2 Institutional Review Board

Note: In the following section and in the remainder of this document, reference to the Institutional Review Board (singular) is meant to refer to all Institutional Review Boards registered to CMU and noted on the most current version of the CMU IRB Registration approved by the Office of Human Research Protections. The membership of each board, the meeting schedule for each board, and, if appropriate, the special areas of review of each board, will be described in separate documents.

CMU has established an Institutional Review Board (IRB) to ensure the protection of human subjects in human subjects research conducted under the auspices of Central Michigan University. All non-exempt human subjects research conducted under the auspices of Central Michigan University must be reviewed and approved by the CMU IRB prior to the initiation of the research.

2.1 IRB Authority and Independence

The IRB derives its authority from the CMU HRPP policy. Under the federal regulations, this authority includes:

1. To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of the CMU;
2. To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants;
3. To observe, or have a third party observe, the consent process; and
4. To observe, or have a third party observe, the conduct of the research.

Under certain conditions, detailed in Section 1.13, the Institutional Official may authorize other IRBs to carry out these functions.

Research that has been reviewed and approved by the IRB may be subject to further review and approval or disapproval by officials of the institution. However, those officials may NOT approve research if it has not been approved by the IRB. CMU officials may strengthen requirements and/or conditions or add other modifications to secure CMU approval or approval by another CMU committee. Previously-approved research proposals and/or consent forms must be re-approved by the IRB before the changes or modifications may be initiated.

2.2 Number of IRBs

The number of active IRBs registered to CMU is specified in the FWA. The IO, the DRC, and the Chair of the IRB will review the activity of the (on-site) IRB on at least an annual basis and determine the appropriate number of IRBs that are needed for the institution.

CMU has two separately constituted and registered IRBs:

- IRB1 meets during the academic year (OHRP registration # IRB00001370)
- IRB2 meets during the summer months (OHRP registration # IRB00009405)

Membership of IRB2 is a subset of the membership of IRB1. Protocols presented to one board may be reviewed by the other board.

2.3 IRB Membership

The structure and composition of each IRB is be appropriate to the amount and nature of the research that is reviewed. Every effort is made to have members that understand the areas of specialty that encompasses most of the research performed at the CMU.

The IRB will include members who are knowledgeable about and experienced working with vulnerable populations that typically participate in CMU research.

Scientific members of the boards are drawn from colleges that submit most of the protocols: Liberal Arts and Social Sciences; Education and Human Services; Health Professions; and Medicine. In recognition of the increasing importance of data security in research, the information technology directors of the various colleges have been appointed as scientific members of the IRB.

No one from the CMU Office of Sponsored Programs, the Office of Development, or the CMU Research Corporation shall serve as members of the IRB or carry out day-to-day operations of the review process. Individuals from these offices may provide information to the IRB and attend IRB meetings as guests.

2.4 Composition of the IRB

The IRB will have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

~~The IRB will be sufficiently qualified through the experience and expertise of its members; the diversity of the members, including consideration of race, gender, and cultural backgrounds; and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.~~

In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of institutional policies and regulations, applicable law, data security, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas.

~~If the IRB regularly reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, or cognitively impaired persons , consideration will be given to the inclusion of one or more individuals on the IRB who are knowledgeable about and experienced in working with these subjects. (See Section 2.10.)~~

No IRB has members who are all males or all females. The IRB shall not consist entirely of members of one discipline or profession.

The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

The IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

The IRB includes at least one member who represents the general perspective of participants.

One member may satisfy more than one membership category.

Staff of the CMU HRPP Office may be voting members of the IRB.

Per institutional policy, the CMU Privacy Officer may serve on the IRB as a voting member.

On an annual basis, the IRB Chairs and the DRC shall review the membership and composition of the IRB to determine if they continue to meet regulatory and Institutional requirements. Changes in IRB membership will be reported to the OHRP by the DRC.

2.5 IRB Coordinator

2.5.1 Qualifications

The IRB Coordinator is expected to be knowledgeable about regulations pertaining to human subjects research protections and be a resource for investigators and their research teams, especially those who may be inexperienced in research, about IRB requirements and human subjects protections training. Certification as either CIM or CIP, either at time of hiring or within 2 years of hiring, is a requirement for this position.

2.5.2 Responsibilities

The Coordinator is responsible for receiving and docketing new protocol applications and revisions and applications for continuing review; assigning reviewers for new and continuing applications; preparing correspondence on behalf of the IRB; developing agendas for convened meetings; and maintaining the IRB document management system. The Coordinator is an alternate member of the IRB and may review and approve minor modifications to approved protocols.

2.5.3 Evaluation

The performance of the Coordinator is evaluated on an ongoing by the DRC, with input from various sources, including the IRB Chair. An integral part of the evaluation process is giving constructive feedback to address any performance areas that are deficient or should be improved. If necessary, formal improvement plans are developed, implemented and reviewed at prespecified intervals.

2.6 Chair and Vice Chair of the IRB

2.6.1 Appointment

The CMU IO, in consultation with the IRB members and the DRC, appoints a Chair and Vice Chair of the IRB to serve for renewable three-year terms. Any change in appointment, including reappointment or removal, requires written notification.

The Vice Chair serves as the Chair of the IRB in the absence of the Chair and will have the same qualifications, authority, and duties as Chair.

2.6.2 Qualifications

The IRB Chair/Vice Chair should be a highly-respected individual, from within Central Michigan University, capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the Chair. The IRB must be perceived to be fair, impartial, and immune to pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources.

2.6.3 Responsibilities

The IRB Chair/Vice Chair is responsible for:

- conducting the meetings.
- designating other IRB members (e.g., the Vice Chair) to perform duties, as appropriate, for review, and other IRB functions or;
- delegating responsibilities to IRB members or HRPP staff as appropriate;
- advising the IO and the DRC about IRB member performance and competence.

2.6.4 Evaluation

The performance of IRB Chair/Vice Chair will be reviewed annually by the DRC. Feedback from this evaluation will be provided to the Chair. If the Chair is not acting in accordance with the IRB's mission, following these policies and procedures, has an undue number of absences, or is not fulfilling the responsibilities of the Chair, he/she may be removed by the IO.

2.7 IRB Members

2.7.1 Appointment

The IRB Chair, Vice Chair, and/or the DRC identifies a need for a new, replacement, or alternate member. The IO solicits nominations from Deans and Chairs and sends the names of the nominees to the HRPP Office. Department Chairs and others may forward nominations to the IO, the HRPP Office, or the IRB Chair. The final decision in selecting a new member is made by the IO in consultation with the IRB Chair and the DRC. Appointments are made for an initial one-year term. Subsequent appointments may be made for a three-year period of service, and may be renewed. The appointment letter explicitly states performance expectations and members explicitly acknowledge the expectations in signing their agreement to serve.

Any change in appointment, including reappointment or removal, requires written notification. Members may resign by written notification to the Chair. The IRB Chair and the DRC review the membership and composition of the IRB to annually to determine if they continue to meet regulatory and institutional requirements.

2.7.2 Qualifications

Required qualifications are willingness to: commit to serve on board and attend meetings; take required training course; take active part in discussions before the board; evaluate protocols assigned for expedited review; and present assigned protocols at convened meetings.

The process for identifying potential unaffiliated members is informal and has operated by the DRC reaching out to members of the Mt Pleasant community either directly or through CMU staff intermediates.

2.7.3 Responsibilities

The agenda, submission materials, protocols, proposed informed consent forms, and other appropriate documents are made available to members at least one week prior to the convened meetings at which the research is scheduled to be discussed. Members review the materials before each meeting in order to participate fully in the review of each proposed project. IRB members will treat specific details regarding research proposals, protocols, and supporting data confidentially.

Members should attend all scheduled meetings.. If a member is unable to attend a scheduled meeting, he/she should inform the IRB Chair, Vice Chair, or an HRPP Office staff member.

If an IRB member is to be absent for an extended time, such as for a sabbatical, he/she must notify the IRB at least 30 days in advance so that an appropriate replacement can be obtained. If the member has a designated alternate (see Section AlternateMembersEvaluation74), the alternate can serve during the primary member's absence, provided the IRB has been notified in advance.

2.7.4 Alternate Members

The appointment, qualifications, and responsibilities of alternate members are the same as those of primary IRB members. Alternate members' expertise and perspective are comparable to those of the primary members with whom they are paired. A single alternate may be paired with more than one primary member and more than one alternate member may be paired with a single primary member.

CMU faculty consider the term "alternate" as indicating a lower level of membership with lower expectations and less credit for university service. Therefore, we have developed a separate nomenclature to describe a rotating voting member system in which:

- All appointments to the board are as undifferentiated "members";
- Rosters filed with OHRP do indicate primary and alternate members;
- Members are grouped according to subject area (eg, medicine, psychology, education, information technology) and rotate responsibilities for serving as either a voting member at convened meetings or an expedited reviewer; members conducting expedited reviews are usually not asked to review protocols at convened meetings;
- All members are encouraged to attend as many meetings as possible, even when they are not designated voting members for particular meetings; and
- All members receive the same training.

The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. The IRB roster identifies the primary member(s) for whom each alternate member may substitute.

An alternate member may attend convened meetings but will not be counted as a voting member unless the primary member is absent or recuses. The IRB minutes will document when an alternate member replaces a primary member at a convened meeting.

To insure a quorum at a convened meeting, the IRB coordinator and the Office of Research Compliance secretary determine approximately 1 week in advance which members will be present and which will serve as voting members.. Voting members – whether primary or designated alternates – are announced at the beginning of each meeting and noted in the minutes.

Any experienced members may conduct expedited reviews.

The DRC is responsible for maintaining current rosters of IRB primary and alternates.

2.7.5 Evaluation

Members are evaluated on their ability to conduct expedited and full board reviews accurately and in a timely manner. If requested, a report of the members' times to complete assigned reviews will be provided. If needed, the DRC and IRB Chair or designee will discuss any issues that might negatively affect a members' ability to complete reviews in a timely manner.

Evaluation is an integral part of the HRPP Quality Assurance and Quality Improvement Programs, as such the results of HRPP QA/QI audits will be utilized for evaluating the effectiveness of protocol reviews. The results of QA/QI audits may be shared with the IRB Chair, the DRC, the IO or the full IRB or discussed with individual members of the IRB as appropriate.

2.8 IRB Member Conflict of Interest

An IRB Member Conflict of Interest is a situation in which a member's financial interest, scientific activities, or personal relationships are inconsistent with the member's ability to evaluate an application to the IRB without prejudice or prejudgment.

No member may participate in the review (initial, continuing, or modification) of any research project in which the member has a conflict of interest (COI), except to provide information as requested. It is the responsibility of each IRB voting member to disclose any COI in a study submitted for review and recuse him/herself from the deliberations and vote by leaving the room.

When first appointed and annually thereafter, all members of the IRB will complete an "IRB Member Human Research Conflict of Interest Assessment Form," which will be consistent with the forms used in connection with CMU's Financial Conflicts of Interest Policies. If a member discloses a potential financial conflict, the Executive Director of the Office of Research and Graduate Studies is notified, and, if necessary, coordinates development of a conflict of interest management plan.

Committee members may find themselves in any of the following conflicts of interest when reviewing research:

1. Where the member is involved in the design, conduct, and reporting of the research.

2. Where an immediate family member of the member or consultant is involved in the design, conduct, and reporting of the research.
3. Where the member holds significant financial interests related to the research being reviewed. (See Section 14.1 for a definition of significant financial interests.)
4. Any other situation where an IRB member believes that another interest conflicts with his/her ability to deliberate objectively on a protocol.

The IRB Chair polls members at each convened meeting to determine if a COI exists regarding any protocols to be considered during the meeting and reminds members that they should recuse themselves by leaving the room during the discussion and vote of the specific protocol. Members with a conflicting interest are excluded from being counted towards quorum, and all recusals are noted in the minutes.

If the Conflict of Interest status of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chair or the DRC.

2.9 Use of Consultants

The IRB Chair or the DRC may solicit individuals with competence in special areas to assist in the review of issues or protocols that require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB. The need for an external reviewer is determined in advance of the meeting by the DRC or the IRB Chair by reviewing the protocols scheduled to be reviewed at the convened meeting. The HRPP Office will ensure that all relevant materials are provided to the external reviewer prior to the convened meeting.

Written statements of consultants will be kept in IRB records, and key information provided by consultants at meetings will be documented in the minutes.

DRC reviews the conflict of interest policy with consultants, and consultants must sign a COI disclosure form prior to conducting a review. Individuals who have a conflicting interest or whose family members have a conflicting interest in the sponsor of the research will generally not be invited to provide consultation.

The consultant's findings will be presented to the full board or the member serving as an expedited reviewer for consideration either in person or in writing. If in attendance at a convened meeting, these individuals will provide consultation but may not participate in or observe the vote.

Ad hoc or informal consultations requested by individual members (rather than the full board) must be requested in a manner that protects the researcher's confidentiality and complies with the IRB conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular PI and the title or specific details of the research protocol).

2.10 Training and Continuing Education of Chair and IRB Members

A vital component of a comprehensive Human Research Protection Program is an education program for IRB Chair and the IRB members. CMU is committed to providing training and an on-going educational process for IRB members and the staff of the HRPP Office related to ethical concerns and regulatory and institutional requirements for the protection of human subjects.

2.10.1 Orientation

New IRB members, including alternate members will meet with the IRB Chair and/or the DRC for an orientation session. At the session, the new member will receive electronic copies of the following documents:

- The Belmont Report;
- CMU Standard Operating Procedures of the Human Research Protection Program; and
- Federal regulations for protection of human subjects.

2.10.2 Initial Education

Prior to serving as primary or independent reviewers, new members are required to complete the Initial Education requirement for IRB members including CITI training; orientation to review procedures with the DRC and/or IRB Chair; orientation with the IRB Coordinator or HRPP staff on the use of the electronic management system for conducting reviews; and work with an experienced IRB member to conduct expedited reviews.

2.10.3 Continuing Education

To ensure that oversight of human research is ethically grounded and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB. Educational activities include, but are not limited to,

1. In-service training at IRB meetings;
2. Training workshops;
3. Copies of appropriate publications.

Identification and dissemination by the DRC of new information that might affect the Human Research Protection Program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to IRB members via email, mail, or during IRB meetings;

2.11 Liability Coverage for IRB Members

Central Michigan University's insurance coverage applies to employees and any other person, including members of the IRB, authorized to act on behalf of Central Michigan University within the scope of their employment or authorized activity.

2.12 Reporting and Investigating Allegations of Undue Influence

If an IRB chair, member, or staff person feels that the IRB has been unduly influenced by any party, they shall make a confidential report to the IO, depending on the circumstances. Issues or concerns involving the IO will be reported to the Provost, and other appropriate institutional official(s) or the CMU ethics hotline. The IO or other official receiving the report will conduct an investigation, and if necessary, prescribe corrective action to prevent additional occurrences.