

# **Modesto Junior College**

## **Institutional Review Board**

### **Investigator Guidelines for Research Using Human Subjects**

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## QUICK START OVERVIEW

This outline gives a brief description of steps for investigators to follow when considering a research project that involves human subjects:

1. Determine research methodology and instruments to be used. (Questions used in surveys or focus groups must be attached with application).
2. Prepare for a 3-4 week review process. Do not plan to begin research until approval is obtained.
3. Prepare an informed consent form for participants.
4. Determine how participants will be debriefed, following participation.
5. Develop a plan for retaining and storing data for three years.
6. Complete and submit the MJC IRB Project Review Form ([link](#)) to the IRB Chair with all required attachments.
7. The IRB will inform you of “Exempt”, “Expedited” or “Full Board Review” status.
8. You may attend the IRB meeting that considers your application.
9. You will receive an email explaining the decision of the IRB with instructions if more information is needed:
  - a. Approved
  - b. Approved Subject to Restrictions
  - c. Tabled
  - d. Disapproved
10. If approved, you may begin your project.

# **Modesto Junior College Institutional Review Board Handbook**

## ***I. Purpose***

The role of the Modesto Junior College Institutional Review Board (IRB) is to protect student and employee participants from potential harm that may be incurred during the research process. The IRB will oversee MJC’s compliance with federal regulations regarding research involving human subjects (45 CFR 46) and the promotion of a favorable climate for academic-oriented inquiry. Modesto Junior College encourages and supports the scholarly endeavors of students, faculty and staff at the college. When scholarly work involves the use of Human Subjects for data collection and analysis, the IRB reviews research proposals to ensure:

- The rights and welfare of human subjects are protected
- Risks have been considered and minimized
- The potential for benefit has been identified and maximized
- Human subjects volunteer to participate in research only after being provided with informed consent
- Research is conducted in an ethical manner and in compliance with established standards

Some research projects involving human subjects are considered exempt from IRB approval requirements. Types of research generally exempt from IRB approval include normal educational practices such as work undertaken as 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. **Only the IRB can determine “exempt” status.**

## **The Regulations**

According to Federal Policy (45 CFR 46), all research involving human participants must be requested, reviewed and approved prior to the project’s or activity’s start date, and before any data is gathered or activities commence.

## **District Policy**

Yosemite Community College District Policies and Administrative Procedures

No. 4-8074

### **Policy**

#### **4-8074 Human Subject Research Protection**

The District recognizes the importance of protecting research subjects and their rights to confidentiality as required by law.

The Chancellor shall ensure that the colleges establish procedures to safeguard the rights and welfare of human participants involved in research and other activities related to research projects conducted within the District. Research involving human participants conducted within the District must be reviewed and approved prior to the gathering of data.

Adopted: February 8, 2012



### **Research that does NOT require IRB review or approval:**

- 1) Institutional Research and Planning Projects: Research intended for campus-wide planning or institutional effectiveness is not subject to IRB review and approval. However, it should be noted that College or District research projects that use students or employees as subjects must comply with the same ethical standards applied to external research proposals.
- 2) Student Research Projects: MJC faculty may use research projects as part of the educational activities of their classes, with the understanding that the faculty member is entirely responsible for these projects, including those designed and/or administered by students. Students may not do research using other individuals as the subjects unless it is under the supervision of an MJC faculty member. As an aid to faculty, the IRB is available for discussion of such projects. (see page 16 – Student Engaged Research)
- 3) Student Learning Outcomes Assessment: Review and analysis of aggregated student outcome data is not subject to IRB review.

### ***II. IRB Process Overview***

The IRB is composed primarily of faculty members from disciplines in which research involving human subjects is integral to that discipline's work, administrators who have responsibility for research, institutional researchers, and members from the community. The IRB is administered through the Office of Research and Institutional Effectiveness.

- 1) Research activities involving the use of human subjects must be reviewed and approved by the IRB before data collection can begin. Investigators may not solicit subject participation or begin data collection without written approval from the IRB. Additionally, research projects may not be approved retroactively. **External proposals require approval from the investigator's institution or agency prior to MJC IRB review.**
- 2) MJC employees seeking to conduct research and/or use existing data and information for publication or public presentation purposes (e.g., doctoral dissertations or master's degree theses) are considered external investigators and must go through the MJC IRB review process to gain approval prior to conducting research even if they have access to information as part of their work responsibility. IRB approval is required from the external institution prior to submission to the MJC IRB.
- 3) Any research that claims exemption must be reviewed by the MJC IRB to confirm the claim.
- 4) 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 to scholarly literature. 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.
- 5) Forms, requirements and a checklist of items to be submitted for review can be found here: [\(link\)](#)
- 6) Project proposal requests that involve research on human subjects are to be submitted to the IRB chairperson by the project's Principal Investigator (PI).

### **III. Definition of Human Subjects and Human Subjects Research**

The Office of Health and Human Services regulations defines the term *human subject* as “a living individual about whom an investigator (whether professional or student) who conducts research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information”. *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”. (45CFR46.102 (f))

### **IV. Basic Principles**

The basic principles that govern the IRB in assuring 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>

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 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. Retroactive approval will not be given to projects that begin before going through the IRB process. Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

## ***V. Authority***

The IRB reviews all projects and programs involving human subjects in accordance with the principles and guidelines outlined in this document.

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

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 or District. However, the College or District may not approve non-exempt research if it has not been approved by the IRB.

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

The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB if they are needed to investigate an adverse incident.

## ***VI. Functional Relationships***

The IRB functions administratively through the Office of Research and Institutional Effectiveness. This structure provides for administrative coordination for the IRB with the various academic and administrative units at MJC.

The IRB advises and makes recommendations to the President, Vice Presidents, the Academic Senate, to policy and administrative bodies, and to any member of the MJC community on all matters related to the use of Human Subjects in research.

## ***VII. Membership***

The IRB is composed of at least five voting members from the following constituencies: three faculty members, (at least one with expertise in the health or biological sciences and one with expertise in the behavioral or social sciences), one campus administrator, and one community member. Five alternate members should also be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are designated to alternate. Non-voting members may also be appointed. Faculty appointments are made by the Academic Senate. Administrative appointments are made by the Vice President of Instruction. Community members are appointed by the President of the College.

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 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 MJC policies, relevant law, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.

Appointment of members shall be identified to the federal Office for Human Research Protections (OHRP) – by name, earned degrees, position or occupation and representative capacity.

### ***VIII. The Management of the IRB***

The Director of Research and Institutional Effectiveness will serve as the IRB Chair. The Chair has authority to sign all IRB action items.

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 determined by the IRB members and has authority to sign all IRB action items in the absence of the Chair.

The IRB Coordinator is identified by the IRB Chair to provide support to the IRB. The responsibilities of the Coordinator focus on management of the process, including: updating federal paperwork, preparing IRB meeting agendas and minutes, assisting investigators or project directors to submit applications, prescreening applications, educating district employees, communicating the IRB determinations to the investigators or project directors and 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. The IRB Office will maintain files, track protocols, and ensure continuing reviews of protocols.

Members and alternates of the IRB shall serve for at least two (2) years. 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 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. Tenure on the IRB may be extended by recommendation of the IRB members and mutual agreement between the member and College Constituents.

Formal training is required of all IRB members at the time of their initial appointment. The on-line tutorial can be found at: <https://www.citiprogram.org/index.cfm?pageID=88>. IRB members must update their training once every two years and complete the Training Verification Form. The IRB Office will maintain a log of continuing education completion dates.

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

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

### ***IX. Guidelines and Procedures of the IRB***

#### **A. General Guidelines**

No research project on the MJC campus or involving MJC students may proceed without approval through the MJC *Institutional Review Board* process. As stated above, institutional research projects for the purpose of planning, evaluation and institutional effectiveness do not require IRB approval.

## **B. Application for Research Involving Human Subjects**

Prospective Principal Investigator or Project Directors (PIs) must submit a signed “IRB Project Review Form” to the IRB Office 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 Research and Institutional Effectiveness web page.

## **C. Applications will be treated as Exempt or Non Exempt**

Non Exempt protocols can be either Expedited or Full Board Review. In accordance with the Federal Policy for the Protection of Human Subjects (45 CFR 46), all research involving human subjects is subject to review and must be approved prior to the gathering of any data, including those projects that may fall within the federal exempt categories 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.

Exempt types of research may include:

- 1) Research in which there is neither intervention nor interaction, (such as questionnaires) and where no results are disseminated by which any individual could be personally identified. Interaction is defined as “any communication or other interpersonal contact between the subject and the researcher”.
- 2) 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 where the project is conducted in such a manner that individual human subjects cannot be identified.
- 3) 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.
- 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) 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. These are activities that (1) present no more than minimal risk to Human Subjects, and (2) involve only procedures specified in federal regulations. 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 following categories of research may be reviewed by the IRB through an expedited review:

- 1) 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.)
- 2) Collection of data from voice, video, digital, or image recordings made for research.
- 3) 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).
- 4) 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.
- 5) 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 decision by the MJC IRB.

#### **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 a signed copy of the IRB Project Review Form. Copies of the form are available on the MJC Research and Institutional Effectiveness web page ([link](#)).

#### **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, a signed copy of the “MJC IRB Project Review” form is distributed to the Principal Investigator, the IRB files, and, if appropriate, the performance site. Approval of the project will be based on the following:
  - The extent to which the project makes explicit in design and procedures the protection of subjects’ rights
  - Sufficient justification that the potential benefits or 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
  - Assurances of acceptable debriefing. It is the responsibility of the PI to give each subject an explanation to questions ensuing from participation in the project following its conclusion. In 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 they receive a full debriefing immediately following participation.
  - The adequacy of facilities and other resources necessary for completion of the study and protection of subjects’ rights
  - The personal risk to the subject in relation to expected benefits
  - The adequacy of procedures for securing informed consent from the subject
  - 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, the Chair notifies the PI in writing of the 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 notifies the PI in writing of the reasons for disapproval. The PI may revise and resubmit his/her project for review.

## **H. Continuing Review**

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 ([link](#)). The 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 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.
2. PIs shall be informed at the time of project approval (both initial and continuing), that 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.

## **J. Adverse Event Reporting Guidance**

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

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

### **K. Close of Study**

The study is closed when data collection and analysis are completed within the scope of the IRB approved protocol. The PI will submit a Close of Study email to the IRB with the details of how data will be protected and stored for three years.

## **X. Process for IRB Review**

### **A. 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.

#### **Time required to complete reviews**

Proposals involving no, or even minimal risk should allow at least two to four weeks for the approval process prior to the proposed project's start date. For projects involving moderate risks, a minimum of two months lead time is strongly recommended. Research may not begin until the approval process is complete.

The Chair of the IRB can help determine the anticipated level of risk for the project, the review process that may be likely and what it will entail, and will provide an estimate (with adequate information) as to how long it may take.

### ***The Research Request***

Investigators should complete the "MJC IRB Project Review Form" and attach copies of instruments to be used for data collected, a copy of the Informed Consent letter, and detailed descriptions of the following components:

- a) The project's purpose and proposed timeline
- b) The data needed or that will be collected
- c) The research methodology/design
- d) The means to be used to ensure voluntary participation
- e) The means to be used to ensure participant confidentiality
- f) The measures that will be taken to protect individuals' data both during and after the conclusion of the project

## **B. 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 complete an adequate review of research activities, and 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; and a conflict of interest statement.
8. The IRB will send **external proposals** to appropriate MJC administrators for institutional support (or lack of support) for the proposed research, prior to IRB review. If endorsed, the proposal will go forward to the MJC IRB for review of Human Subjects protocol.

## **C. 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.

## D. 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.

## E. 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.

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

- 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 un-validated 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)

**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 **significant changes** to a study may include, but are not limited to:

- 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.

## **F. Grievances**

The IRB Coordinator shall be informed of all grievances 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 Vice President of Instruction.

## **G. Cooperative Activities**

Cooperative activities relating to Human Subjects are those which involve MJC and another institution. In addition to approvals by other educational institutions, any research involving human subjects at MJC or MJC students must be reviewed and approved by the MJC IRB.

## **XI. *Principles of Informed Consent***

- A. A participant in a research study or project is entitled to certain information, including 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.
- 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.

- 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 IRB may approve a telephone 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.

- D. The IRB shall determine whether the consent is adequate in light of the risks to the subject and the circumstances of the research. 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. Some research may not impose on the rights and welfare of Human Subjects so as to make informed consent a requirement. 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.

The IRB may also choose to 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.
- F. 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.

## ***XII. 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 except, research involving observation of public behavior when the investigator(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. MJC will adhere to 45CFR Part 46 Subpart B and C.
1. **Pregnant Women, Neonates and Fetuses:** 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.** 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.
  3. **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.
  4. **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. Participation in subject pool research must be completely voluntary. Departments may provide students with incentives (usually extra credit) to participate in the subject pool.

### ***XIII. Student Engaged Research***

Undergraduate research is 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 MJC 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.

#### **A. 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 MJC 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.

#### **B. 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.

#### **C. 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. These guidelines apply to MJC employees enrolled in a graduate program as well as outside investigators.

### ***XIV. Conflict of Interest Guidelines***

Investigator or Project Directors will be asked in MJC'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.

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.

#### ***XV. 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 MJC 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 MJC regulations should require its release through a formal request or funding requirement).

## APPENDICES

### ACRONYMS

DHHS	Department of Health and Human Safety
FERPA	Family Educational Rights and Privacy Act
FWA	Federal Wide Assurance
HHS	Health and Human Safety
HSR	Human Subjects Research
IRB	Institutional Review Board
OHRP	Office for Human Research Protection (federal office)

### 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.

**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.

**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 that 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.

## **Contents of an Informed Consent Letter**

Any known risks, benefits, and/or uncertainties for participation must be disclosed to the participant before they engage in the research activity, with an explanation as to what is expected. They must also be informed of their opportunity to opt out of the research study or experiment at any time without any negative effects, penalties, or threats or denial of benefits in any way for nonparticipation.

The following information must be conveyed to each participant prior to participation:

1. Statements about the study that clearly outlines the reasons for the research, an explanation of how the results of the research will be used, the expected duration of the time for participation, a description of any procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the participant;
3. A description of any benefits to the participant or to others which may reasonably be expected from the research;
4. Where applicable, a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation is available, or an explanation as to whether any medical treatments are available if injury occurs; and if so, what they will consist of, and/or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research, and the research participant's rights where applicable, and whom to contact in the event of a research-related injury to the participant;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;
9. A line for indication that the participant is 18 years of age or older or similar way to identify age; and
10. A line for the signature of the participant or legal representative, or a means to electronically verify voluntary participation (except in the case for research with an approved waiver from the Research Office and/or HSRC indicating the written consent is not required).

Reference HHS regulations: 45 CFR 46, 45 CFR.116(a), (b) or (d), 45 CFR 46.117

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