INSTITUTIONAL REVIEW BOARD POLICIES AND PROCEDURES

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IRB FWA No. 00024897

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Macomb Community College
Education • Enrichment • Economic Development

Discover. Connect. *Advance.*

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Deirdre Syms
IRB Chair
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INTRODUCTION

The purpose of this manual is to outline the responsibilities of the Macomb Community College (Macomb) Institutional Review Board (IRB) and provide a written description of IRB policies and procedures for faculty, staff and students conducting human subjects research.

The mission of the IRB is to protect the rights and welfare of human research subjects. The policies outlined herein are in accordance with the U.S. Department of Health and Human Services (DHHS) regulations and guidance on the Protection of Human Subjects (45 CFR Part 46) under the revised Common Rule (2018).

Macomb is responsible for the protection of human subjects for any research activities conducted by, or under the supervision of, its faculty, staff or students, regardless of funding source and the location of the project. Macomb's IRB reviews research proposals involving human subjects and evaluates and protects against risk for those subjects. Macomb and principal investigators are responsible for ensuring that high ethical standards are maintained for all research involving human subjects.

The Macomb IRB reviews human subjects research proposals to ensure that the rights and welfare of human subjects used in research studies by Macomb 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 IRB.

The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor 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 risk to the participants.

Any changes to applicable federal regulations will be implemented immediately, announced, and will supersede these policies and procedures. Macomb IRB policies and procedures will be reviewed and updated as frequently as new federal guidelines are enacted.

Principal investigators are responsible for following the latest version of this document and using the most recent forms that accompany it. Principal investigators should go to http://www.macomb.edu/about-macomb/institutional-review-board/index.html for the most up-to-date information and forms.

PURPOSE OF THE IRB

The purpose of the IRB is to protect the welfare of human subjects participating in research. The IRB fulfills this purpose primarily by evaluating the risks and benefits, if any, to subjects, ensuring that the risks have been minimized, that benefits are being distributed equitably, and that subjects fully understand any risks involved in the research.

INSTITUTIONAL AUTHORITY

Research at Macomb is conducted in accordance with the approved Federalwide Assurance (FWA No. 00024897) on file with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) in which the Macomb IRB #1 is designated as the IRB of record. The Federalwide Assurance (FWA) is an assurance that Macomb will comply with the federal regulations for the protection of human subjects in research. It is a commitment from the Macomb president that the institution will have written IRB procedures, provide review of nonexempt research covered by the FWA, obtain and document informed consent unless otherwise waived in accordance with the regulations, ensure that all collaborating institutions operate under an approved FWA, have formal written agreements of compliance from all nonaffiliated investigators, and the IRB will be provided with sufficient resources to fulfill these responsibilities.

This *Policies and Procedures Manual* establishes and empowers the Macomb IRB. The IRB reviews research projects involving human subjects in accordance with these policies and procedures, applicable federal regulations, laws of the State of Michigan, and any relevant sponsor policies and guidelines.

Individuals seeking to conduct human subjects research may not solicit subject participation or begin data collection until they have obtained clearance by the Macomb IRB. The IRB meets as needed to review research protocols. The IRB is authorized to review, approve, require modifications in, or disapprove research activities using human subjects that are conducted by or through the College. It is important to the institution that the Macomb IRB has a high level of respect from the research community in order to better fulfill its charge and develop trust between all parties concerned.

The IRB senior officer, the Chair, is appointed by the College president to have responsibility for oversight of human subjects research. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the president, provost or their designees. However, the president, provost or their designees may not approve non-exempt research if it has not been approved by the IRB.

Macomb's institutional policy conveys the authority to the IRB to:

- Provide advice and counsel to personnel engaged in research activities involving human subjects.
- Review all research studies involving human participants before their involvement may begin.
- Require revisions in research studies and consent documents as a condition of approval.
- Approve new research studies and the continuation of previously approved studies.
- Disapprove the initiation of new research studies, if necessary for the well-being of participants.
- Monitor the activities of approved studies. This may include a continuing review, if the IRB deems necessary due to the research design or participation of vulnerable subjects. Monitoring may also involve, if justified, verification of compliance with approved studies and informed consent procedures. Verification may include observing the informed consent process as practiced by any investigator or authorized person in any approved protocol especially in cases where the consentee is from a vulnerable population.[1]
- Develop mechanisms for prompt reporting to the IRB of unanticipated problems occurring in approved studies, or in other studies related in context to the approved studies.
- Suspend or terminate a previously approved study, if necessary for the well-being of participants.
- Restrict aspects of a research study if necessary for participant protection.
- Access, and 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 those records, for any reason. 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.

GUIDING PRINCIPLES

The basic principles that govern the Macomb IRB 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*, (45 CFR 46), revised January 19, 2018. For these documents, see http://www.hhs.gov/ohrp/humansubjects/index.html.

The following principles apply to all human subjects research, as federally-defined, and conducted by Macomb, regardless of funding, 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.

[1] Vulnerable populations include minors, prisoners, cognitively impaired, and economically or educationally disadvantaged.

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 otherwise justified scientifically.

5. Research involving human subjects must be conducted and supervised by qualified persons.

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

7. All human subjects research studies (as federally defined below) must be reviewed by and must receive approval by the IRB ***prior*** to their initiation or ***prior*** to initiating any changes to the protocol. Some continuing research studies are subject to periodic review, under certain circumstances, to be carried out no less often than once per year.

DEFINITIONS AND TYPES OF RESEARCH

Research Defined

Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (intended for publication or public dissemination).[2] Proposed research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.

Program evaluations and assessments that are used for internal purposes *only* are not considered to be human subject research.[3] However if the investigator anticipates he/she may want to disseminate the work in the future, IRB approval is required before data are collected.

Classroom research projects conducted for the purpose of learning research methodology usually do not require IRB approval because the activity usually does not meet the federal definition of research. But if

[2] Research is defined in federal regulations revised Common Rule, 45 CFR 46.102(d).

[3] Program evaluations and assessments include internal reviews of academic, occupational programs or services that are conducted to achieve improvements in student outcomes or operational efficiencies. They are not meant to achieve generalizable knowledge, and are not published.

the classroom research will be shared outside the institution, it requires IRB approval. Consult the IRB Chair for more information at IRB@Macomb.edu.

Human Subjects Defined

A human subject is defined as a living individual about whom an investigator (whether professional researcher or student researcher): 1) obtains information or biospecimens through intervention or interaction with the individual (directly or indirectly), and uses, studies, or analyzes the information or biospecimens; or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.[4]

The words "subject" and "participant" can be used interchangeably in describing the individuals who volunteer to be subjects/participants in a research study.

Only human subjects research is subject to IRB review by federal regulation, 45 CFR part 46.101.

Informed Consent

In order to protect and promote individual autonomy, participants must be given the opportunity to provide voluntary informed consent, prior to joining a non-Exempt study. The Informed Consent form is used for this purpose. The form is for researchers to provide a succinct overview of the nature of the research, what participation will entail, and the level of risk anticipated. There are specific, regulatory requirements on the information that must be provided to research participants. They are explained on pages 35-7.

Broad Consent

Broad Consent is a type of Informed Consent that can be used to protect the privacy of subjects and maintain confidentiality of their data that might be stored for, or used for, secondary research. There are specific, regulatory requirements on the information that must be provided to individuals regarding secondary use of their information or biospecimens. It is not expected that Broad Consent will be utilized at this educational institution; hence this type of consent will not be discussed further in this manual.

Intervention

In the context of human subjects research, intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

[4] Human subject is defined in federal regulations 45 CFR 46.102(e).

Benign Behavioral Intervention

For an intervention to be considered benign, it must be brief in duration, harmless, painless and not physically invasive. It cannot have an adverse lasting impact on a subject. The research must not include material or activity that is offensive or embarrassing to subjects.

Interaction between Subject and Investigator

An interaction includes communication or interpersonal contact between investigator and subject. The contact need not be in-person; it includes contact by telephone, email, text, etc.

Minimal Risk

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the 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.

Principal Investigator

The principal investigator (PI) is the lead researcher for a project. He/she is the person who makes the final decisions on a given research project, and hence has the greatest responsibility for it. The PI is responsible for completing an IRB application for any applicable research and must do so prior to recruiting subjects or initiating the research.

Private information

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a person's educational record or medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information) in order for the information to constitute research involving human subjects.

Research Protocol

A research protocol is a written description and scientific rationale for a proposed research activity. The protocol is submitted by the principal investigator to the IRB and includes a discussion of the human subject protection issues that are relevant to the study. At a minimum, the protocol should address the methods, benefits and risks to subjects, experimental procedures, anticipated number of subjects, proposed consent document and consent process to be used, recruitment plan, and appropriate *additional* safeguards if vulnerable subjects are to be enrolled. For more information about Vulnerable Subjects see page 13.

Socio-Behavioral Research

A common type of research conducted at Macomb is socio-behavioral research, which may include surveys, interviews, focus groups, ethnographic or experimental research where risks to the subjects are usually minimal and generally related to the release of information gathered, rather than direct interaction with the physical body. Socio-behavioral research that involves surveys are usually considered low risk, non-invasive, and are usually designated as exempt or expedited status by the IRB.

When reviewing behavioral and social sciences research, the IRB ensures that investigators have made every attempt to minimize risk and possible harm to participants, whether it be social, psychological, economic or physical harm.

Risks to Participants in Socio-Behavioral Research

Potential risks to subjects participating in behavioral, education and social science research could be, but are not limited to, breach of confidentiality, invasion of privacy, validation of bad behavior, stigmatization, embarrassment, impeding educational advancement, and risk to reputation, employability or insurability.

Educational Research

Research that is conducted in an educational setting, involving normal educational practices, is exempt from IRB review. Federal regulations [CFR 45 part 46.101.b(1)] describe normal educational practice 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." College faculty commonly engage in this type of research in which their primary goal is to improve instructional effectiveness. This type of research is exempt from IRB review, UNLESS the faculty intend to publish, present, report, or otherwise make public the results of the research. If any type of dissemination of the research is planned (outside of the college), under federal regulations the PI must complete an IRB review.

Educational Research Planned for Public Dissemination

Normal educational practices, such as educational tests when the subjects are not identified, and classroom activities that are solely for instructional purposes, do not require review by the IRB. But, if the instructor or a student wishes to present or publish information gathered from human subjects in a context beyond the class for which it was gathered, the activity is considered to be research and must be reviewed by the IRB. Any researcher who is in doubt about the above distinction is encouraged to contact the IRB Chair with questions or submit their proposal to the IRB.

When Faculty Simultaneously Engage in Instruction and Research

For faculty engaged in the both the practices of teaching and researching, where classroom research is conducted with the consent of the students, faculty must consider faculty-student dynamics when designing a research protocol. The following research practices should be utilized to avoid the appearance of coercion, favorable treatment for participating students or unfair grading practices:

- A faculty member engaged in classroom research is encouraged to announce research opportunities to the entire class rather than approach individual students.

- To insure that student participation in faculty research is not connected to their grades, the faculty may employ the help of another person to collect and hold data until after grades are submitted.

- Extra credit in a course cannot be an inducement provided for student participation in a faculty member's research project, unless all students may earn the extra credit even if they do not participate in the research. An equivalent option for earning the extra credit must be provided to non-participants in the research.

Whereas classroom research is designed to focus on systematic investigations that lead to improved learning for all students, keeping a balance between systematic investigation and the needs of students in a particular classroom can present unique problems for a professor who is serving simultaneously as teacher and researcher. Please consult an IRB faculty member or IRB Chair for assistance in navigating potential areas of conflict.

Vulnerable Subjects

A vulnerable subject is a person "who is likely to have compromised autonomy relating to decisions about research participation to a degree that would violate the principle of respect for persons."[5] Under federal regulations, vulnerable subjects include the following populations:

1. Minors,[6]
2. Cognitively impaired,
3. Economically or educationally disadvantaged,
4. Prisoners or other persons involuntarily confined.

Given the nature of research conducted at this college, which the IRB anticipates will be socio-behavioral or educational, the IRB expects that the first three categories of vulnerable populations (minors, cognitively impaired and economically or educationally disadvantaged) are those which we are likely to encounter in research proposals. If a PI proposes to conduct research on the fourth group of vulnerable populations (involuntarily confined or prisoners), he/she should reach out to the IRB Chair early in the application process for questions about applicable federal guidelines.

Research involving vulnerable subjects must undergo a Full IRB Review.

[5] Respect for persons is one of the three foundational principles in the Belmont Report and the basis for an IRB. See the Institutional Review Board Member Handbook, Third Edition, by Robert Amdur and Elizabeth A Bankert, page 21.

[6] Michigan State law defines a minor as anyone under the age of 18.

Minors Involved as Research Participants

Minors, i.e., persons under the age of 18, are considered to be vulnerable subjects by federal regulation and state law. As such, the IRB has an obligation to provide additional protections to them when they are subjects of research. The IRB must consider the potential benefits, risks and discomforts of the research to minors and assess the justification for their inclusion in the research.[7] Minors are not permitted to be subjects in any research that has greater than minimal risk, except under the condition in which the risk is smaller than, and justified by, the anticipated benefits to the subject. For research involving minors, the investigators must obtain the consent of at least one parent or guardian, and the *assent* (affirmative agreement) of the minor.[8]

Research involving minors must undergo a Full Board Review. PIs must complete the IRB review application for a Full Board Review.

IRB ORGANIZATIONAL STRUCTURE

The IRB functions administratively under the Office of the President and operationally through the Macomb Office of Institutional Research. This structure provides for administrative coordination for the IRB with the various academic and administrative units at the College.

The IRB advises and makes recommendations to the signatory official and president, to policy and administrative bodies, and to any member of the Macomb community on all matters related to the use of human subjects in research.

IRB Membership

IRB members are appointed for a three-year renewable term on a rotating basis. The IRB is composed of at least five voting members. All appointments are made by the provost and documented by the IRB Chair.

Qualifications

Committee members are required to complete training and should possess broad specific competence sufficient to comprehend the nature of the research, and other competencies necessary for judgments as to acceptability of the research in terms of Macomb policies, relevant law and regulations, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed. Consultants may not vote on proposals.

[7] See 45 CFR 46.404 and 45 CFR 46.405.
[8] See 45 CFR 46.402(b).

Diversity Requirements for an IRB

The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Federal regulations require that an IRB includes at least one member whose primary concerns are in science areas, at least one whose primary concerns are nonscientific areas, and at least one community member who is not otherwise affiliated (either directly or through immediate family) with Macomb. Members with a behavioral/social science or biomedical research discipline should be considered scientists, while members whose expertise would incline them to view research activities from a standpoint outside of a biomedical or behavioral scientific discipline should be considered nonscientists. Degrees in education are considered nonscientific.

No person shall be excluded from serving on the IRB based on sex, race, color, national origin religion, disability or sexual orientation.[9]

IRB Roles and Responsibilities

IRB Signatory Official

The signatory official is an individual who has the authority to make a commitment on behalf of the institution that the appropriate regulatory requirements will be met. This individual is responsible for preparing regulatory documents for review and has the authority to sign the Federalwide Assurance submitted to OHRP. The Macomb IRB signatory official is the vice president of finance, who reports to the president.

IRB Chair

The IRB Chair is the individual assigned with the administrative responsibility for oversight of the human protection programs. On the FWA this role is referred to as the Human Protections Administrator. According to federal regulation, the IRB Chair must maintain knowledge to serve as a regulatory resource on human subjects protection and to ensure that proposals are in compliance with federal regulations and guidelines. The IRB Chair shall have an understanding of ethical issues, state law, institutional policies, and federal human subject research protection issues and regulations. The Chair must be willing to commit the time required and possess administrative and organizational skills involved in conducting committee meetings. The Chair is responsible for assuring the protection of human subject research participants and serving in a leadership role to encourage respect and compliance for the IRB process.

The federal regulatory duties of the Chair may include:

- Reviewing protocols submitted for exempt or expedited review,
- Assigning studies to IRB reviewers,
- Soliciting feedback from one or more reviewers for research receiving expedited review,
- Scheduling IRB meetings, arranging meeting location(s), creating agendas, distributing materials for review, arranging meeting minutes, documenting meeting actions,
- Communicating actions to PIs in a timely manner, and responsible for entering and tracking all related documentation in a database,

[9] The Macomb IRB will follow the Macomb Board of Trustees diversity statement, which is more inclusive than the federal statement.

- Summarizing IRB review recommendations for dissemination to PIs,
- Reviewing and signing letters to PIs and others indicating board actions,
- Approving minor amendments and determining which amendments go to the convened IRB,
- Responding to concerns or complaints from research participants, research staff, or investigators and determining when they should be referred to the convened IRB,
- Leading ongoing development of IRB policies and procedures,
- Reviewing and approving protocol exemption requests or appointing a designee to do so,
- Suspending or terminating research protocols, if necessary,
- Coordinating the reviewing and managing of all documents for the IRB to ensure that:
    - Research protocols are reviewed appropriately and in a timely manner,
    - Records and files are maintained,
    - Information is communicated to the appropriate parties, and
    - Macomb is in compliance with federal human research regulations and other applicable federal guidelines.

IRB Vice Chair (Optional Position)

The IRB Vice Chair is a voting member of the IRB, and in the absence of the Chair, presides over convened IRB meetings. The Vice Chair is appointed by the Chair and has authority to sign all IRB action items in the absence of the Chair. The above duties of the Chair may be assigned to the Vice Chair in the Chair's absence or if a conflict of interest arises. The Vice Chair should be an active, respected member of the IRB who is well informed of the regulations relevant to the use of human participants in research.

Board Members

Members are appointed for a period of three years and may be re-appointed. The term of appointment may be terminated by notice of the board member to the Chair or vice versa. Members are not compensated for their service. 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.

Members are required to meet training requirements, perform the assigned duties for the IRB or notify the Chair of their inability to do so, be available to attend regularly scheduled meetings, acquire and maintain a working knowledge of federal human subject protection through the education and training requirements, review, understand and approve IRB policies and procedures, review protocols prior to meetings, and come to meetings prepared to discuss them.

Alternate Board Members

Alternate members may be appointed to serve at-large or to take the place of a regular appointed member. If both the alternate and the regular member(s) attend the same meeting, only one may vote and the meeting minutes must reflect who is in attendance as the voting member.

Removal of Board Members

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 other manifestations of unwillingness or incapability to

serve the committee adequately. In either event, the Chair will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member and the Chair.

Liability Insurance for IRB Members

Liability coverage for IRB members is provided through the Macomb general liability insurance, whether or not the IRB member is an employee of Macomb.

Training Requirements for IRB Members

Federal regulations require that IRB members must complete the minimum institutional requirement for training to demonstrate knowledge of human subject research, including research ethics.

To complete this requirement, members undergo the no-cost Office of Human Research Protection (OHRP) Online Assurance Training at https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html.

The IRB Chair will maintain electronic copies of training certifications.

Principal Investigators Responsibilities

Principal investigators are responsible for consulting with appropriate IRB staff to determine whether research requires IRB review and approval, regardless of whether or not it is funded research. PIs who intend to gather data as part of evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice **AND** intend to use the data as research data for the purpose of publishing or sharing with a research community or the public at large, must obtain IRB approval from the Macomb IRB **PRIOR** to conducting the activity.

If an IRB review is required, the PI must ensure that an application and research protocol are submitted to the IRB. PIs must comply with IRB decisions, conditions, and requirements and obtain informed consent (except if the IRB deems the research to be exempt) to insure that no human subject will be involved in the research without consent. PIs are responsible for retaining consent documents for three years after research conclusion, and reporting adverse events on an IRB form, reporting any amendments for changes in research, and submitting a final report at the conclusion of each project.

PIs are responsible for being aware of any new research publications in the peer-reviewed scientific literature that may impact their ongoing human subject research in regards to the risks of research subjects.

PIs and their personnel involved in conducting human subject research must agree to maintain in strict confidence the names, characteristics and data gathered from any research instruments, along with any other information or data on any subjects they encounter so as not to conflict with state and federal laws and regulations. PIs and their research personnel must understand that “confidentiality” means they may not discuss nor divulge in any manner a subject’s name or any identifying information or characteristics,

scores, ratings, comments, or information about a subject with anyone who is not an authorized member of the research team.

Confidentiality/Anonymity Must Be Ensured

The PI must ensure confidentiality of subjects' data. Secure data storage, limitation of access, masking of identities, and coding are the best measures to minimize risk of inadvertent disclosure to unauthorized parties. Measures to prevent this problem should be described in IRB applications for studies in which the data collected are sensitive.

Doctoral, Masters and Other Student Researchers

Student researchers, regardless of level (undergraduate, graduate, post-graduate), who are conducting human subject research as part of their degree work must be knowledgeable of human subject research, including ethics. Course projects that are developed solely for academic requirements do not require IRB approval.

Course or dissertation projects that will be, or may be, developed as research to share outside of the institution will require IRB approval. Student researchers, who intend to gather data as part of evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice **AND** intend to use the data as research data for the purpose of publishing or sharing with a research community outside the institution, must obtain IRB approval from the Macomb IRB **PRIOR** to conducting the activity.

Principal and Other Investigators - Knowledge and Training

All investigators involved in human subjects research are required to have knowledge of, and comply with, the following:

- Relevant ethical principles,
- Relevant federal regulations,
- Written IRB procedures – as stated in this Policies and Procedures Manual,
- IRB decisions made on a researcher's proposal,
- State and local laws, and
- Institutional policies.

The OHRP offers guidance for investigators at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html.

There is no requirement in 45 CFR part 46 for principal investigators to be trained in human subjects research. However, an institution holding an OHRP-approved Federalwide Assurance (FWA) is responsible for ensuring that its investigators conducting human subjects research understand and act in accordance with the requirements of federal regulations for the protection of human subjects.[10]

[10] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html

CONFLICT OF INTEREST GUIDELINES

Conflict of Interest Defined

Conflict of interest, defined as a set of conditions in which judgment concerning a primary interest may be biased by a secondary interest, is inherent in the conduct of research. In any given situation, conflict of interest can and should be managed through a system of identification, disclosure, containment, reduction, and elimination.

A conflict of interest may include an affiliation with an organization, company, venture or other body with whom the person has a direct financial interest; this includes any financial benefit, directly or through relatives by blood or marriage, connected to the subject matter or materials of a research proposal. While the focus is often on financial conflicts, which are quantifiable, non-financial interests exist as well. Non-financial interests may clash with the protection of research participants and hence, should also be disclosed and managed when present.

Research Personnel Conflicts of Interest

The IRB requires that PIs provide written information regarding any potential conflict of interest relevant to research studies submitted for IRB review. Investigators will disclose whether they have a vested interest in any commercial enterprise associated with any aspect of the protocol, and, if yes, to fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process.

To ensure that conflict of interest does not compromise the rights and welfare of human participants of research, the IRB will determine:

1. If methods used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human participants;
2. Whether additional actions are necessary to minimize risks to participants; and
3. The kind, amount, and level of detailed information to be provided to research participants regarding a conflict of interest.

IRB Members Conflicts of Interest

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. If assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that potential reviewers examine the documents which they are assigned upon receipt to determine whether they may have a conflict.

Two Levels of Conflicts of Interests

Possible conflicts of interest for IRB members can originate at two levels and may include:

Individual Level Conflicts of Interest

- Member is a researcher on a study under review
- Member holds significant financial interest in research sponsor
- Loyalty to colleagues submitting proposal for review
- Member is very closely tied to area of research under review
- Possible impact of decisions on member's own work
- Personal agenda relates closely to research

Institutional Level Conflicts of Interest

- Pressure or desire to protect or promote the institution
- Concern for institution's reputation or prestige
- Promotion of research vs. protection of human participants
- Potential liability concerns
- Pressure for rapid reviews

A conflict of interest is appropriately managed by adhering to the following two restrictions on all IRB members:

1. No IRB members will participate in the review of or vote on any research study in which the member has a conflict of interest, except to provide information requested by the IRB; and

2. Members with a conflict of interest will be excused from the final deliberation to prevent them from voting on studies in which they have declared a potential conflict of interest;

A member with a conflict of interest will be required to recuse him/herself and leave the room during final deliberation and voting for any research in which the member has a potential conflict of interest. Such members are excluded from the quorum count for the study being considered. The meeting minutes will reflect by name all individuals not participating due to a conflict of interest and their absence from the room and re-entry.

IRB members are permitted to vote on studies submitted by members of their own department or division, because often they are the most knowledgeable about the topic being investigated, but only if the IRB member has no other potential conflicting interest, such as responsibility for the design, oversight or supervision of the study. Members who believe they have been involved in attempts by investigators or others to influence the review of a particular study will bring the matter to the attention of the IRB Chair. The member may be advised to recuse him/herself or abstain from the final deliberation and vote if a perceived conflict of interest exists.

Institutional Officials and Potential Conflict

As academic institutions have increasingly entered into financial and collaborative research arrangements with private industry, institutional conflicts of interest have become a topic of growing concern and increasing public scrutiny. To avoid conflicts of interest, executive leaders such as trustees, president, provost and vice presidents shall not serve as an IRB board member unless a compelling situation exists.

TYPES OF IRB REVIEW

Following federal regulations and guidelines, there are three types of IRB review: Exempt Status Determination, Expedited Review and Full IRB Review. Depending on the level of risk of the research protocol and the participant population, IRBs may conduct either Full IRB Review or Expedited Review. The IRB Chair makes the Exempt Status Determination without consultation with the IRB members. The circumstances under which this occurs are outlined below.

Exempt Status Determination

Only the IRB Chair or designee, not the PI, has the authority to make the exempt status determination. Certain low-risk research is exempt from the requirements in the federal regulations concerning IRB review and approval. Under federal regulations, certain categories of activity are considered research but may be declared exempt from review by the IRB. This determination must be made by the IRB Chair prior to the research being conducted. If a study falls into one of the exempt categories, researchers still have ethical responsibilities to protect participants' rights.

There are eight federally-approved categories of exemption. [11, 12] They are as follows:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as: (a) research on regular and special education instructional strategies; (b) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods. To qualify as exempt, the research must not be likely to adversely impact the student's opportunity to learn the educational material or impede their assessment of the instructor.

2. Research that **only** includes the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless:** (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** (b) any disclosure of the human subjects' responses outside the research reasonably places the subjects at risk of criminal or civil liability or damage to the subjects' financial standing, employability, reputation or educational advancement; **and** (c) the research protocol does not provide adequate privacy and confidentiality protections to the subjects.

   For some studies that qualify under Exemption 2, the IRB will conduct a limited review to insure there are adequate privacy and confidentiality protections in the study.

[11] See federal regulation 45 CFR 46.104.

[12] The sixth category of exemption involves taste and food quality evaluations and consumer acceptance studies. It may involve restrictions on additives, ingredients by the FDA, EPA and other federal agencies and departments. The Macomb IRB does not anticipate studies of this nature at Macomb, and does not possess the qualifications to conduct reviews of proposed research in this category.

3. Benign behavioral intervention research (see description, page 11) involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior that is **not** exempt under Category 2 if: (a) Information recorded cannot be readily linked back to the subjects in such a manner that subjects' identity can be readily ascertained, directly or through identifiers linked to the subjects; **or** (b) Any disclosure of this information would not place the subjects at risk of certain harms; or (c) Information is recorded in an identifiable manner, even if sensitive, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study. Exemption 3 is NOT applicable to biomedical research or research involving minors.

Seek guidance from the IRB Chair if unclear as to whether or not a research proposal would be considered benign.

For some studies that qualify under Exemption 3, the IRB will conduct a limited review to insure there are adequate privacy and confidentiality protections in the study.

4. Secondary research involving the study of identifiable information (e.g., data, case files, etc.) or identifiable biospecimens under one or more of the following conditions:

a. The identifiable materials are publicly available, **or**
b. Information is recorded by the investigator in a non-identifiable manner, **or**
c. The research involves the secondary use of private health information regulated under HIPAA, **or**
d. The research is conducted by or on behalf of a federal agency, using data collected by the government for nonresearch purposes, **AND** the information is subject to federal privacy standards and other requirements specified under 45 CFR 46.104(d)(4).

5. Research and demonstration projects which are conducted by or supported (e.g., grant funded) by a federal agency, and which are designed to study, evaluate, or otherwise examine:

a. Public benefit or service programs; **or**
b. Procedures for obtaining benefits or services under those programs; **or**
c. Possible changes in, or alternatives to, those programs or procedures; **or**
d. Possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies:
Not applicable to Macomb Community College

7. Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research. This exemption can apply when the materials were originally obtained for nonresearch purposes or for research other than the current research proposal. This exemption can apply **ONLY IF Broad Consent was obtained** from the subjects for the secondary research of their identifiable materials.

For studies that qualify under Exemption 7, the IRB will conduct a limited review to insure there are adequate privacy and confidentiality protections in the study.

8. Secondary research on identifiable private information or identifiable biospecimens that were originally obtained for nonresearch purposes or for research other than the current research proposal.

There are four requirements that must be satisfied for Exemption 8 to apply:

a. Broad consent must be obtained from the subjects for the secondary research on their identifiable materials, **and**
b. Documentation or waiver of documentation of informed consent must be obtained, **and**
c. An IRB must conduct a limited review to make certain determinations relating to privacy and confidentiality protections and broad consent, **and**
d. Investigators cannot include the return of individual research results to subjects in the study.

For studies that qualify under Exemption 8, the IRB will conduct a limited review to insure there are adequate privacy and confidentiality protections in the study.

Expedited Review

Under federal regulations [45 CFR 46.110] certain types of research may qualify for an Expedited Review. For certain kinds of research involving no more than minimal risk, and for minor changes in approved research, the IRB Chair or designated voting member(s) review the proposed research, rather than the entire IRB. An expedited reviewer can approve research, but cannot disapprove research; rather, the application must go to the full IRB for review.

While personal identifiers may be collected, the method of data collection does not determine the level of risk. For example, it cannot be assumed that research poses minimal risk because it involves only survey or interview data collection. Surveys and interviews can include sensitive questions leading to participant distress that exposes them to greater than minimal risk. And, surveys and interviews could collect data on participants that could cause them harm if there were a breach of confidentiality. For more information, see the section entitled, Risks to Participants in Socio-Behavioral Research, on page 12.

There are nine research categories that may be reviewed by an IRB through an expedited review process. The first five categories involve minor medical/health related research for which the Macomb IRB will not review, as they do not fall within this IRB's areas of expertise. Hence, the details for the health/medical expedited categories are not discussed any further in this manual.

The PI should designate on the application form which of the following categories best applies to qualify the research for expedited review.

Expedited Categories of Socio-behavioral Research

Shown below are categories of expedited research for which the Macomb IRB will conduct an initial review, a continuing review, or a review of previously approved research.

1. Collection and analysis of data from voice, video, digital, or image recordings made for research purposes. (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This category refers only to research that is not exempt from federal regulations.)

2. 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 from federal regulations.)

3. Review of minor changes in previously approved research.

4. Continuing review of research previously approved by the convened IRB if the IRB has determined the continuing review is required to adequately protect the human subjects.

Full IRB Review

For any research that does not meet either the criteria for Exempt Status Determination or Expedited Review, the PI must complete an application for Full IRB Review. When Full IRB review is necessary, the IRB application is presented and discussed at a meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those voting members present. Further details about Full IRB Review begin on page 24.

THE APPLICATION PROCESS

Before an Investigator Applies to the IRB

As soon as a PI decides to pursue a research project, he/she should contact the IRB Chair or a member of the IRB to discuss the project. Gathering information about human subjects protections and the IRB process will allow the PI to better prepare a project timeline. The aim should be to understand the level of risk the project entails for the subjects and the steps involved in submitting an IRB application.

Information about the IRB application process, and necessary forms are available for Macomb personnel on Macomb's staff portal; and available for non-Macomb personnel on Macomb's public website at http://www.macomb.edu/about-macomb/institutional-review-board/index.html .

The IRB Chair and any IRB members can review draft applications and answer PI questions along every step of the process, as the entire process is meant to be transparent and straightforward.

Who Must Apply to the IRB

All research involving human subjects that is conducted by those acting as an agent of Macomb, regardless of where the research is to be conducted, regardless of the designated review category (exempt, expedited or full board review), and regardless of funding source (if any), must be submitted to the IRB for review.

Application Submission Process

Applications and all supporting documentation should be submitted to the IRB Chair electronically as MS Word or PDF documents. Original signatures must be included on the PI Signature and Assurance page and may be scanned and sent electronically or mailed to the IRB Chair. Applications will be checked for completeness and assigned a project/protocol number. The IRB Chair verifies the appropriate level of review (full, expedited, or exempt from further IRB oversight). The IRB Chair notifies the PI of the appropriate review level. The Chair either conducts an Exempt Status Determination, or assigns an expedited review to one or more designated members, or schedules a Full IRB review for the next IRB meeting and assigns primary and secondary reviewers.

REVIEW PROCESSES

Exempt Application Process

The IRB Chair is authorized to determine research that meets exempt status requirements. Projects reviewed and approved under exempt status do not require submission of any other forms for IRB review unless a change to the research results in a change of the exempt status determination. If a research protocol changes, it is the responsibility of the PI to consult with the IRB Chair.

Expedited Review Process

The IRB Chair alone may review projects that qualify under a category of Expedited Review. Alternatively, the Chair may assign responsibility for expedited reviews to IRB members on a rotating basis. Complex research applications may require certain types of expertise for adequate review. In these situations, applications will be assigned specifically to those IRB members with the appropriate expertise needed. Assignment of a review allows for IRB members to anticipate when they need to make themselves available to review applications and ensure an appropriate turn-around time.[13]

An IRB member who has been assigned responsibility for an expedited review, should conduct a preliminary review of the application to determine if he/she has a conflict of interest. If he/she believes he/she has a conflict of interest, he/she should immediately request that the application be assigned to another member. For more information, see the section entitled, "Conflict of Interest Guidelines," on pages 19-20.

Minor changes to an IRB approved research protocol may be submitted to the IRB for review under the continuing review process and will undergo an Expedited Review.

Full IRB Review Process

The research proposal must clearly describe the research team, funding source, research methodology, the subjects of the research, subject recruitment process, the risks and benefits of the research to the subjects, the consent process and form, plans to ensure data security and plans to destroy subjects' identifiable data at the completion of the study. If the research is grant-funded, the PI must have the original grant proposal reviewed by the IRB Chair or designated IRB members, in addition to the IRB application review. The Full IRB Review Application lists all information necessary for submission for Full IRB Review.

The IRB Chair preliminarily reviews the application, then assigns a primary and secondary reviewer from among the IRB members. The primary and secondary reviewers will lead the discussion of the research protocol at the IRB meeting.

Once an application has been reviewed by the IRB, the IRB Chair will notify the PI in writing of the IRB's decision. For approved protocols, the written notification should include the date of the approval, and, if a continuing review is justified, include the justification used, as well as the date of the continuing review.

For additional information see the section entitled, "Full IRB Review and Meeting Procedures," on pages 29-31.

[13] The amount of time needed to review and respond to fully complete applications depends on the complexity of the research project. For most exempt and expedited research, the response time will normally be within two weeks. For a project requiring Full-Board Review, questions from the IRB Chair to the PI will occur within two weeks; the board meeting will be scheduled normally within 30 days during fall and winter terms. Notification of Board decision will take roughly 7 days. No Full-Board meetings will occur during summer term unless the matter is urgent.

BOARD PROCEDURES

The primary goal of the IRB is the protection of the rights and welfare of human subjects in research. The efforts of the IRB are directed at

1. Identification of the risk(s) to the subjects of the research,
2. Evaluation of the risk level,
3. Evaluation of procedures to minimize risk, and
4. Evaluation of the informed consent document which explains the risks to the subjects.

The following procedures are designed to ensure that the IRB accomplishes the above goal.

Board Meetings

Meeting schedules are set to accommodate, as best as possible, the availability of all the members. Schedules are set by major semester (fall and winter) to accommodate faculty and to allow for the maximum number of IRB members to be available and present. The expected frequency of meetings is typically once during the fall and winter semesters, and the meeting duration is approximately two hours. The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least five days prior to the meeting. Additional meetings will be scheduled, if necessary to manage the application workload.

Meetings during the summer months are not scheduled unless urgently needed.

Meetings by telephone or video-conference are authorized if in-person meeting cannot be scheduled or some members cannot attend in person. Members who participate in meetings via phone or video-conference are included in the quorum. Meetings requiring a vote of the full IRB may not be held via email or text. Discussion, deliberation and voting must occur in real time.

Principal investigators, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not participate in the review or vote, even if this means being unable to continue the meeting because of quorum requirements.

Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, 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 then any visitors will be asked to leave the room until the executive session has ended.

Quorum

A quorum is needed to record all official actions. A quorum is one more member than half the membership; a nonscientist must be present to meet the quorum requirement. 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 the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting.

Procedures for the Three Types of Review

There are three types of IRB review: Exempt, Expedited, and Full Review. The procedures differ by review type.

Exempt Review Procedures

The IRB Chair is responsible for exempt status determination and may consult with others as appropriate. Exempt applications are reviewed upon submission to the IRB Chair throughout the year. The IRB Chair or designee, not the investigator, shall make the determination as to whether a project is or is not exempt. For research to qualify for exempt status determination, it must meet the federal criteria for this category. For details, see the section, "Types of IRB Review," on pages 21-23.

Every effort is made to complete exempt reviews in a timely manner, but the amount of review time may vary depending on the clarity and completeness of the application, the complexity of the project, reviewers' schedules, and whether there are concerns that will need to be addressed by the full IRB. The IRB Chair may return an application without a board decision, if the application is incomplete or requires clarification. All grant-funded projects coming to Institutional Review Board must have their original grant proposal reviewed by the IRB chair in addition to the IRB application.

The IRB Chair will notify the PI of all decisions in writing relating to the status of an Exempt Review application. No research may be initiated until approval is issued by the IRB Chair.

Expedited Review Meeting Procedures

Expedited reviews may be handled by the IRB Chair alone or assigned by the Chair to one or more designated IRB members. The designated IRB member(s) will review the Expedited Review application and provide a written summary of the proposal, including their opinions on the following:

- Does the proposal provides sufficient protection for the research subjects?
- Is the risk level minimal (no more than occurring through normal daily life) or not?
- Are there sufficient privacy and confidentiality provisions in place?
- Will data used in the research be identifiable or de-identified?
- Does the Informed Consent form include all required information as specified by federal regulation? *(The member(s) will check the proposed consent form against each item listed on the Informed Consent Checklist.)*
- Will minors or other vulnerable populations be subjects of the research?

All grant-funded projects coming to the IRB must have their original grant proposal reviewed by the IRB Chair or designated IRB members, in addition to the IRB application review.

The IRB Chair will notify the PI of all decisions in writing relating to the status of an Expedited Review application. No research may be initiated until approval is issued by the IRB chair.

Protocol Changes or Amendments Using Expedited Review

Protocol changes or amendments to IRB approved projects must be submitted to the IRB for Expedited Review.

Full IRB Review – Review and Meeting Procedures

For Full IRB Review applications, a primary and secondary reviewer will be assigned to lead the discussion of that protocol at the full IRB meeting. The full IRB will review application information and have access to additional study documentation upon request.

All grant-funded projects coming to Institutional Review Board must have their original grant proposal reviewed by the IRB, in addition to the IRB application.

If external reviewers are necessary, they must be subject to the same conflict of interest policies as IRB members. For more information on conflicts of interest, see pages 19-20.

Applications for full review that are submitted at least three weeks in advance of a scheduled IRB meeting should be able to be addressed at that meeting. Any necessary revisions to the application or the informed consent document may be addressed after the meeting.

Incomplete applications or full review proposals requiring revisions may take longer for final approval, especially if the submission date is on or close to a scheduled IRB meeting.

Every attempt will be made to complete the review process in a timely manner.

Any IRB members with a conflict of interest must recuse themselves before voting.

The PI may be invited to the IRB meeting to answer IRB member questions about the research application, but the PI may not be present for the vote.

The IRB Chair will notify the PI of all IRB decisions in writing relating to the Full IRB Review. No research may be initiated until approval is issued by the IRB and written notification received from the IRB Chair.

Conflict of Interest Statement

No member with a conflict of interest may participate in the IRB review or vote on an IRB action for any such project. This conflict of interest policy will be stated at the beginning of each meeting and members that do have a conflict of interest must identify and recuse themselves from voting on that application.

Confidentiality Statement

IRB members are required to keep all information related to research applications confidential. This means that information reviewed by the members, which may be sensitive in nature, should not be discussed outside of the review process or discussed in a place where the discussion might be overheard.

Board Actions

The IRB may vote to approve, approve with modifications, defer, or disapprove a research protocol. For applications requiring full IRB review, these actions require a vote of the majority of the members present, at a meeting with a quorum present. If the vote is not unanimous, the minority opinion(s) must be recorded in or attached to the minutes.

An IRB member may abstain from voting for any reason, without explanation. An abstention is counted in the quorum. (An abstention vote is typically done if a member was not present for important discussion, so does not believe he/she has enough information for a vote.)

PIs are informed in writing of all IRB decisions.

Voting Decisions

There are four possible voting decisions; each is described briefly below.

Approval

Approval of the application will be based on a majority vote and the following:

- Completeness of the application packet and supporting documents,
- Extent to which the human subject rights are protected,
- 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,
- Adequacy of procedures for securing informed consent from the subjects,
- Adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subjects,
- Adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of information or biospecimens,
- Adequacy of institutional facilities and other resources necessary for completion of the study and protection of subjects' rights.

When a protocol has been approved, the Chair will issue a letter that indicates the IRB's action, sign and date it, and distribute one copy of the form to the PI and one for the IRB files. Distributions may be physical or electronic.

Along with the notification of approval, PIs are informed that any subsequent changes in projects must be reviewed and approved by the IRB before they are initiated and that unanticipated problems must be reported.

Dissenting votes must be recorded with reason(s) noted.

Approval with Modifications

An Approval with Modifications action is taken if the IRB requires minor additional information and/or modifications to the protocol, informed consent, or other element of the proposal. Necessary modifications are agreed upon and communicated to the PI. When the PI makes the modifications, either the IRB Chair or the designated representative is authorized to provide approval for the study to begin. This action will be documented in the IRB records.

The details of the modification may be discussed with the PI during or after the IRB meeting. The PI cannot proceed with the research until the modification has been completed, communicated to the IRB Chair, and written approval from the Chair has been received in return.

Deferral

A Deferral action is taken if substantial modification or revision is required or if insufficient information is provided to evaluate the application adequately. To receive approval for a deferred protocol, it must again be submitted for an IRB review. The PI is notified by the IRB Chair and the additional information necessary for completion of the review is requested. In the case of a deferred protocol, the PI may be invited to attend an IRB meeting to present/clarify the protocol for the IRB.

Disapproval

A vote of disapproval action is done if a majority considers that the committee decision would not be changed by modifications or revisions to the protocol. If the protocol is disapproved, the PI will be informed in writing of the reasons for disapproval. The PI may revise and resubmit his/her protocol for another review.

A PI cannot seek approval from an alternate IRB or another Macomb College official. A vote of disapproval by an IRB can only be addressed by a revision of a protocol and resubmission to the original IRB that took the disapproval action.

Other Board Actions

Non-Binding Recommendations

The IRB may offer non-binding recommendations with its action to approve or defer a protocol.

Withdrawn

Applications that are withdrawn by the PI will be discarded and noted accordingly.

Suspension or Termination of Research

The IRB is authorized to modify, suspend, or terminate approval of research that has been associated with unexpected serious harm to subjects, or is not being conducted in accordance with 45 CFR 46 or the decisions, conditions, and requirements set forth by the IRB. PIs must respond in writing to IRB

stipulations and recommendations on new protocols and continuing reviews within 90 days or the application will be terminated.

Appeal of an IRB Action by Principal Investigator

The PI may appeal the decision of the IRB when a protocol has been disapproved or approved with restrictions, and mutual agreement cannot be reached as to an acceptable alternative. By federal regulation, institutional officials may not approve research that has not been approved by the IRB. A PI may approach the IRB to appeal or reconsider a decision regarding a human subject research activity. A final decision regarding the appeal will be made by a vote of the IRB. PIs do **not**, however, have the option to seek the reversal of an IRB decision by submitting the same protocol to another IRB or other Macomb College official.

Periodic Review and Update of Policies and Procedures

IRB policies and procedures will be reviewed annually to assure compliance with changes in regulatory requirements, to provide additional information or improve clarification of information already contained within the document.

Any changes to applicable federal regulations will be implemented immediately, announced, and will supersede these policies and procedures.

Principal investigators are responsible for following the latest version of this document and using the most recent IRB forms available. Principal investigators should go to http://www.macomb.edu/about-macomb/institutional-review-board/index.html for the most up-to-date information and forms.

RECORD KEEPING

IRB Chair Record-Keeping Responsibilities

The IRB Chair or designee is responsible for preparing and maintaining adequate documentation of IRB activities, including the following:

- All records for protocol reviews, including research applications, approved informed consent documents, annual/continuing review reports, modifications, statements of significant new findings provided to subjects, general project information provided to subjects (e.g., fact sheets, brochures) and final reports submitted by investigators.
- Detailed minutes of IRB meetings, showing all information required by HHS regulations in 45 CFR 46.115. This includes:
    - Members present (any consultants, guests or others shown separately),
    - Results of discussions on debated issues and record of IRB decisions,
    - Approved consent form(s),

    - Record of voting (showing votes for, against and abstentions),
    - Basis for requiring a continuing review, and
    - Basis for disapproving a proposal.

- Copies of all correspondence between IRB and the investigators related to research applications. Significant emails or other electronic communication should be printed or stored electronically and kept on file at the Chair's discretion.
- Adverse reactions or incident reports and documentation that the IRB has reviewed such reports.
- List of IRB members that includes all of the information required by HHS regulations in 46.103(b)(3). The required information includes: name, earned degrees, representative capacity, indications of experience such as IRB certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of an affiliate organization or IRB.
- Federalwide assurance documents
    - Written procedures of the IRB, including an assurance that the institution complies with the federal policy for the protection of human subjects as described in 45 CFR 46.103.
- Training certification records for each IRB member.

The above documentation should be kept on file (physical or electronic) for at least three years. They shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

Records related to a research protocol shall be retained for at least three 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, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

The IRB Chair will assign a protocol number to an incoming application, record the number, and include the number in all official documentation to PIs, and to the DHHS and other federal regulatory agencies.

Principal investigators' Record-Keeping and Reporting Responsibilities

Principal investigators must keep all research records, including evidence of informed consent, for at least three years after completion of the research.

Informed consent forms must be accessible for inspection and copying by the Macomb IRB and authorized representatives of the U.S. DHHS and other federal regulatory agencies upon request. Consent forms must be stored securely by the PI in locked files or a locked office; and procedures must be developed to ensure that the consent forms are kept continuously in a secure location, yet can be retrieved expeditiously when necessary upon request by regulatory authorities or Macomb IRB administrative personnel.

Adverse Events Occurring During Research

Adverse events and unanticipated incidents that occur during the research must be reported immediately to the IRB Chair. See pages 41-42 for more information.

Minor Changes to an Approved Research Protocol

If a PI wants to make a minor change to an approved research protocol, the PI must submit an Expedited Review application before the change can begin. The IRB Chair or designee can review the application without need for a Full Board Review. Changes that would qualify as "minor" would be those that will not increase the risk to subjects or remove or reduce any privacy or confidentiality safeguards. Minor changes would include, for example, the addition of new subjects who are over the age of 18 years with no change to the research protocol, or an updated Informed Consent form with updated contact information for the PI.

Major Changes to an Approved Research Protocol

Major changes to an approved project must be submitted through an IRB amendment process. The PI should consult with the IRB Chair prior to completing a new application or instituting the change in the research project. An example of a "major" change would be a proposed addition of minors as subjects, or significant changes to an Informed Consent document, or a revision to an approved survey instrument that includes sensitive questions.

RECRUITMENT OF PARTICIPANTS AND INFORMED CONSENT

Federal regulations require that investigators obtain legally effective informed consent from the subject or the subject's legally authorized representative. The informed consent process is intended to educate potential subjects about the research project, outline their involvement and request their voluntary participation. It is intended to be an active process of sharing information and providing critical communication about the research study between the PI and the prospective subject.

A verbal explanation of the project, with discussion and questions, is important in augmenting the written consent form. The informed consent document is a guide to this process and is the written record that the subject entered the study voluntarily and with full understanding of the research project. The informed consent document serves as a reminder to the participant of what they have agreed to do or are considering, and provides contact information in case the participant wants to withdraw from the study or believes their rights are being violated.

Recruitment of Participants

Advertising to recruit study participants should be conducted in a manner that ensures that participation is voluntary. All recruitment materials must be submitted with the IRB application for review, regardless of the type of review. The IRB reviews all recruitment documents and the methods and materials that PIs propose to use to recruit subjects. Recruitment advertising includes methods such as newspaper, radio, television, bulletin IRBs, posters, flyers, email and classroom announcements intended for prospective

subjects. The IRB reviews the materials to assure that the recruitment method is not unduly coercive. This is especially important for studies that may include subjects who are likely to be vulnerable to undue influence. Procedures should be clearly outlined so that the IRB is assured that the information collected is handled appropriately; and if sensitive information is gathered, the PI should outline the steps that will be taken to protect the subjects' confidentiality.

Recruitment of College Students

PIs must recruit college students by public announcement and not by personal solicitation. If a PI intends to recruit participants in any other way, justification must be presented to the IRB and approval must be granted.

It is inadvisable for an instructor to recruit students in their classes for a research study, unless provisions have been made to recruit all individuals in the class by class announcement, and study participants' course grades have already been issued prior to the instructor reviewing any research participant's data of any type. See pages 12-13 for additional information relating to this topic.

Recruitment Incentives

It is not uncommon for incentives to be offered to subjects for participation in research (e.g., payment, gift cards, etc.). This is not considered a benefit of the research, but a recruitment incentive. Incentives, if used, must be clearly explained in the informed consent document. An explanation of procedures for early withdrawal must be included. Incentives should be set to encourage participation in the research, but not an amount that could be considered coercive. The amount and schedule of all incentives should be presented in the informed consent document.

Informed Consent Process

When an individual participates in a research project, the individual 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.

Steps in the Informed Consent Process

The required steps in the informed consent process include the following:

1. Inform the prospective subject that there is a study in which he/she might wish to participate;
2. Provide the prospective subject a consent form to review;
3. Explain the potential risks and/or benefits of participating in the research study;
4. Ask the prospective subject whether he/she has any questions;
5. Collect a signed informed consent document, if required, and retain the original for a minimum of three years after the close of the study;
6. Provide a duplicate copy of the informed consent document for the participant to keep;
7. Keep one copy for a minimum of three years;
8. Signed consent forms must be available for the IRB or the OHRP to review upon request.

Required Elements in the Informed Consent Form

Since each research project is different, there is no generic informed consent form. However, the following provides a description of specific, required information that is clearly stated in a prescribed order. In developing a consent form for any research project, please note the following requirements:

1. The informed consent document must provide full and complete information about the project and be organized carefully so that the specific elements of informed consent, described below, are covered clearly and concisely, and in the following order:
    a) Study purpose and statement that the study involves research,
    b) Description of procedures, including identification of any procedures that are experimental,
    c) Expected duration of the subject's participation,
    d) Statement of any risks and benefits,
    f) Disclosure of an alternative to the intervention, if any,
    e) Statement of data confidentiality, plans for de-identification of data, if appropriate, and intentions regarding storage and use for secondary research,
    g) An offer to answer any questions, and contact information of the researcher and the Macomb IRB Chair,
    h) Statement that participation is voluntary and a person may withdraw from the study at any time without penalty or consequences,
    i) Verification that participant is 18 years of age or older, and
    j) Date and signature lines for the participant and/or legally authorized representative (if participant is a minor).

2. The informed consent document must be written in language that is understandable without using jargon or technical language. Writing at a sixth- to eighth-grade reading level is suggested.
3. The language should be written in the second person. The final Statement(s) of Consent, however, should be written in the first person.
4. The degree of detail, and the length of the consent form, should reflect the level of risk that the project entails for the subject.
5. If a study involves minors (individuals who are under the age of 18 years) or participants with impaired decision-making ability, consent must be provided by the legally authorized representative and *assent* of the participants in addition to informed consent.
6. Separate forms may be required for different subject groups (e.g., parents, minors, and non-English speakers), different types of activities and different kinds of information (photographs, audiotapes, videotapes) in order to insure that participants have a clear understanding of the project.

Consent Form Documentation Storage

The PI is responsible for secure storage of all consent forms for a period of three years after the completion of the study. For detailed requirements, see the section entitled, "Principal Investigator Responsibilities" on pages 17-18.

Deception Studies

In studies that propose to mislead or deceive the subjects during data collection, the IRB has even more responsibility to protect the rights of the subjects. The IRB may set limits for such procedures and recommend alternate procedures to achieve research objectives that involve deception.

Special considerations and modified consent documents are required when disclosure of the purpose and/or methodology could bias the outcome of the study. In situations where participants will be deceived, some information may be omitted from the Consent Form and participants are told (on the signed Consent Form) that disclosure of the purpose and/or methodology could bias the outcome of the study and that they will be debriefed at the conclusion of the activity.

Waivers of Informed Consent

Waiving the consent procedure may be used if the research is considered minimal risk or justification is provided to document the request for the waiver.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent as stated, or waives the requirement to obtain informed consent as outlined in 45CFR 46.116(f) provided the PI demonstrates and the IRB agrees on all of the following:

- Research involves no more than minimal risk to the participants;
- Waiver or alteration will not adversely affect the rights and welfare of the participant;
- Research could not practicably be carried out without the waiver or alteration; and
- When appropriate, participants will be provided with additional pertinent information after participation.

Requests for any type of waiver for informed consent must be documented by the PI and specifically approved and documented by the IRB member(s) reviewing the application.

Waivers of Documentation of Informed Consent

A request for waiver of documentation by the PI must include justifiable reasons in the IRB application and must be specifically approved by the IRB reviewer.

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:

- 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. For example, if the

research topic were highly sensitive, and if the accidental release of the consent documentation could put the participant at risk of harm (such as social stigmatization), then the *documentation* could be waived. An oral consent (containing all required information) could be sufficient.

- 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. For example, for low risk surveys or interviews conducted by telephone, the participant could orally consent. Or, for web-based surveys, the participant could read the informed consent information, then check a box indicating he/she read and understood the risk(s) and agrees to participate.

INSTITUTIONAL ENGAGEMENT IN RESEARCH

Macomb is considered to be engaged in human subject research when research is conducted by or under the direction of any employee or agent of this institution using any property or facility of the College, or the research involves the use of the College's non-public information to identify or contact human research subjects or prospective subjects.[14] OHRP considers institutions to be engaged in human subjects research when employees or agents for the purposes of the research project obtain:

1. Information about the subjects of the research through intervention or interaction with them, directly or indirectly, including manipulation of the subject's environment.
2. Grant-related human subjects research, even if the research activities are carried out by employees or agents of another institution.
3. Identifiable private information or biospecimens from any source for the purpose of research, or
4. Informed consent of human subjects for the research.

OHRP does **not** consider institutions to be engaged in human subject research when employees or agents:

1. Inform prospective subjects about availability of the research;
2. Provide prospective subjects with information about the research but do not obtain subjects' consent for the research or act as representatives of the investigators;
3. Provide prospective subjects with information about contacting investigators for information or enrollment;
4. Seek or obtain the prospective subjects' permission for investigators to contact them;
5. Permit the use of the institution's facilities for intervention or interaction with subjects by investigators from another institution, when the research activity is NOT associated with an awarded grant.

[14] See OHRP Guidance, "Engagement of Institutions in Human Subjects Research (2008)" reviewed 2016, found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

There are additional guidelines explaining conditions in which an institution is or is not engaged in human subjects research. See the OHRP's Guidance on Engagement of Institutions in Human Subjects Research http://www.hhs.gov/ohrp/policy/engage08.html.[15]

All administrators, faculty, staff and students are responsible for determining whether their research activities require IRB approval; and if so, seek such approval. If a college employee or student has any doubt concerning the classification of the research activities, he/she is encouraged to contact the IRB Chair at IRB@Macomb.edu.

Cooperative Research, Institutional Consortiums

Cooperative Research (a.k.a. institutional consortiums) are cooperative activities relating to human subjects research that involve Macomb College and at least one other institution.

Federally Supported Cooperative Research

Under the revised Common Rule (45 CFR 46.114), for institutions located in the United States engaged in research supported by or conducted by a federal agency or department, the institutions must rely upon the approval by a single IRB, avoiding duplication of effort. However, each institution retains responsibility for safeguarding the rights and welfare of human subjects. And, each institution's responsibilities must be documented.

The reviewing IRB will be identified by the federal department or agency supporting or conducting the research, or proposed by the lead institution, subject to the acceptance of the Federal department or agency supporting the research.

Some exceptions to the use of a single IRB apply: (i) Cooperative research for which more than single IRB review is required by law (including tribal law); or (ii) Research for which any federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

Non-federally Supported Cooperative Research

For research not supported by or conducted by a federal department or agency, an institution participating in a cooperative project may choose to enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort. Each institution retains responsibility for safeguarding the rights and welfare of human subjects. Agreements and responsibilities must be documented through a Reliance Agreement.[16]

See an OHRP template of a Reliance Agreement at: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

[15] OHRP has not made updates to this guidance since their last review on 3-7-2016.
[16] For additional information see HHS guidance, "IRB Review Considerations for Cooperative Research," Engagement of Institutions in Human Subjects Research (2008) | HHS.gov

CONTINUING REVIEW, FINAL REPORTS AND STUDY CLOSURE

Continuing Review

Continuing review is required only for research projects that were approved under a Full Board review, and for which there is continuing interaction or intervention with human subjects beyond one year from initial IRB approval. Continuing review is not required for research that has progressed to the point that it involves only data analysis or "accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.[17]

Continuing review is not required for studies that were qualified as Exempt (as determined by the IRB), or underwent Expedited Review, unless the IRB explicitly justifies why continuing review would enhance protection of research subjects.

The IRB can override the regulatory defaults and choose to require continuing review, as long as the IRB documents the decision and the rationale for this decision.

Expedited Process for Continuing Review

If the research involves no more than minimal risk to participants, the expedited review process may be used for continuing review.

Principle Investigator documentation for a Continuing Review should include a written summary of the following:

- Number of subjects that participated in the study,
- Unanticipated problems,
- Withdrawal of subjects,
- Complaints about the research,
- Recent literature that may be relevant to research participant safety,
- Copy of current informed consent form,
- New proposed consent documents.

Notice to PI of Continuing Review

If a Continuing Review is required, the PI will be sent a notice from the IRB approximately 30 days before the anniversary date of their approval. If a PI fails to provide continuing review information to the IRB, the research must stop, unless the IRB determines that it is in the best interest of the individual subjects to continue participating in the research.

Enrollments of new subjects cannot occur after the expiration of IRB approval. If continuing review of a research protocol does not occur prior to the end of the approval period, approval automatically expires.[18]

[17] See 45 CFR 46.109(f)(1)(iii).
[18] Refer to 45 CFR 46.109(f), 46.110, and 46.115(a)(8) of the revised Common Rule.

Final Report for Closure Required from Principal Investigator

If all research-related interventions and interactions with participants have been completed and collection and analysis of identifiable private data have concluded, the PI should close the study with the IRB.

It is the PI's responsibility to complete a final report in a timely manner to close out the study with the IRB. The PI will notify the IRB Chair when the research is completed. If no continuing review is requested by the IRB, or no final report is received within one year and one month following the original IRB approval, the IRB Chair will mark the file "expired" and close the project. No research involving human subjects or their identifiable data will be allowed to continue.

COMPLIANCE AND INCIDENT REPORTING

Research conducted at Macomb is expected to follow Macomb policies and procedures and adhere to federal regulations regarding the protection of human subjects, regardless of who is conducting the research. Failure to do so may result in noncompliance, which may result in disciplinary actions or sanctions such as suspension or termination of IRB approval of specific or all research protocols, institutional or individual action by the federal Office of Human Research Protections (OHRP), recommendations for individual disciplinary action for failing to secure IRB approval before commencing human subject research will be reported to the signatory official, suspension or termination of project support, loss of indemnification from liability by the institution for adverse events if a PI fails to follow approved procedures.

Noncompliance Defined

Noncompliance is defined as research that is not conducted in accordance with institutional policy or federal regulatory requirements for human subject protection. Protocol deviations and variances from the protocol do not fall within these definitions until they are considered serious or continuous. Serious or continuing practices are those that appear to cause injury (physical, psychological, emotional, etc.) or any other unanticipated problems involving risks to participants and/or others or constitute serious/continuous noncompliance with IRB determinations or federal regulations.

IRB actions on a noncompliance event are final and not subject to appeal. Copies of all letters of warning from the IRB Chair to PIs must be sent to the signatory official. Copies of all responses to program audits related to IRB compliance submitted to outside agencies must be reviewed by the signatory official prior to submission.

Adverse or Unanticipated Event

Adverse events and unanticipated incidents that occur during the research must be reported immediately to the IRB Chair. The report should provide the IRB Chair with a reasonably detailed analysis of the incident and allow the PI to assess the situation and determine whether the protocol requires modification to

minimize risk, whether the informed consent should be revised, or if subjects should be contacted to re-consent to participate in the research study. An adverse or unanticipated event report should include:

- Description of the event in sufficient detail as to allow an informed review of the occurrence,
- Explanation as to why the event is unexpected and related to the research study,
- Description of changes to the protocol to minimize further risk or a rationale if no changes are required,
- Description of changes to the informed consent or a rationale if no changes are required,
- Description of the plan to re-consent current participants or a rationale if no re-consent is required,
- Risk/benefit analysis update – explain why the overall risk/benefit relationship of the research is still acceptable in light of the information of the incident.