2.050 Institutional Review Board 2.050

Mohave Community College shall create, maintain and utilize an Institutional Review Board to oversee research utilizing human subjects.

Acronyms and Glossary: Definition of terms are located in Appendix 1 of the IRB Handbook.

Institutional Authority: Standard Operating Procedures (IRB Handbook) establish and empower the Mohave Community College (MCC) Human Subjects protection committee. MCC has one committee, registered with the federal Office for Human Research Protections (OHRP) as Institutional Review Board. This committee is hereinafter referred to as "the IRB."

Purpose: The primary purpose of the IRB is to protect the welfare of Human Subjects used in research.

Basic Principles

A. The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in Ethical Principles and Guidelines for the Protection of Human Subjects of Research ("The Belmont Report"), and The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [April 18, 1979.]. The three principles are Beneficence, Justice and Respect for Persons.

B. The following principles apply to all research, including student projects, involving Human Subjects at MCC to ensure that adequate safeguards are provided:

1. Subjects‟ legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.

2. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.

4. Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.

5. Research involving Human Subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions and faculty members for undergraduate research projects.

6. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.

7. All research programs that involve Human Subjects must be reviewed by and must receive approval of a formally constituted review prior to their initiation or prior to initiating any changes to the project. Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

The Authority of the IRB

A. MCC holds a Federal-wide Assurance (FWA) through OHRP. As part of this Assurance, MCC agrees to consider all research involving the use of humans as research participants as being subject to federal regulations regardless of the source of funding, if one or more of the following apply:

1. The research is sponsored by this institution (unless the research is conducted at another institution with which MCC has an "IRB Authorization Agreement" as specified in MCC's FWA); or

2. The research is conducted by or under the direction of any employee or agent of this institution (unless the research is conducted at another institution with which MCC has an "IRB Authorization Agreement" as specified in MCC's FWA); or

3. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution; or

4. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

5. Definition of Human Subjects and Human Subjects Research.

a. Definition of Human Subjects are defined as follows: A human subject is a living individual about whom an investigator (a professional or a student) conducting research obtains data through intervention or interaction with the individual or identifiable private information through any means. Intervention means any physical procedures undertaken with the subject or any manipulation of the subject or the subject's environment for research purposes. Interaction means any communication or other interpersonal contact between the subject and the researcher.

b. Definition of Human Subject Research. Human subject research is any research involving a human subject as defined above. Such research includes that conducted by an outside researcher using subjects associated with the college or district (system of colleges).

6. Scope of Research Covered. All human subject research as defined in the section above is covered by this policy except:

a. Assessment done in the context of a class for the purpose of evaluating student performance, for the purpose of improving teaching or augmenting class content so long as the rights and privacy of individuals are not violated.

b. Research and reporting done in the context of respond to required Federal or State submissions or accrediting bodies so long as the rights and privacy of individuals are not violated.

c. Research in which there is neither intervention nor interaction as defined above and which no results are disseminated by which any individual could be personally identified.

B. The IRB reviews all projects and programs involving Human Subjects in accordance with these Standard Operating Procedures, applicable federal regulations, and sponsor policies and guidelines.

C. The IRB provides continuing advice and counsel to personnel engaged in activities involving Human Subjects.

D. In some instances, students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing, and/or interacting with other individuals. The course instructor is responsible for ensuring that MCC Institutional Review Board processes are followed. If the instructor has any doubt concerning the classification of these activities, they are required to complete the Application for Human Subjects Research Project Form, submit it along with the project and any accompanying consent form(s), cover letter(s), and/or questionnaire(s), have the IRB review these.

E. The IRB has approval authority of human subject projects, and can disapprove, modify or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the College as appropriate. However, the College may not approve the non-exempt research if it has not been approved by the IRB.

F. The IRB has authority to require progress reports from the Investigator or Project Directors and oversee the conduct of the study.

G. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the subjects in that study.

H. The IRB has authority to observe the informed consent process as practiced by any Investigator or Project Director or authorized person in any approved project, especially in cases where the consenter is from a vulnerable population.

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I. The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement) regardless of the location of the records if they are needed to investigate an adverse incident. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going research.

The Institutional Review Board (IRB) Handbook: Detailed information on standard operating procedures as follows of the IRB can be referenced in the IRB Handbook.

The IRB's Functional Relationships
The Membership of the IRB
Management of the IRB
Procedures of the IRB
Operations of the IRB
Record Requirements
Information the Investigator or Project Director Provides to the IRB
Principles of Informed Consent
Special Populations
Student Engaged Research
Conflict of Interest Guidelines
Confidentiality Guidelines
College Research Review Committees

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References: