

1.11.6 INSTITUTIONAL REVIEW BOARD

(Revised December 2013)

I. PURPOSE

Mountain Empire Community College (MECC) abides by the Code of Federal Regulations, Title 45, Part 46: Protection of Human Subjects (45 CFR 46, revised June 23, 2005). The purpose of the Institutional Review Board (IRB) is to ensure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research studies conducted by or with Mountain Empire Community College employees or students, or on the MECC campus.

This IRB policy was developed in order to establish the IRB as a permanent committee of the college, identify the types of projects that are subject to IRB review, and provide an overview of the IRB approval process. This policy is NOT intended to serve as a comprehensive guide to IRB operational procedures, and should not be construed to take the place of the MECC Institutional Review Board's operational manual.¹

II. AUTHORITY & APPROVAL SEQUENCE

Before the Institutional Review Board will consider any research protocol, the project must be reviewed and approved by the College President and his Executive Staff. The purpose of the President's Staff review is to evaluate the capacity of the college to support the project in terms of staff time, data requests, and other resources. Research protocols that are disapproved by the President's Staff will not be considered by the IRB.

President's Staff approval allows a project to proceed through the IRB review process, but does not guarantee IRB approval. The IRB may disapprove projects that the President's Staff has approved.

The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and MECC policy. Research that has been reviewed and approved by the IRB is subject to continuing review and must be reevaluated at least annually or more frequently if specified by the IRB.

III. PERSONS AFFECTED

- A. Employees and students of MECC who engage in human subject and/or scientific research under the auspices of the college.
- B. Individuals from other organizations seeking to conduct research in collaboration with MECC.
- C. All other individuals or groups seeking to conduct research using MECC resources.

IV. COMPOSITION

The composition of the Institutional Review Board and the procedures for selecting members differ from standing committees at the college because the criteria for IRB membership are largely dictated by federal regulations.

¹ The MECC IRB operational manual, entitled "Mountain Empire Community College Institutional Review Board Guidelines," is maintained by the Grants Coordinator/IRB Manager in the Office of Institutional Advancement.

At minimum, the membership shall consist of:

1. Both men and women;
2. At least five voting members with varying backgrounds;
3. At least one representative from each of the academic divisions:
 - Division of Arts and Sciences
 - Division of Business and Information Technology
 - Division of Health Science and Industrial Technology
4. At least one representative from Student Services;
5. At least one representative with expertise/experience in institutional effectiveness and/or institutional research;
6. At least one member whose background is in scientific areas, and at least one member whose background is in nonscientific areas;
7. At least one representative from the external community, with no affiliation to the college.

The IRB Manager will issue invitations for individuals to serve on the Institutional Review Board, in consultation with the Vice President for Academic and Student Services and Division Deans. Invitations will be issued as needed to replace outgoing members and ensure that the composition of the committee remains consistent with federal guidelines and MECC policy.

All IRB members are required to undergo formal training at the time of their initial appointment to the committee, and participate in refresher training on a regular basis during their service.

Committee members will serve for a term of three years and may be reappointed by mutual agreement between the member, the Chair, and the IRB Manager. The Chair and Vice Chair of the Institutional Review Board shall be elected annually by the membership.

The Grants Coordinator will serve as the administrative liaison, or “IRB Manager.” Alternate voting members may be appointed to serve in the absence of regular members.

The IRB may solicit ad hoc reviewers with specific expertise to assist with reviews of research protocols as needed. Ad hoc reviewers may not vote.

V. WORKING PROCEDURES

A. Meetings

1. Meetings of the IRB will be held as needed. Meeting notices will be distributed by the IRB Manager at least seven (7) days in advance of a meeting.
2. **Quorum:** A majority of the IRB members, including at least one member whose primary concerns are in nonscientific areas, must participate in all decisions and actions of the committee, except in the case of an expedited review procedure.
3. The IRB Manager shall be responsible for recording minutes of all IRB meetings.

B. Application for IRB Review

The IRB Manager will serve as the first and primary point of contact for all inquiries and submissions related to the IRB. Investigators seeking to conduct research on the MECC campus, or

involving MECC employees or students, are required to contact the IRB Manager, who will guide the investigator through the review process, beginning with the President's Staff review.

Upon approval by the President's Staff, the investigator will be required to submit an application to the IRB for a Human Subject Research (HSR) Determination.

If the IRB Chair determines that the proposed research qualifies as human subject research, the investigator will be instructed to apply for an IRB review. The IRB Manager will consult with the IRB Chair and the investigator to determine which type of IRB review is appropriate for the project (Exempt Review, Expedited Review, or Full Review). (See the MECC IRB Guidelines for more information on the IRB review application process.)

Investigators are required to submit the appropriate applications to the IRB two months prior to the anticipated start date of the research project. The IRB must take action within thirty days of application submission.

C. IRB Action

The IRB may take one of five actions, in writing, in regard to proposed human subject research:

1. Exempt from full review
2. Approve
3. Approve subject to requested changes/restrictions
4. Disapprove
5. Suspend or terminate

Investigators **may not** solicit subject participation or begin data collection until they have received IRB approval.