedures

Incentives and Paying Research Subjects

Incentives (such as gift cards) must be equal and provided to all subjects. Incentives may not be given if the subjects perceive the incentive as a reward for the quality of performance.

Subjects may be paid for inconvenience, time spent, and as reimbursement for expenses. Subjects may not be paid relative to the potential risks of study participation, nor for the amount or nature of a biological material that may be collected as part of the research procedures. Payments should not be judged to be so large as to potentially induce prospective subjects to consent to participate in the research against their better judgment regarding the benefits and risks of participation.

Appendix

- Sample of a Consent Form

Sample of a Consent Form

Participant/Subject Representative

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I will receive a signed copy of this form for my records and future reference.

Print Name of Participant: _____

Signature of Participant: _____ Date: _____

OR

Participant/Authorized Signer

Print Name of Person Authorized: _____

Signature of Person Authorized: _____ Date: _____

Relationship to Participant: _____

Person Obtaining Consent

I have read this form to the participant and/or the participant has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the participant's satisfaction. In my judgment, the participant has demonstrated comprehension of the information.

Print Name: _____

Signature: _____ Date: _____

Witness (if research greater than minimal risk)

The participant has indicated to me that the research has been explained to the participant, that the participant has read (or had read to the participant) this consent form, and that all of the participant's questions have been answered. In my judgment, the participant is voluntarily signing this consent form.

Print Name of Witness: _____

Signature of Witness: _____ Date: _____