MCC Mohave Community College

IMPROVING **LIVES.** IMPROVING **COMMUNITIES.**

IRB Handbook

2022-2023

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I. INTRODUCTION

The Mohave Community College (MCC) encourages and supports the scholarly endeavors of students, faculty, and staff of the College. Pursuit of scholarly work and research will often involve the use of Human Subjects for data collection and analysis. MCC's Institutional Review Board (IRB) reviews Human Subjects research proposals to ensure that the rights and welfare of Human Subjects used in research studies by District personnel are protected; that risks have been considered and minimized, that the potential for benefit has been identified and maximized, that all Human Subjects only volunteer to participate in research after being provided with legally effective informed consent, and that any research is conducted in an ethical manner and in compliance with established standards. Those individuals seeking to conduct such research may not solicit subject participation or begin data collection until they have obtained clearance by the MCC Institutional Review Board.

While some research projects involving Human Subjects are considered "exempt" from IRB approval requirements, they must still go through a review process. The types of research generally "exempt" from IRB approval requirements include normal educational practices such as work undertaken as a part of a course, educational tests when the subjects are not identified, and surveys or interviews in which the subjects volunteer and are not personally identified. They all need to be reviewed, but only the IRB can determine "exempt" status.

The Institutional Review Board (IRB) for Human Subjects Research at MCC has responsibility to oversee procedures for carrying out the College's commitment to protect Human Subjects in research. The role of the IRB is to review proposed research projects that involve the use of Human Subjects, ensure that the individuals involved in the project are treated ethically, ensure that all subjects are provided with substantial information about the study and consent to be a subject in the study, and that all private information will be handled with confidentiality. The IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College using Human Subjects.

The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, or the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.

II. INSTITUTIONAL AUTHORITY

These Standard Operating Procedures 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."

III. PURPOSE

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

IV. 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.
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm

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.

V. 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 participant is from a vulnerable population.

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.

VI. THE IRB'S FUNCTIONAL RELATIONSHIPS

A. The IRB functions administratively through the Dean of Instruction's office and the IRB Committee. This structure provides for administrative coordination for the IRB with the various academic and administrative units at MCC.

B. The IRB advises and makes recommendations to the Dean of Instruction, to policy and administrative bodies, and to any member of the MCC community on all matters related to the use of Human Subjects in research.

VII. THE MEMBERSHIP OF THE IRB

A. The IRB is composed of at least five voting members. Alternates and non-voting members may also be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are designated. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting. All appointments are made by the Dean of Instruction, with recommendations from the Associate Deans of Instruction.

B. The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of MCC regulations, relevant law, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.

C. The IRB must include both men and women, at least one member whose primary concerns are in science areas and at least one member whose primary concerns are in nonscientific areas (such as lawyers, members of the clergy, ethicists), and at least one member who is not otherwise affiliated (either directly or through immediate family) with the MCC. No Board may consist entirely of women or entirely of men, or entirely of members of one profession.

D. No person shall be excluded from serving on the IRB based on sex, race, color or national origin.

VIII. MANAGEMENT OF THE IRB

A. The IRB Chair is selected by the Dean of instruction. The Chair has authority to sign all IRB action items.

B. The IRB Vice-Chair is a voting member of the IRB and presides over all convened IRB meetings in the absence of the Chair. The Vice Chair is appointed by the Dean of Instruction, and has authority to sign all IRB action items in the absence of the Chair.

C. The IRB Coordinator is identified by the Dean of Instruction. The responsibilities focus on management of the process, including: updating federal paperwork, preparing IRB meeting

agendas and minutes, assisting investigators or project directors in submitting applications, prescreen proposals, and applications, educating district employees, communicating the IRB determinations to the investigators or project directors as well as communicating as needed with various parties, keeping apprised of current HSR developments, designing and maintain content for web site, and working with the IRB chair to orient new IRB members.

D. Members and alternates of the IRB shall be appointed by the Dean of Instruction with input from the Chair of the IRB for tenure of at least two (2) years. However, the term of appointment may be terminated by notice of the Committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for unwillingness or incapability to serve the committee adequately. In either event, the Dean of Instruction will appoint a replacement. The recommended continuous tenure is two terms. Tenure on the IRB may be extended by recommendation of the IRB Chair and mutual agreement between the member and the Dean of Instruction in consultation with the Associate Deans of Instruction.

E. Initial formal training is required of all IRB members at the time of their initial appointment. IRB members must update their training once every two years. Continuing education of IRB members also will be supported through information resources on the MCC Instruction and Student Services IRB web site.

F. Liability coverage for IRB members is provided through MCC's liability insurance coverage.

G. Consultants or individuals with competence in special areas may be used when deemed appropriate by the IRB Chair and the Dean of Instruction.

IX. PROCEDURES OF THE IRB

A. Training

All MCC Principal Investigators and Project Directors must complete the MCC-approved Human Subjects Research Training prior to submitting research.

B. Application for Human Subjects Research Project

Prospective Principal Investigator or Project Directors (PIs) must submit one (1) original with signatures and one (1) electronic version of the "Application for Human Subjects Research Project Form" to the IRB Committee at least fourteen (14) days prior to any proposal deadline in order to provide time for review and processing. Copies of the form are available on the MCC web site. (See Section XII which outlines the procedures for handling the application.)

C. Applications will be treated as Exempt or Non Exempt

Non Exempt protocols can be either Expedited or Full Board Review. These categories are further detailed below.

D. Exempt Protocols

Under the auspices of the IRB, the IRB Chair or Designee will review the Application for Human Subjects Research Project form to determine if the project is eligible for "exempt" (see below) or expedited review or, if significant risk is inherent in the study, refer the petition to the IRB for full board review. The investigator or project director cannot make this determination.

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise

[see http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.101].

Exempt types of research include:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (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, unless: (i) information obtained is recorded in such a manner that Human Subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the Human Subjects' responses outside the research could 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, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the Human Subjects are elected or appointed public officials or candidates for public office; or (ii) 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 or Project Director 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: (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.

The IRB Chair or Designee, not the Investigator or Project Director, shall make the determination as to whether a project is Exempt or Nonexempt.

E. Expedited Protocols

Under federal regulations certain types of research qualify for an "expedited" review [see http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm]. These are activities that (1) present no more than minimal risk to Human Subjects, and (2) involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list.

Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to Human Subjects.

The list of categories of research that may be reviewed by the IRB through an expedited review is as follows:

(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 non-disfiguring 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 non-research 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 convened IRB as follows:
(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
(b) where no subjects have been enrolled and no additional risks have been identified; or
(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

(10) The IRB Chair or Designee does the initial screening. The IRB Chair or Designee may recommend a project to the IRB for expedited review, for expedited review pending recommended changes/clarifications, or for review by the full board. The IRB Chair or Designee cannot "disapprove" of a project protocol but may table action pending further information/clarifications. The IRB Chair or Designee will inform the PI of its actions. Any disagreement between the PI and, the IRB Chair or Designee must be resolved by the IRB.

The PI will be notified officially of the IRB decision by the MCC IRB Board.

F. Full Board Review
Protocols that involve more than minimal risk must go to Full Board Review.
The PI should allow at least six weeks for projects for full-board (IRB) review. The prospective PI will submit to the IRB Office one (1) original and one (1) electronic copy of the Application for Human Subjects Research form.

In the application form, the Investigator or Project Director assures the IRB that he/she will follow the principles, procedures and guidelines established in the present document and agrees to allow the IRB access to pertinent records or research. In addition, the Investigator or Project Director: 1) should present any information that will aid in evaluating the proposal for compliance with this policy, and 2) must be available to discuss the project and/or consent forms at the discretion of the IRB.

G. Actions of the IRB
The IRB may take one of the following four actions in regard to the proposed project and consent form: Approved, Approved Subject to Restrictions, Tabled, or Disapproved.

1. Approved
   When a project has been approved, the Chair completes the "Action of the IRB" form, signs and dates it, and distributes one copy of the form to the principal Investigator or Project Director, the IRB files, and, if appropriate, the performance site. This form constitutes certification of approval when certifications are requested from various sources (e.g., institutions, funding sources, journals, conferences).

Approval of the project will be based on the following:
a. The extent to which the project makes explicit in design and procedures the protection of subjects‟ rights.

b. Sufficient justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception, should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative.

c. Assurances of acceptable debriefing, if appropriate.
It is the responsibility of the PI to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if such information could adversely affect subsequent data collection in the same study according to the judgment of the IRB, the full explanation may be delayed for a reasonable period of time.

There is an exception to this delay: In those cases in which it is unavoidable to mislead the subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.

d. The adequacy of facilities and other resources necessary for completion of the study and protection of subjects rights.

e. Anticipated benefits, if any.

f. The personal risk to the subject in relation to expected benefits.

g. The adequacy of procedures for securing informed consent from the subject.

h. The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject.

i. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

2. Approved Subject to Restrictions
If the project is approved subject to restrictions, then the Chair completes the “Action of the IRB” form, signs and dates it, and distributes it to the PI as a project approved with restrictions. The PI then must respond to the restrictions as indicated by the IRB. Upon receipt and approval of the responses, the restrictions are removed and the project is then processed as an approved project and distributed as described above.

3. Tabled
Tabled action means that the project was not sufficiently complete for the IRB to reach a final decision. In this case, the PI is notified by the Chair of the IRB or Coordinator and the additional information necessary for completion of the IRB review is requested. In the case of a tabled project, the PI may be invited to attend an IRB meeting to present/clarify the project for the Board.

4. Disapproved If the project is disapproved, the Chair of the IRB completes the "Action of the IRB" form and notifies the PI in writing of the reasons for disapproval. The PI may revise and resubmit his/her project for another review.

H. Continuing Review T
The IRB may conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Principal Investigator or Project Directors will be informed of the annual review by receipt of a Continuing Review Form. This Continuing Review Form is to be completed and returned to the Chair of the IRB along with the informed consent document currently in use with the project being reviewed. The PI will be notified of the action taken (e.g., Approved, Approved Subject to Restrictions, etc.).

When a Continuing Review request is submitted, the IRB Chair shall consider the following: changes to the research, project deviations and violations since the last scheduled review, adverse event reports, reports of unanticipated problems involving risks to subjects and, if available, data safety monitoring reports, and Investigator or Project Director compliance.

If the project and/or other documents used in the project have been amended within the past five years, the PI will be requested to submit a new project incorporating these amendments if such has not previously been submitted.

Pursuant to OHRP guidelines, the IRB approval period may be held constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. However, if an Investigator or Project Director has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB Chair or Co-Chair find that it is in the best interests of individual subjects to continue participating in the research interventions or interactions, and this finding is ratified at the next convened IRB meeting. However, after the expiration of IRB approval, the project or protocol will be considered closed and enrollment of new subjects cannot occur, nor can any data collected be used for research purposes.

I. Procedures Pertaining to Both Initial and Continuing Review
1. The IRB shall have authority to determine which studies need verification from sources other than the Investigator or Project Directors that no material changes have occurred since previous IRB review, particularly: (i) complex projects involving unusual levels or types of risk to

subjects; (ii) projects conducted by Investigator or Project Directors who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; (iii) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources; and (iv) projects where the PI changes the purpose/use to which subjects were informed for providing the data.

2. PIs shall be informed at the time of project approval (both initial and continuing) those changes in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects.

3. PIs shall be informed at the time of project approval (both initial and continuing) that any serious or on-going problems are to be reported promptly to the IRB.

4. Serious or continuing noncompliance by an Investigator or Project Director, or any suspension or termination of activities, is to be reported promptly to the IRB Chair or Designee so that appropriate remedial action can be taken, including, but not limited to, appropriate reporting to the granting agency.

J. Adverse Event Reporting Guidance

1. The Office of Human Research Protections (OHRP) recognizes that any adverse event in a trial is a potentially important occurrence because it may reflect additional risks to subjects. In accordance with their requirements, these regulatory bodies have charged Institutional Review Boards with the responsibility of conducting continuing review of research. Included in this review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103).

2. The PI must promptly notify the IRB Chair and IRB Coordinator of any adverse events in the research protocol (within 48 hours).

3. Per federal regulations, all adverse events will be reported to the Dean of Instruction and the federal office overseeing protection of Human Subjects in research, the OHRP.

K. Close Out of Study Form

1. The study is closed when data collection and analysis are completed within the scope of the IRB approved protocol.

2. If the investigator or project director seeks to do further analysis, or to use and apply the data in ways that deviate from the original purpose stated on the HSR application and reviewed by the IRB, the investigator or project director must submit a new application to the IRB.

X. OPERATIONS OF THE IRB

A. IRB Meetings

1. IRB meetings are scheduled as required.

2. IRB members are notified of the place and time of meeting and the agenda at least seven (7) days prior to the meeting.

B. Reviews

The IRB Chair assigns one primary reviewer and at least one secondary reviewer for each new project, who receive the complete study documentation for review. The primary reviewer is assigned consistent with project content and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. The reviewers, who are assigned based on their expertise, lead the discussion of that project. Other IRB members review summary information only, but have access to complete study documentation upon request. If external reviewers are also assigned, they must be subject to the same conflict of interest and confidentiality policies as IRB members.

C. Voting Requirements

1. Except when an expedited review procedure is used, a quorum of the IRB, duly convened through written notice, shall be a majority of voting members (including at least 1 external community) with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.

2. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines.

3. Principal Investigators or Project Directors, including those who are also IRB members, may offer information and answer questions about their projects at a convened meeting.

4. No member of an IRB shall be involved in either the initial or continuing review of an activity in which he or she has a professional responsibility, except to provide information requested by the IRB. They may not be present during voting, and will not vote on any activity in which they have a conflicting interest (even if this means being unable to continue the meeting because of quorum requirements).

5. In cases where research activities were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions reached at the convened meeting shall supersede any decisions made through the expedited review.

6. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of projects, and individual votes are considered confidential and should not be discussed outside of the meeting context. If during an IRB meeting the Chair moves the

meeting to executive session, any visitors will be asked to leave the room until the executive session has ended.

7. Prior to service all members of the IRB must sign two agreements:
    a. confidentiality agreement
    b. conflict of interest statement

D. Notification

The IRB Office shall officially notify the principal investigator or project directors in writing (email) of the IRB‟s decisions, conditions, and requirements regarding the protocols. If the IRB does not have enough information to review the study, the IRB can table the study.

The IRB has the authority to terminate or suspend its approval of the research in the event of harm to human subjects or if a project is not being conducted in accordance with the Board's conditions and/or requirements. The IRB Office shall officially notify the investigator or project director should this occur.

E. Appeals

The PI may appeal the decision of the IRB when a project has been disapproved or approved subject to restrictions and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the appeal will go back to the IRB. The IRB Chair will convene an ad hoc committee to review the appeal and make a recommendation to the IRB. Then the IRB will make a final determination. The IRB is the final determiner by law. Final disapproval of the IRB cannot be overridden by any institutional official.

F. Amendments to the Project

When a project is modified, an amendment must be completed and provided to the IRB Coordinator within three business days. When the modification is significant, the project director or investigator must request approval by the IRB prior to the modification.

1. Amendments are categorized into minor changes and significant changes:

Minor modification/change - A proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

Significant modification/change - A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Examples of minor changes to a research study include, but are not limited to, the following:

- Addition or deletion of study team members
- Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study

- Removal of research procedures that would thereby reduce the risk to subjects
- Addition of non-sensitive questions to unvalidated survey or interview procedures
- Addition of or revisions to recruitment materials or strategies
- Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors)

Examples of significant changes to a study may include, but are not limited to, the following:

- Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.)
- Addition of research procedures that involve greater than minimal risk to subjects
- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation
- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare
- Change in the purpose of the original project or study or use of the data, from that initially provided to subjects and to the IRB

2. Level of Review for Amendments Significant modifications/changes will generally be reviewed at the same level of review in which the study was first reviewed: by the IRB Chair or Designee, or by the full IRB. If an amendment is determined to increase the level of risk beyond minimal risk, the amendment will be referred to the full IRB.

Minor modifications/changes may be reviewed and approved using an "administrative approval" process. Administrative approval may be given by the IRB Coordinator. Such approvals are then put on the agenda of the next IRB or screening committee, as appropriate, for concurrence.

3. Sponsor Agency Modifications

Modifications can be made only to IRB approved studies. A sponsor agency may modify the research project before the study has received final approval from the IRB. If this occurs, the Investigator or Project Director will immediately notify the IRB and await receipt of the IRB approval letter before making changes to the research project.

Sponsor agency generated modifications (or addenda) require review and approval by the IRB. The Investigator or Project Director will provide all sponsor documentation and summarize how the changes affect the approved project, recruitment, enrollment, treatment and follow-up of participants.

G. Grievances

The IRB Coordinator shall be informed of all grievances (e.g., of a research subject against a PI) and inform the IRB. If the grievance is by a subject, the grievance will go to the IRB. If the grievance is by a PI, the grievance will go to the Dean of Instruction.

H. Cooperative Activities

Cooperative activities relating to Human Subjects are those which involve MCC and another institution. Normally, the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

1. Both institutions have Federal-wide Assurances (FWAs) approved by OHRP;
2. Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties; and
3. The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRBs. The IRB Coordinator will verify (via the OHRP website) that the other institutions have approved FWA's.

XI. RECORD REQUIREMENTS

A. The IRB prepares and maintains adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by Investigator or Project Directors.

2. Detailed minutes of IRB meetings, showing:
   a. Members present (any consultants/ guests/other shown separately).
   b. Results of discussions on debated issues and record of IRB decisions.
   c. Record of voting (showing votes for, against, and abstentions).

3. Records of continuing review activities, updated consent documents, and summaries of on-going project activities. Consent documents are stamped to show IRB approval and date of approval expiration.

4. Copies of all correspondence between IRB and the Investigator or Project Directors.

5. Any statements of significant new findings (unanticipated risks or adverse reactions) provided to subjects.

6. Adverse reactions reports and documentation that the IRB reviews such reports.

7. Emergency use reports.

8. General project information provided to subjects (e.g., fact sheets, brochures).

These documents and records shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug

Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

In addition, the IRB maintains a permanent record of the list of current IRB members, written procedures for the IRB, and self-assessments at least once a year. The IRB will provide an annual report to MCC – for the President and the Governing Board.

B. All forms submitted or retained as evidence of informed consent must be preserved by the Investigator or Project Director indefinitely. Should the PI leave MCC, signed consent forms are to be transferred to the IRB Chair.

XII. INFORMATION THE INVESTIGATOR OR PROJECT DIRECTOR PROVIDES TO THE IRB

A. Professional qualifications to do the research (including a description of necessary support services and facilities);

B. Appropriate MCC Application for Human Subjects Research Project Form (including project summary);

C. Appropriate certification of training in Human Subjects Research

D. Complete study project which includes/addresses:

I. Abstract Describing Project and Purpose:
Briefly describe (a) the project or study and its purpose, and (b) what human participants will experience during the proposed study or project. Describe all strategies or experimental methods to be used, design, and program activities. Indicate what data, measures, or observations will be collected and used in the study or for the project. If any questionnaires, tests or other instruments are to be used, include a brief description and one copy of the instruments.
Special note to Grant Projects Directors: *In the case of educational or training grants, data collected about the participants served, assessment testing, pre- and post-testing and other aspects of project evaluation plans are critical.*

II. Methodology:
Specify who the project participants or research subjects will be. Indicate how they will be solicited, recruited, or contacted. Include any recruitment letters and materials with this document. State how much time will be required of each participant or subject. Describe procedures to which individuals will be subjected. Use additional pages if necessary.

III. Voluntary Participation:
Specify the steps that will be taken to ensure that each individual's participation is voluntary. State what, if any, inducements will be offered for their participation.

IV. Confidentiality of Data and Privacy Protection:
Describe the methods to be used to safeguard the privacy of your participants and ensure the confidentiality of data obtained,
including plans for publication, disposition and destruction of data, including that of computer, print, videotape and audio materials.

V. Informed Consent:
Attach a copy of all consent forms to be signed by the participants and/or any statements to be read to or provided to the participant.

VI. Risks to Participants:
Describe a) any potential risks to participating individuals– physical, psychological, social, legal, or other; b) include all known and anticipated risks to the participants such as side effects, risks of placebo (inert) treatments, etc.; and c) in research that proposes substantial risk to human participants, list emergency backup procedures that are in place such as medical or counseling interventions.

VII. Benefits:
(a) Describe the benefits and/or any compensation that the participating individuals can expect, and (b) describe the gains in knowledge that may result from the project or research study

XIII. PRINCIPLES OF INFORMED CONSENT

A. When an activity does not involve therapy, diagnosis, or management, and a professional/subject relationship exists (e.g., participation in a research project), the subject is entitled to certain information. This information includes a full and frank disclosure of all the facts, probabilities, options, and opinions which a reasonable person might be expected to consider before giving his/her consent. A copy of the signed consent form must be given to the person signing the form and a copy must be kept on file with the Investigator or Project Director as indicated below.

B. The informed consent of subjects will be obtained by methods that are adequate and appropriate. Consent must be obtained from the subjects themselves except when the subjects are not legally capable of giving informed consent because of age, mental incapacity, or inability to communicate. In the case of a minor, the IRB may accept the permission of the minor's parents (or parent) or legal guardian, along with the assent of the minor, in accordance with applicable federal regulations. In the case of other subjects not legally capable of giving informed consent, the IRB may accept the consent from a legally authorized representative. The representative must be authorized either by a power of attorney or a court order.

C. "Informed consent" means insuring that potential subjects and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of

information necessary to such consent are found at
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.116

The IRB may approve a telephonic consent procedure under which the subject's legally authorized representative is sent a faxed or hand-carried version of the informed consent document and a consent interview is conducted by phone while the authorized representative has the document in hand and signs and returns the signed document to the Investigator or Project Director by return fax (or courier) before the subject is enrolled in the study. In cases where this process is used, a witness who is not connected to the study (e.g., as an Investigator or Project Director, coordinator, etc.) should monitor the consent process.

D. The IRB shall determine whether the consent is adequate in light of the risks to the subject and the circumstances of the research. The IRB shall also determine whether the information to be given to the subject or to qualified third parties, verbally or in writing, is a fair explanation of the procedure, its possible benefits, and its attendant hazards. Where debriefing procedures are considered a necessary part of the research plan, the IRB will ascertain that any such debriefings will be complete and prompt. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon (i.e., use lay language appropriate to the subject population).

E. For research involving more than minimal risk to subjects or if determined by the IRB during the ordinary review process to involve more than minimal risk, a compensation for injury statement will be required in the consent form. This statement should clarify who is responsible for any costs associated with any medical treatments required or any personal compensation for injuries received as a result of participation in the research.

F. Some research may not impose on the rights and welfare of Human Subjects so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the Investigator or Project Director to provide subjects with a written statement regarding the research (e.g., a cover letter). Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the PI must include justifiable reasons in the project.

The IRB may also choose to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

G. Informed consent need not be based on full pre-study information. However, it is the responsibility of the IRB to set limits on the incompleteness of such information. Further, in those studies in which it is proposed to mislead the subjects during data collection, the IRB has the responsibility of assessing the degree to which this violates the rights of the subjects, and then setting the limits for such procedures.

XIV. SPECIAL POPULATIONS

A. Children

The following considerations only apply to studies that intentionally target minors. The exemptions listed in 45CFR46.101(b)1 through (b)(6) apply to research involving children except for 45CFR46.101(b)(2) for research involving surveys, interview procedures, or observations of public behavior. Activities listed under 45CFR46.101(b)(2) do not apply to research covered by subpart D, except, research involving observation of public behavior when the investigators(s) do not participate in the activities being observed. Nonexempt studies involving children require parental or guardian consent and participation assent.

B. Vulnerable Populations

Federal Regulations 45CFR46 has special procedures in place that provide additional safeguards for the protection of vulnerable populations. These groups include prisoners, pregnant women, neonates and fetuses. MCC will adhere to 45CFR Part 46 Subpart B and C.

1. Pregnant Women, Neonates and Fetuses

The IRB reviews all guidelines as set forth in Subpart B of 45CFR 46 and approves only the studies that it had determined to fulfill all necessary regulatory requirements. Investigators should describe the rationale and details for the inclusion of pregnant women, fetuses, or neonates in the research. Investigators should ensure that the informed consent form adequately addresses the risk(s) to the pregnant women, fetus, or neonate. The IRB ensures that there is adequate expertise, scientific and scholarly, to review the research and reserves the right to request expert consultation as needed.

2. Prisoners

The IRB will adhere to Subpart C of 45 CFR 46. The IRB will apply the prisoner specific definition of minimal risk as stated in 45 CFR 46.303(d) and will follow the requirements for IRB membership outline in 45 CFR 46.107. Investigators using prisoners as human subjects should provide specific detail and rationale in the human subjects application. Investigators are also required to take extra measures to ensure appropriate informed consent since prisoners may be influenced by their incarceration to participate in research. If at some point a participant in a study becomes incarcerated, it is the responsibility of the Principal Investigator (PI) to notify the IRB. The protocol will then be re-reviewed according to Subpart C. Subpart C of 45 CFR 46 provides four research categories that the IRB may approve for prisoner researcher. The IRB will review the proposed research to ensure one of the four categories is applicable.

C. Native Americans

All studies that take place on tribal land will be reviewed by an IRB member familiar with the subject population and receive approval by the Tribal Counsel. Researchers must document Tribal Council approval or appropriate approval as part of the application process. All research conducted on Tribal Land involving Native Americans must be reviewed by the Full Board IRB except those studies that meet the federal definition as exempt.

D. Other Population Groups Research involving populations groups such as the mentally and physically infirm, and others in conditions of dependency, helplessness, or deprivation, may require additional precautions and procedures to assure their protection. Subjects may be paid to encourage their participation. Where subjects are drawn from particularly vulnerable groups, however, compensation may under certain circumstances cast doubt upon the voluntary nature of their consent. In such circumstances, the IRB may either limit or disapprove compensation.

E. Student Subject Pools

Subject pools are undergraduate students enrolled in particular departmental courses requiring participation in one or more research projects. The IRB provides guidance and oversight of departmental subject pools and review all research requesting subject pool participation. All student participation in subject pool research must be completely voluntary. Departments may provide students with incentives (usually extra credit) to participate in the subject pool.

XV. STUDENT ENGAGED RESEARCH

A. Undergraduate research is to be encouraged. Learning the human subjects process is an important part of a college education. Undergraduates are to be strongly discouraged from engaging in research that poses more than minimal risk to subjects, as they are unlikely to have received sufficient training or experience at MCC to safely conduct such research. Faculty members can encourage course research activities such that students become familiar with developing research proposals that can fall into the exempt or expedited categories.

B. Procedures
1. Classroom projects that involve systematic collection of data and for which the research objective or design is to develop or contribute to generalizable knowledge are considered research. If the student plans to use the data outside of the classroom, then the project is considered research. Such projects should be reviewed by the IRB.

All undergraduate research proposals should be submitted to the Chair of the College Research Review Committee at the college and a member of the MCC IRB.

2. Classroom projects that are designed with the objective of providing students with training about and experience with research methods are not considered research. In these cases, students will not use the data outside of the classroom. Such projects do not require IRB review.

C. Responsibility of Faculty as Course Instructors
1. Faculty are responsible for overseeing their student's conduct of a research project. They have the primary responsibility for ensuring that human subjects are treated ethically in research.

2. Faculty will inform students of the ethical principles for the protection of human subjects in research. This includes providing students with training about human subjects research through the CITI Program online training course.

3. Sponsoring faculty are responsible for student research and thus must serve as the Principal Investigator (PI) and provide his/her signature on the application (American Psychological Association). The student can be identified as the Co-PI.

D. Theses and Dissertations
Research for honor's theses, master's theses, dissertations, and independent research studies is not considered classroom research. As such, these proposals must comply with the usual IRB review procedures.

XVI. CONFLICT OF INTEREST GUIDELINES

A. Investigator or Project Directors will be asked in MCC's Conflict of Interest form whether they have a vested interest in any commercial enterprise associated with any aspect of the project and, if yes, to fully explain and identify the safeguards taken to prevent Investigator or Project Director bias in subject recruitment and/or the consent process.

B. Investigators or Project Directors and IRB members who are MCC employees and who apply for federal grants and contracts are subject to the MCC Conflict of Interest Policy.

C. The Dean of Instruction's Office will forward to the IRB any financial interest disclosures received in connection with proposals for extramural funding that involve Human Subjects.

D. An IRB member is said to have a conflicting interest whenever that IRB member, or spouse, or dependent child of the member:

1. Is an Investigator or Project Director or Co-investigator or Co-project director on the project;
2. Has a "significant financial interest" in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest.
3. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or
4. Has identified him or herself for any other reason as having a conflicting interest.

E. It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which they are a member. If the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that potential reviewers peruse the matters for which they are assigned reviewers immediately upon receipt to determine whether they may have a conflict. If the Chair of the IRB or another IRB member should perceive a conflict of interest, they have a responsibility to bring this matter to the attention of the IRB Chair and the IRB.

F. Typically, there are three distinct phases of an IRB's consideration of a matter: discussion, deliberation and actions (including vote). In general, IRB member(s) who have a real or perceived conflict of interest may remain in the meeting room at the discretion of the IRB Chair during the discussion of the matter in order to provide answers to questions, clarifications, etc. However, said member must leave the meeting room for deliberations and actions/votes regarding the matter.

G. Minutes of IRB meetings will reflect the absence of a member (by name) when he or she leaves the meeting during deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest.

XVII. CONFIDENTIALITY GUIDELINES

1. Research proposals and grant application often include confidential, sensitive or competitive data and information. Examples include personally identifiable information which is outside the scope of what is considered "directory information" provided on MCC students and employees, financial information about students or programs, and innovative programmatic activities.

2. Members will keep confidential and refrain from discussing any such data or information outside of the IRB meeting. This information will remain confined to the IRB meeting (unless federal, state or MCC regulations should require its release through a formal request or funding requirement).

APPENDIX 1:
Acronyms and Glossary

ACRONYMS

DHHS	Department of Health and Human Safety
FDA	Federal Drug Administration
FERPA	Family Educational Rights and Privacy Act
FWA	Federal Wide Assurance
HIPPA	Health Insurance Portability and Accountability Act
HHS	Health and Human Safety HSR Human Subjects Research
IRB	Institutional Review Board
IRB Handbook	Handbook of Standard Procedures of Operation for the IRB
OHRP	Office for Human Research Protection (federal office)
VPSA	Vice President of Instruction and Student Services
Dean	Dean of Instruction

GLOSSARY

ADVERSE EVENT. An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention.

ASSENT. Explicit agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

AUTONOMY. Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

BELMONT REPORT. A statement of basic ethical principles governing research involving Human Subjects issued by the National Commission for the Protection of Human Subjects.

BENEFICENCE. An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.
COHORT. A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.

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 without permission in ways that are inconsistent with the understanding of the original disclosure.

DEBRIEFING. Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

EXPEDITED REVIEW. Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

FEDERALWIDE ASSURANCE (FWA). Agreement that fulfills the requirements of 45CFR part 46 approved by the Secretary of Health and Human Services. MCC has an approved FWA on file with DHHS – Assurance Number FWA0XXXXX. A copy of the assurance is available upon request from the Office of the Dean of Instruction.

FULL BOARD REVIEW. Research that is reviewed at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

GRANT. Financial support provided for a project or research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant.

GUARDIAN. An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care.

HUMAN SUBJECTS. Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, Human Subjects are defined as living individual(s) about whom an investigator 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. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

INSTITUTIONAL REVIEW BOARD. A specially constituted review body established or designated by an entity to protect the welfare of Human Subjects recruited to participate in biomedical or behavioral research. JUSTICE. An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; it is often expressed in terms of treating persons of similar circumstances or characteristics similarly.

LEGALLY AUTHORIZED REPRESENTATIVE. A person authorized either by statute or by court appointment to make decisions on behalf of another person. In Human Subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

MINIMAL RISK. A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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. For

example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

MONITORING. The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design, and subject protections.

OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP). The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving Human Subjects.

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

PROTOCOL. The formal design or plan of an experiment or research activity: specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

RESEARCH. A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

RESPECT FOR PERSONS. An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and those persons with diminished autonomy be protected.

RETROSPECTIVE STUDIES. Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

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". (See also: Minimal Risk.)

VOLUNTARY. Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.