Institutional Review Board
(IRB-FLINT)
Standard Operating Procedures

June 2015
Flint Institutional Review Board (IRB-Flint)............................................................. i

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PART 1 - GENERAL INTRODUCTION

Institutional Review Boards (IRBs) protect the rights and welfare of human subjects participating in research. The University of Michigan IRBs review and oversee research conducted by the University to assure that it meets ethical principles and complies with federal regulations that pertain to human subject protection at 45 CFR 46 and other pertinent regulations, policies and guidance and the ethical principles articulated in the Belmont Report.

The Vice President for Research (VPR) serves as the Institutional Official (IO). The IO has developed and implemented a Human Research Protection Program (HRPP); an integrated system consisting of research leadership, administration, and oversight functions including education, quality assurance and compliance, and research review units. The research review units include (IRBs) and other organizations charged with responsibility for protecting human subjects, investigators, sponsors and research participants. Together these individuals and organizations promote excellence in all aspects of human research.

The purpose of the HRPP is to protect the rights and welfare of human subjects participating in biomedical and behavioral research conducted at the University of Michigan or elsewhere by University faculty, staff and trainees. Its goals are to promote compliance with relevant legal requirements and ethical standards at all levels, while addressing the needs and concerns of researchers and enhancing support of their endeavors.

The HRPP Operations Manual (OM) is designed to illuminate the system and its overarching governing rules and serves as a reference for investigators, IRBs, administrators, and others and the Standard Operating Procedures (SOPs) serves as the method by which the IRBs implement the policy.

All human subjects research conducted by the University must be approved by an IRB or granted an exemption by a University IRB (through its members or staff) or the IO as specified in the IRBs SOPs. Research that has been reviewed and approved by a University IRB may be subject to additional review and disapproval by other review bodies or officials (including the IO); however, no person or organization may override an IRB’s disapproval determination. The U-M Office of Research (UMOR) maintains a research website where extensive information concerning human subjects research conducted at the University and by its faculty, staff, and students may be found.

Except for research that is specifically exempted in accordance with applicable laws and regulations and OM Part 4.VI, the University’s IRBs review and monitor all University research involving human subjects, regardless of funding source. In addition, certain types of research involving human subjects must be reviewed and approved by additional departments, division or units of the University. Depending on the nature and scope of a project, a University IRB may withhold its approval pending confirmation of approval by and/or receipt of additional information from any of these units and/or from review units at other performance sites or other external agencies or offices.

The IRB’s first and most important function is to protect the rights and welfare of human research subjects. Secondarily, within that over-riding mandate, the IRBs seek to support the design and conduct of sound research by U-M investigators in pursuit of the University’s mission to develop and disseminate new knowledge in the public interest. The safeguarding of subject rights and welfare must, at all times, take precedence over the goals and requirements of any research endeavor overseen by the IRB. Institutional Review Board members and staff, as well
as researchers submitting applications to the IRB, must be informed of and understand this obligation.

Additional resources:
HRPP Operations Manual Parts I, II, III, IV
45 CFR 46
PART 2 - ORGANIZATION OF THE HRPP SUPPORTING IRB-FLINT

I. Administrative Structure for IRB-Flint
The Institutional Review Board-Flint consists of one separately constituted IRB registered with the Office for Human Research Protections (OHRP), supported by an administrative office and infrastructure. The IRB meets approximately once per month, but by agreement and collaboration via the chair and the core members, agrees to work collaboratively in order to facilitate the review of time-sensitive applications.

The University of Michigan Office of Research (UMOR) provides administrative and compliance support for IRB-Flint with the Senior Vice Provost (SVP) on the Flint campus assigned responsibility for oversight of the office.

The SVP and the IRB-Flint chair meet periodically to review IRB workflow, consider guideline, Standard Operation Procedures (SOPs) and policy modifications, provide general direction for the IRB, consider development of new initiatives and receive updates on progress for existing initiatives.

The day-to-day operation of the IRB is under the direction of the IRB-Flint chair. The Director of Research, Flint Office of Research and Sponsored Programs (ORSP) provides administrative oversight of the IRB budget; office space and administrative support are also provided by ORSP.

II. Organizational Entities That Support IRB-Flint

Numerous additional organizational entities contribute to the operation of the University of Michigan’s Human Research Protection Program (HRPP) and IRB-Flint. These include:

- The ORSP-Flint, the Office for Human Research Compliance Review (OHRCR), and coordinating committees such as the IRB Council
- The schools, colleges and other academic units in which faculty, staff and trainees engage in human research are appointed
- Other research review units with responsibility for monitoring specific categories of research
- Key executive and administrative offices and functions including the SVP and Office of the Vice President and General Counsel.

Refer to the OM Part 2.II for a detailed description of each of these entities.
PART 3 - IRB-FLINT POLICY

I. Introduction

The Bylaws of the Board of Regents of the University of Michigan assign to the Vice President for Research (VPR) general executive responsibility for the research programs of the University, including maintenance of appropriate liaisons between the University and government agencies and other organizations supporting University research. The VPR, in turn, has established the Human Research Protection Program (HRPP). The VPR serves as the Institutional Official (IO) and may delegate certain responsibilities to the Deputy Institutional Official (DIO). A detailed discussion of the HRPP and its institutional policy can be found in the Operations Manual (OM Part 3). The University policy statement on the U-M HRPP is at Standard Practice Guide (SPG) 303.05.

II. The Operations Manual (OM)

The Operations Manual (OM) is the primary location for compiling, organizing, and integrating the rules, policies, practices, and guidance encompassing the University’s HRPP. The IO has approved the OM and approves each modification or amendment to it. Records of such approval are maintained in the U-M Office of Research (UMOR).

At periodic intervals, UMOR initiates a comprehensive review of the OM. Revisions may be made at any time however, as required by changes in law, ethical standards, institutional policy, quality assurance activities, or other considerations. Non-substantive revisions (e.g. to correct typographical errors, update links, or incorporate summaries of new or revised laws or regulations governing the HRPP) may be made upon approval of the DIO with notice to the IO.

III. IRB-Flint Standard Operating Procedures and Policies

A. General Provisions

IRB-Flint, to which these SOPs refer, is mandated by and follows Federal regulations, is accountable to the Senior Vice Provost (SVP), and operates under the authority of the University’s VPR. Refer to OM Part 3 for detailed information. IRB-Flint has oversight of human subject research conducted by all the schools, colleges, and units of the University of Michigan Flint. The following is a list of major schools and units served by IRB-Flint:

- College of Arts and Sciences
- School of Education and Human Services
- School of Health Professions and Studies
- School of Management
- School of Nursing
- University Outreach

IRB-Flint assures that where applicable, research will comply with state and local laws and regulations and University policies that relate to research involving human subjects. Additionally, IRB-Flint complies with any other federal and state regulations and statutes which apply to research under its jurisdiction, including the Health Insurance Portability and Accountability Act (HIPAA) of 1996.
The IRB may, in its discretion, consider other ethical guidelines as well, including those set forth in the Nuremberg Code, the Declaration of Helsinki, the International Conference on Harmonisation, professional society codes of ethics and reports and recommendations from national advisory bodies, such as the Secretary’s Advisory Committee on Human Research Protections (SACHRP).

The IRB-Flint cooperates with UMOR to establish, review, and revise these SOPs. These SOPs and any substantive revisions thereto, are subject to review and approval by UMOR. Any changes made to maintain compliance with a new law, regulation, or order or formal guidance of a governmental agency, or to add or change administrative information (contact, resource, etc.) is not considered a substantive revision. Standard forms, guidance documents, and similar information developed by IRB-Flint do not require further review or approval by UMOR.

IV. IRB-Flint Membership and Staff

The IRB-Flint membership is selected so as to be sufficiently qualified through the experience, expertise, and diversity of its members.

A. Qualification and Appointment of Chair and Reviewers

1. Chair
IRB-Flint has one chair appointed by the Senior Vice Provost (SVP). The chair serves at the will of the SVP and is a respected faculty member of, and has an appointment in, one of the schools whose research is subject to IRB-Flint jurisdiction. The chair shall be qualified through experience and expertise, concerned about human rights and ethical issues, and familiar with regulations relevant to the use of human subjects in research.

The chair also may serve as a board representative of their respective school, college, or unit. The appointment of a chair will, as practical, rotate among the major units under IRB-Flint jurisdiction.

One or more members of the IRB may be selected by the chair as alternate chair in the event that the chair is absent and not able to convene an IRB-Flint meeting. An IRB member or core staff member may be designated to fulfill an administrative function associated with the chair’s role (e.g., attend IRB Council), but that designation does not carry the full authority of the chair unless specifically authorized.

2. Expediting Reviewers
Expeditied review is conducted by a single reviewer with relevant expertise. IRB-Flint chair or IRB members appointed by the chair may conduct expedited reviews under the regulations stated in 45 CFR 46.110. Expediting reviewers are selected based on their knowledge of pertinent content areas and concern for human rights and ethical issues.

Expediting reviewers have authority to review and approve expedited and exempt applications or refer them to the convened board, as necessary.
Staff members who are sufficiently qualified through experience and expertise and are familiar with regulations relevant to the use of human subjects in research may be appointed to the IRB as alternates and review and may approve scheduled continuing renewals according to criteria set by IRB policy. As IRB members, these staff members may also perform expedited review of other selected initial applications or amendments.

3. Exempt Reviewers
Expediting reviewers and qualified members of the IRB staff may conduct exempt reviews and issue determinations. Refer to OM Part 4.VI.C.

Exempt reviewers are provided training on federal exemption categories, U-M exemption categories and use of eResearch to conduct reviews.

IRB staff members acting as exempt reviewers must be qualified through experience and expertise, and familiar with regulations relevant to the use of human subjects in research. The IRB chair will assess the readiness of staff to conduct autonomous exempt reviews based on previous education and experience and performance in their current role.

Institutional policy does not permit exempt determinations to be made by investigators.

B. Qualifications and Appointment of IRB-Flint Members

1. Regular Members
IRB-Flint will consist of not fewer than five persons. Representatives from the primary academic units under IRB-Flint jurisdiction (one of whom must be a scientist), plus at least one community member not affiliated with the University of Michigan, and one non-scientist will be appointed to serve.

Membership shall be sufficiently diverse in order to evaluate categories of research presented to the Board. IRB-Flint must have members with knowledge of the specific scientific disciplines relevant to the research that it reviews. If the IRB regularly reviews research involving identified vulnerable populations, the IRB will secure members experienced in working with such populations. The IRB must also possess knowledge of the local research context to fulfill its review responsibilities under federal regulations and the OM. If the appointed membership is not sufficiently knowledgeable about the scientific discipline or research context, consultants or other information may be used to supplement IRB-Flint reviews (refer to section D, below).

Scientist members have the necessary training, background and occupations to review scientific activities within a behavioral or biomedical research discipline.

Non-scientist members do not have the training, background, and occupation to review research activities from a biomedical or behavioral scientific discipline.

Community representatives may be scientists or non-scientists. Community members are individuals who are sensitive to community attitudes and mores in the promotion of respect regardless of race, gender and cultural background, and
provide counsel to safeguard the rights and welfare of human subjects. To be eligible for participation on IRB-Flint as a community representative, neither the member nor any member of his/her immediate family may otherwise have a direct affiliation (for example, as an employee, contractor, student in a degree program, volunteer at the institution on business unrelated to the IRB, or active emeritus faculty member) with U-M-Flint. The fact that an individual is an alumnus or former faculty or staff member of the University, or contributes to University fundraising drives, does not necessarily constitute a direct affiliation.

A copy of the current membership roster is on file in the IRB-Flint office. The roster is updated as required, at least quarterly, and provided to UMOR. UMOR is responsible for providing required updates of membership changes to the Office of Human Research Protection (OHRP).

Members are expected to attend, actively participate in, and vote at monthly meetings of the IRB-Flint and to serve as reviewers of assigned applications. Issues regarding poor attendance of members will be addressed by the IRB-Flint chair and IRB office staff on a case-by-case basis.

2. Alternate Members
Alternate members may be chosen by, among other qualifications, their ability to expand the expertise and/or diversity of the IRB-Flint. Alternate members will be appointed from the academic units whose research is subject to the jurisdiction of the IRB-Flint and may also be appointed for community and non-scientist members. Alternates are encouraged to attend meetings even when the corresponding member is present in order to gain experience. IRB staff members may also be appointed as alternate members, depending on their qualifications. Alternate voting members are designated to serve for specific regular voting members based on expertise (e.g., social scientist for social scientist).

Alternate members may attend all meetings of the IRB, but are not counted towards quorum and may not vote unless the regular member for whom they are appointed as an alternate is absent.

Alternate members may be assigned to replace full members in the event the full member is on leave from the University (e.g., for a sabbatical or medical leave).

Alternate members may serve as primary or secondary reviewers for expedited, exempt and full board reviews.

3. Appointment and Reappointment
Potential IRB-Flint members affiliated with the University may self-nominate or be identified by the IRB-Flint chair or representative of the academic unit under the jurisdiction of IRB-Flint. Community and/or non-scientist members (not affiliated with the University) may self-nominate or be recommended for nomination by third parties.

The IRB-Flint chair and designated staff will evaluate each identified candidate. Candidates for membership meet with the IRB-Flint chair and IRB administrator. Candidates are asked to provide a curriculum vitae or a resume summarizing
previous educational, professional, and/or personal experiences that may contribute to the IRB.

The IRB-Flint chair recommends appropriately qualified candidates to the SVP for appointment. Upon agreement with the recommendation, the SVP will sign a letter of appointment indicating the term and status of the candidate’s appointment as an alternate or regular member. Changes in appointment status (i.e., status as a full member decreased to an alternate member during a leave from the University) can be approved. The letter of appointment may be issued by either the IRB-Flint chair or the SVP.

C. Terms of Appointment

1. Term of Service
   The IRB-Flint chair serves a five-year term and may be reappointed based on an assessment of the SVP and mutual agreement by the chair.

   Regular or alternate members serve three-year terms subject to reappointment based on recommendations of the IRB-Flint chair, IRB staff, and mutual agreement by the member.

2. Termination of Appointment
   The IRB-Flint chair serves at the pleasure of the SVP and their appointment can be terminated by the SVP. If it becomes necessary to terminate a regular or alternate member before expiration of their appointment, the SVP on the advice of the IRB-Flint chair, will effect termination.

   Reasons for early termination include: failure to attend meetings, failure to participate at meetings, failure to uphold the central tenants of the Belmont Report or other applicable policies or ethical principles, engaging in activities deemed inappropriate or incompatible with IRB membership.

3. Compensation of Chairs and Members
   The rates of compensation for the roles of chair and expediting reviewer are determined by the SVP in consultation with the academic units, if necessary.

   Rates of compensation for community members are determined by the SVP in consultation with the IRB chair.

4. Liability Coverage
   Liability coverage is a matter of institutional policy and is further described in OM Part 3.III.B.

D. Periodic Review of Membership and Composition

1. Review of Membership
   The membership and composition of the board is reviewed at least annually with the IRB-Flint chair and IRB administrative staff. Changes are made to the membership or composition of the board to meet regulatory or organizational requirements as needed.
2. Reappointment of Members
Members may be recommended for reappointment as full or alternate members, or their reappointment may be declined. Members are assessed based on their continuing interest and availability, preparation and participation at meetings and the ongoing requirement for their special expertise.

3. Reappointment of the Chair
Prior to the end of their term, the chair is evaluated by the SVP with input from the IRB staff and IRB membership, as appropriate. The chair is assessed based on their continuing interest and availability, preparation and participation at meetings, participation in policy efforts, and the ongoing requirement for their special expertise. Upon the recommendation of the IRB members the SVP may choose to reappoint the chair. A chair desiring to continue IRB-Flint service at the end of their term as chair may be reappointed by the SVP as a full or alternate member of the IRB.

4. Member and Chair Evaluation
The SVP evaluates the IRB-Flint chair each year, and feedback is provided. IRB members are evaluated and given feedback every year by the IRB chair. Criteria for evaluation include: attendance at meetings, level of participation at meetings, thoroughness of review and regulatory knowledge, use of eResearch, working relationship with IRB staff and interactions with principal investigators (where indicated). Members may be evaluated more often if circumstances dictate. Members are informed of these expectations and the evaluation process at the time of their appointment(s).

E. Consultants, Advisors and Ad Hoc Reviewers

1. Selection
The IRB must possess sufficient knowledge of the local research context to fulfill its review responsibilities under federal regulations and the OM. To supplement this knowledge, the IRB chair, IRB membership and IRB staff may, at their discretion, invite from among the faculty and staff of the University or the community at large, persons whose experience or expertise may aid the IRB in performing its responsibilities, whether during meetings or otherwise.

Consultants may include, but are not limited to, ad hoc reviewers for individual protocols, legal advisors or others. Alternate members may serve as non-voting consultants to the IRB when their expertise would contribute to the evaluation of the research.

2. Participation
Consultants may participate in the deliberations concerning any application, but shall not be counted for the purposes of establishing quorum, nor shall they vote on the approval/ disapproval or other disposition of any application. Information provided by consultants is documented in the minutes of the meeting at which the relevant protocol is reviewed.

A consultant, who is unable to attend the convened board meeting or meet directly with an expediting reviewer, will send a written communication for review and consideration. Information presented by the consultants will be added to the application file.
F. IRB-Flint Staff

1. Support and Supervision
   The IRB-Flint is supported by a professional staff who reports to the chair of the IRB. Day-to-day supervision is provided by the IRB chair. The Director of Research provides administrative oversight of the IRB budget, administrative support, and timekeeping for IRB staff.

2. Hiring
   Qualified personnel are hired according to the University policies and procedures. A summary of positions and job descriptions is kept on file in the IRB office.

3. Duties
   The IRB-Flint staff is responsible for facilitating IRB operations (e.g., protocol review, documentation and record retention, fact-finding, creation of informational resource development and educational activities) in such a manner as to maintain compliance with applicable regulations and University policies. IRB staff assist faculty, staff, and students seeking IRB approval, provide educational programming in support of the responsible conduct of research and support the operations of the board. The IRB staff manages the application workflow and communications between the investigators and reviewers. IRB staff may also participate in additional projects and assignments, as directed.

4. Staff Evaluation
   Staff members are evaluated yearly in a performance appraisal conducted by the IRB chair in consultation with the Director of Research. If circumstances dictate, staff members are evaluated more often.

G. Orientation and Continuing Education of IRB-Flint Members and Staff

IRB-Flint provides IRB administrative staff and IRB members with sufficient training and opportunities for continuing education in order for them to effectively discharge their duties.

1. IRB-Flint Membership
   a. New Member Orientation
      New IRB-Flint members are provided a detailed orientation designed to prepare them to effectively discharge their duties. The orientation includes a series of meetings with the chair and IRB staff. Most members attend one or more convened meetings as a non-voting guest prior to the initiation of their formal appointment.

      During the orientation process, IRB procedures are described and discussed, basic resource materials are distributed (including copies of pertinent federal regulations, the Belmont Report, OHRP information, guidelines and policies and standard operating procedures) and paths for acquiring additional information are provided.

      Members review the relevant educational modules of the U-M Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS) and complete the associated testing.
IRB members are also encouraged to obtain membership in, and monitor the dialogue of, the IRB-Forum listserv.

b. Current Member Continuing Education
IRB-Flint members are informed of opportunities for continuing education. As permitted by the number of agenda items at an individual convened meeting, time is devoted to educational activities. Current developments and the application of regulations in human subjects protection may be discussed. Invited speakers on special topics may be scheduled.

IRB members are encouraged to attend local presentations from other units of the University or other locally available educational opportunities or courses such as those offered by IRBMED, Michigan State University or other local universities, societies, or webinars from organizations such as those offered by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), Office of Human Research Protections (OHRP) and Public Responsibility in Medicine and Research (PRIM&R).

As budget and availability permit, support is available for members to pursue other opportunities such as national meetings sponsored by PRIM&R or OHRP.

2. IRB-Flint Staff
a. New Staff Orientation
New staff members receive an orientation to IRB office policies, procedures, and practices which will be conducted with staff from the Institutional Review Board–Health Sciences Behavioral Sciences (IRB-HSBS).

Staff members receive specialized training of the eResearch system in order to conduct reviews of electronically submitted applications.

IRB staff members are required to take and pass the Human Subjects module in PEERRS and it is strongly recommended that additional modules in research administration, conflict of interest, or other appropriate modules be completed.

b. Current Staff Continuing Education
As budget and availability permit, IRB staff are provided with opportunities to attend local and national conferences and encouraged to attend locally available educational opportunities or courses such as those offered by IRBMED, Michigan State University or other local universities, societies, or organizations.

IRB staff participate in learning activities on the main campus such as webinars and other educational presentations and as time allows attends the weekly IRB HSBS staff meeting to discuss questions arising from review of applications.

IRB staff are also encouraged to monitor the dialogue of the IRB-Forum listserv.
PART 4 - IRB-FLINT FUNCTIONS AND OPERATIONS

I. Application Submissions in eResearch

Research applications (initial, scheduled continuing review, amendments and reports of adverse events (AEs) and Other Reportable Information or Occurrences (ORIOs)) requiring the Institutional Review Board (IRB-Flint) review are submitted via the web-based eResearch Regulatory Management System (http://eresearch.umich.edu). The eResearch application is designed as a comprehensive application for investigators and a review tool for IRB members and staff and offers customized application paths for a variety of research activities, including:

- Standard, non-exempt, research projects
- Secondary use of existing identifiable data/records/specimens
- Exempt human subjects research
- Activities not regulated as human subjects research
- Projects lacking immediate plans for involvement of human subjects, their data, and/or their specimens
- Request for review by a non-UM IRB

II. General Review and Approval Procedures

eResearch applications submitted to IRB-Flint are assigned to IRB staff for administrative review. The eResearch application is designed to gather information and materials necessary for the IRB to evaluate and approve research in accordance with human subjects regulations (45 CFR 46). IRB staff, IRB reviewers, board members, and study team members all have access to the same application materials via the eResearch system. IRB staff and reviewers utilize regulatory checklists embedded in the eResearch system to guide their review of application materials.

The eResearch application uses smartform technology routing users to appropriate sections. Because applications may undergo revision and changes during the approval process the official record of the IRB application is based upon the printer friendly version in eResearch.

eResearch submissions are accepted and reviewed by the IRB-Flint on a continuing basis, during University business hours, except during seasonal holidays when University administrative offices are closed.

Each IRB submission is assigned to an IRB staff member. Prior to administrative review of an eResearch application, IRB notifies the IRB chair if they have a potential or actual conflict of interest with any aspect of the application. If a conflict is validated, the staff member will be excused from any IRB duties directly relating to the processing, review, or outcome determination of the application.

Using the staff checklist, the designated IRB staff member conducts a preliminary review of the application and supporting documentation to ensure that it contains sufficient information to enable the expediting reviewer or full board to determine whether the research meets the regulatory criteria for approval. When necessary, the eResearch application is returned to the study team for additional information, documentation or clarification prior to determining the next steps in the review process.
A. Initial and Continuing Review

1. Determining Whether and Under What Authority the Research is Regulated

For each application for initial or continuing review, the IRB staff, in consultation with IRB directors or reviewers, as appropriate, must determine whether:

- The activity is considered research as defined in the Common Rule
- The research involves the use of human subjects as defined in the Common Rule
- The University of Michigan-Flint is engaged in the research
- The research is conducted as part of the investigator’s “university responsibilities”
- The research is exempt from IRB oversight

Guidance to aid in making these determinations is found at:

- OHRP Decision Charts
- OHRP guidance on “Engagement of Institutions in Research”
- OM Part 4
- U-M eResearch application

In addition, the staff member confirms that the study has been correctly submitted to the IRB-Flint rather than one of the other U-M IRBs. If the research is not regulated or is exempt, the application will be referred to the appropriate IRB staff member to review the materials and issue the “Not Regulated” or exempt determination via the eResearch system. Research subject to the U.S. Department of Health and Human Services (HHS) Food and Drug Administration (FDA) regulation (e.g., Investigational New Drug (IND) and Investigational Device Exemption (IDE) and certain clinical research applications are reassigned to IRBMED.

2. Initial Review

Any investigator intending to initiate a research study involving human subjects that is under IRB-Flint jurisdiction must submit an initial application for review and approval of the study. No aspect of the study (including testing performed solely to determine eligibility for the study) may begin until IRB-Flint has approved the application or issued an exemption determination via eResearch.

Once the IRB staff member has determined that an initial application is complete and represents research requiring IRB-Flint review, a preliminary assessment as to whether the proposed research qualifies for expedited review or must be scheduled for convened board review is made, in consultation with the IRB chair, as necessary (refer to Standard Operation Procedures (SOP) Part 4.IV for the expedited and convened board review procedures). As applicable to the research, the following information is reviewed:

- The research protocol
- Proposed informed consent documents
- Copies of advertisements or other recruiting materials (including, but not limited to: posters, flyers, letters, websites, email text, oral scripts)
• Surveys, questionnaires, interview guides used to collect data from participants
• Documentation of approval from other performance sites
• Federal grant applications via links into the eResearch proposal management system
• Any other supporting documents required by the IRB-Flint

An initial application is eligible for approval only when the criteria found in 45 CFR 46.111 is met.

3. Scheduled Continuing Review
Continuing review is required in accordance with 45 CFR 46 for all research studies under IRB-Flint oversight at intervals appropriate to the magnitude of risk of the project and other considerations. For research studies with federal sponsorship, IRB conducts a continuing review at least once each year. Some research may require continuing review at an interval of less than one year as assessed by the convened board or expediting reviewer. Some non-federally supported, minimal risk research may qualify for scheduled continuing review at two year intervals if the project meets the criteria as defined by U-M policy (refer to SOP Part 4.II.D. and HRPP Innovation and Demonstration Website.)

The eResearch Scheduled Continuing Review (SCR) application contains the following information:

• Current study status
• Interim findings or citations to recent relevant literature
• Investigator’s current assessment of research risk
• Number of participants accrued
• Report of AEs, unanticipated problems, participant withdrawals, or complaints

The currently approved eResearch application and supporting documents, including current informed consent documents, study protocols, survey instruments, and recruitment materials, are available through links in the SCR application. Materials that cannot be provided via eResearch are set aside for review within the IRB office. These materials provide the primary reviewer and IRB-Flint members with the relevant information necessary to determine whether the study continues to meet the regulatory criteria for approval at 45 CFR 46.111.

At the time of the continuing review, the IRB-Flint will confirm that the current consent document is still accurate and complete. When appropriate, the IRB-Flint will seek verification from an outside party that no material changes to the research have been made since the last IRB approval. The IRB-Flint will also ensure that any new findings arising from the continuing review process that may relate to the willingness of participants to continue in the research will be communicated to participants. If appropriate, research qualifying for exemption under 45 CFR 46.101 or U-M and IRB-Flint policies will receive an exempt determination.

a. Lapses in Approval
If a scheduled continuing review (SCR) application is not submitted and approved by the expiration date, the eResearch system triggers an expiration
notice for the project. The notice informs the investigator that all research activity on the project, including data analysis, must stop until a SCR application is approved by the IRB-Flint. Enrollment of new subjects is prohibited during a lapse. If IRB approval does lapse, the PI will be required to submit an ORIO report disclosing the reason for the lapse and reporting any project activity that has taken place during the period of the lapse.

It is the responsibility of the principal investigator (PI) to submit a continuing review application before expiration of IRB approval and in ample time for IRB-Flint review. eResearch provides notification of impending expiration and directions for submitting a continuing review application at 90, 60, and 30 day intervals prior to the expiration date. If an investigator fails to submit a continuing review application for an active research project, or if IRB-Flint has not reviewed and approved a submitted continuing review application by the expiration date (regardless of the reason or circumstances), the study will be considered lapsed and the research must stop unless the IRB or the investigator determine that it is in the best interest of individual subjects currently participating in the study to continue the research interventions or interactions. A notice sent through the eResearch system informs investigators that sponsored project resources must not be expended for unapproved research activities. Enrollment of new subjects during a lapse is prohibited. The PI must submit a continuing review application as soon as possible.

In addition, projects in the state of Approved with Contingencies that have not received final approval by the expiration date set at the time of contingent approval are considered to be lapsed and must be resubmitted to the IRB for full review.

Following a lapse in approval, the investigator must also submit an ORIO to document activities (if any) that were conducted during the lapse.

If an approved research project is not renewed or terminated and remains in an expired state, IRB-Flint may contact the investigator to assess the investigator’s intent to continue the project or terminate the research. If the researcher indicates the intent to terminate the application, the IRB will request the submission of an SCR application in eResearch to report the project closure (termination report).

b. Study Closure or Termination
The principal investigator is responsible for notifying the IRB-Flint of the completion (including all data analysis) of a study. The SCR application is used to submit the investigator’s study completion report (termination report).

B. Reporting Changes to Approved Applications (Amendments)
A PI may not implement any changes to an approved study that is subject to IRB oversight (including to the protocol or informed consent document) without prior IRB review and approval, unless the change is necessary to eliminate apparent immediate hazards to the subjects. Changes made to eliminate an immediate hazard must be reported promptly to the IRB and are reviewed to determine whether each change was consistent with ensuring participant welfare.
An eResearch amendment application is submitted to request a modification to an approved study. The application consists of an amendment cover sheet that includes a narrative description of the proposed modifications and reasons for the requested changes, and a modified version of the eResearch application containing proposed changes to the approved application and to study documentation, including informed consent documents. These materials provide the IRB-Flint with the relevant information necessary to determine whether the revised research continues to fulfill the regulatory criteria for approval under 45 CFR 46.111.

Modifications to a study that require an eResearch amendment include, but are not limited to:

- Proposed changes to the study protocol, including changes to eligibility criteria or to study materials such as recruitment materials and advertisements, subject incentive payments, questionnaires, surveys, and scripts, including the addition of new materials
- Proposed changes to previously approved informed consent documents
- Proposed changes in study team roles (including principal investigator, co-investigators or study staff) or performance sites(s).
- Changes in funding or project support.
- Changes in any other aspect of the research.

In its review, the IRB-Flint considers whether the proposed amendment changes the risk to participants, whether there is a need to revise the consent documents or process, whether the proposed change might impact the willingness of participants to continue in the research or whether it requires re-consent of previously enrolled subjects.

The IRB-Flint may authorize its staff to acknowledge amendments containing non-material changes to protocols and informed consent without review of the amendment application by the convened board or an expedited reviewer. These may include: correction of typographical or grammatical errors and/or changes in investigator or IRB contact information.

The IRB may use the expedited review procedure to review minor changes in research previously approved by the convened board. Minor changes are defined as those that do not significantly impact the risks and benefits to subjects and do not substantively change the aims or design of the study.

Examples of changes that may be reviewed by the expedited procedure include:

- Addition or deletion of study team members other than the principal investigator or co-investigator
- Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study (i.e., new procedures that fall under any of the expedited categories can usually qualify as minimal risk)
- Removal of research procedures that would thereby reduce the risk to no more than minimal (i.e., procedures now meet expedited research categories)
- Addition of non-sensitive questions to non-validated survey or interview procedures
• Addition of or revision to recruitment materials or strategies
• Change to improve the clarity of statements or to correct typographical errors, provided that such changes do not alter the content or intent of the statement

The date of IRB approval of a modification to an application does not change the date by which a regularly scheduled continuing review must be completed.

For projects in exempt status, an amendment may be required for significant modifications to the study that would move the project outside the definition of the exemption granted for the study.

C. Engagement in Research

IRB-Flint staff in consultation with the IRB chair, as necessary, determine whether U-M is “engaged” in a non-exempt research project. A performance site becomes engaged in human-subjects research when its employees or agents intervene or interact with living individuals for research purposes, or obtain individually identifiable private information for those purposes. A site is always deemed to be engaged when it receives a direct federal grant or other award to support non-exempt human subjects research. See OHRP guidance on “Engagement of Institutions in Research” and the OM Part 5.

IRB-Flint has oversight only for research in which UM Flint is engaged or has completed an IRB Authorization Agreement (IAA) or Individual Investigator Agreement (IIA) and accepted additional responsibility for oversight of a research project or personnel. All such agreements are authorized by UMOR.

D. Frequency of Review

The IRB-Flint may approve an initial application or scheduled continuing review for intervals of less than one year when it is deemed appropriate. Criteria for this consideration include, but are not limited to:

• Overall risk level of the study
• Elements of the proposed Data Safety Monitoring Plan (DSMP)
• Demonstrated need for additional oversight of the PI and/or study team
• Questions as to the sufficiency of the data to lead to generalized knowledge
• Excessive numbers of serious adverse events or protocol deviations
• Additional regulatory compliance requirements, such as Certificates of Confidentiality (COC) or research involving vulnerable populations such as prisoners
• Research locations in an international or other off-site location(s) where the IRB-Flint is serving as the IRB-of-record
• Principal investigator conducting the research has a potential conflict of interest that warrants more frequent reporting and review
• Additional circumstances that the board would consider serious enough to warrant the additional oversight

The IRB-Flint may approve an initial application or scheduled continuing review for a two-year interval if the project meets the following criteria as defined by the U-M HRPP Innovation and Demonstration Initiative:
• No more than minimal risk to subjects
• No federal sponsorship including students supported by federal training grants
• No FDA-regulated components
• No sponsor or contractual restrictions
• Does not involve clinical interventions (including clinical behavioral interventions)
• Does not include prisoners as subjects
• Does not have a National Institutes of Health (NIH)-issued COC

E. Monitoring and Verification

1. Data Monitoring
Detailed information about Data and Safety Monitoring Plans (DSMP) can be found in the OM Part 7.II. With respect to any research project or class of research projects, the IRB may impose additional conditions on the conduct of the research at any time prior to, concurrent with, or following approval, when in the judgment of the IRB such additional conditions are necessary or appropriate for the protection of human subjects.

a. Considerations for the Imposition of Special Monitoring Requirements
The IRB-Flint may, at its discretion, perform monitoring or request monitoring (via UMOR) of a project in addition to that accomplished through initial, amendment, and annual continuing reviews, and analyses of interim reports such as adverse event and audit reports. For example, the IRB may choose to undertake extra monitoring for research that presents greater than minimal risk or to gauge the progress of recruitment for vulnerable subjects or to follow the research progress on controversial subject matter. The IRB may also consider the frequency and nature of adverse events reported to-date. The IRB may also choose to monitor one or more of the projects of a single investigator in consideration of the experience of the investigator or as follow-up to previous reports of complaints or noncompliance or prior IRB interactions with the individual.

b. Examples of Special Monitoring Requirements
Monitoring may include, but is not limited to:

• Shortened approval periods and/or interim, scheduled reports from the investigator during the approval period
• Site visits to research locations
• Interviews of subjects
• Third party witness to the informed consent process
• Review of research records
• Independent, third-party monitoring to confirm that no material changes in the study have occurred
• Independent Data Safety and Monitoring Board (DSMB)

The IRB shall communicate with investigators, as appropriate, regarding the outcomes of these additional monitoring efforts.
III. Projects Not Regulated or Exempt under the Common Rule

The IRB-Flint staff members, in consultation with the chair, will review all applications to determine whether they meet the definition of human subjects research regulated under the Common Rule, using guidance found in the U-M HRPP OM Part 4 and Part 3.III.C and the OHRP Decision Charts.

A. Not Regulated

By using the tools available within eResearch, PIs can self-assess a proposed project to determine whether it meets the definition of IRB-regulated human subjects research. Submission of an eResearch application is not required for those activities deemed outside of IRB regulatory authority. PIs may, however, submit a brief eResearch application to self-generate a determination letter for support or publication purposes, or may consult with the IRB staff or chair to confirm the not regulated status of the project.

Some types of projects that are not regulated under the Common Rule may require initial IRB review only for the purpose of assessing compliance with Health Insurance Portability and Accountability Act (HIPAA) or other regulations or institutional policies.

Quality Improvement (QI) projects generally are systematic, data-guided activities which are designed to implement best practices in clinical care, patient safety, or health care management at a specific health care site. Due in part to the specificity of both intent and location of activity, QI projects are not regulated by the IRB. Publication of the results is permissible. The principal investigator has the responsibility to follow any institution specific requirements for the use of private health information (PHI) and to take appropriate actions to safeguard the data.

Once a not regulated determination has been issued, the IRB is no longer involved in the oversight or monitoring of that activity.

B. Projects Meeting the Criteria for Exemption

As per the University HRPP OM, in order to be deemed exempt, human research activities must be reviewed and determined to fall within one or more of the explicit exemption categories listed in the federal regulations or, for non-federally supported research, fall under exemption categories described in UM policy (refer to HRPP Innovation and Demonstration Initiative Website). Consistent with the requirements of 45 CFR 46 subparts B-D, exemptions are not granted for research involving prisoners or for some types of research activities involving children. FDA-regulated research does not qualify for exempt status.

Federal Exemption Categories under 45 CFR 46.101(b)

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude,
achievement), survey procedures, interview procedures or observations of public behavior, unless: unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (For research involving children, this exemption applies only to projects using educational tests or observation of public behavior where the investigators do not participate in the activities being observed. See 45 CFR 46.401(b).)

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available; or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects that are conducted by or subject to the approval of federal department or agency heads, and that are designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs. This exemption is for federally-supported projects and is most appropriately invoked with authorization or concurrence by the supporting agency. The following criteria must be satisfied to invoke this exemption:

- The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act [SSA]) or service (e.g., social, supportive, or nutritional services under the OlderAmericansAct)
- It must be conducted pursuant to specific federal statutory authority;
- There must be no statutory requirements that the project be reviewed by an IRB
- The project must not involve significant physical invasions or intrusions upon the privacy of participants

Non-federally supported research and demonstration projects conducted by or subject to the approval of state department or agency heads, and that otherwise meet the above requirements, are also eligible for exemption.

The University has already departed from federal regulations by creating a new "exemption" parallel to existing Exemption 5 for projects sponsored by the State of Michigan. Additional exemptions may be considered, or additional flexibility in applying exemption categories may be considered, for non-federally sponsored research that poses little or no risk to subjects or for which another institutional oversight mechanism is better designed.

6. Taste and food quality evaluation and consumer acceptance studies if wholesome
foods without additives are consumed; or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration (FDA) or approved by the Environmental Protections Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture.

U-M Exemption Categories

The following are exemptions defined by U-M policy (refer to HRPP Innovation and Demonstration Initiative). To qualify for a U-M exemption, a study must:

- Pose no more than minimal risk to subjects, and

Must not include any of the following:

- Federal funding (direct or prime sponsorship)  
  - And is not intended to collect pilot data to support proposals for federal funding
- FDA regulated components
- Sponsor or other contractual restrictions
- Clinical interventions (including clinical behavioral interventions)
- Prisoners as subjects
- Receipt of an NIH issued Certificate of Confidentiality to protect identifiable research data

U-M Exemption 2(a): Minimal risk research that involves a non-invasive intervention followed by data collection via survey, interview (including focus groups), or observation unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation. This exemption does not apply to research with children. Some examples include:

- Reading a story or vignette
- Playing an economic game
- Using a computer program or website
- Watching a video
- Using a robot arm or device

U-M Exemption 5(a): Research and demonstration projects sponsored by the State of Michigan parallel to existing federal exemption 5 (above).

U-M Exemption 7: Research in which study activity is limited to analysis of identifiable data. For purposes of this research study, all research subject interactions and interventions have been completed and the data continues to contain subject identifiers or links.

C. Authority to Grant Exemptions

Under U-M policy (OM Part 4.VI.C), only the IRB has the authority to issue an exempt determination. Designated IRB-Flint staff, IRB chair(s), or expediting reviewers, may
determine as exempt any project that meets the exemption criteria set out at 45 CFR 46.101(b) or in institutional policy, with the exception of Exemption 5, which must be issued by the IO or designee. Exempt determinations may not be made by investigators because of the inherent conflict of interest in their own research.

D. Review of Applications for Exemption

The eResearch application provides an exempt application pathway to assist PIs and the IRB-Flint in the review of exempt research. The application captures the information necessary for the IRB-Flint staff to evaluate the research to ensure that it is consistent with the ethical principles of the Belmont Report, that there are adequate provisions in place to maintain the confidentiality of the data and privacy interests of participants, and to determine whether the project fits the specific criteria for an exemption category. While the informed consent document/process is not reviewed by the IRB, researchers are reminded of their ethical obligation to ensure that participants are fully informed about the nature of a research project so that they can make an informed decision to participate. Samples of consent documents for exempt projects are available to investigators via the IRB website.

If necessary, an exempt application may be returned to the investigator for clarification if the reviewer is unable to make a determination of exemption based upon the information provided. Applications that do not meet the criteria for exemption are returned to the investigator with instructions regarding the correct application type to be submitted. Applications submitted for convened or expedited review may also be deemed exempt, as determined by the board or the expediting reviewer. The IRB-Flint may also choose to conduct a full review of a study that meets the criteria for exemption but raises ethical concerns or requires additional measures to protect participants.

Research that poses more than minimal risk or includes vulnerable subject populations may be considered exempt under the regulations. While the IRB does not have regulatory oversight, it may provide guidance on minimizing risks to subjects or provide information on additional protections for vulnerable participants.

E. Exemption Determination

The exempt determination is issued to the investigator via eResearch. Once an exemption has been granted, the project is not subject to continuing IRB oversight, unless the scope of the project changes such that it no longer meets the criteria required for exemption.

The notification letter includes the exemption category assigned to the study as well as instructions to amend the eResearch application for IRB for review if the scope of the project changes beyond the criteria for exemption.

Refer to OM Part 4.VI.D for additional information.

IV. Standard Review Procedures for Non-Exempt Research

For projects that are subject to IRB-Flint oversight, the IRB staff, in consultation with IRB chair(s) and IRB administration, as necessary, makes a preliminary assessment as to whether the proposed research qualifies for expedited review or must be scheduled for convened board review. Non-exempt research projects involving human subjects must be reviewed by an
expediting reviewer or by the convened IRB. The expedited and convened board review procedures are used for initial applications, amendments, scheduled continuing review applications, and AE/ORIO reports.

A. Expedited Review

1. Criteria for Expedited Review

DHHS regulations at 45 CFR 46 identify certain types of research that may be reviewed and approved by expedited review. The following criteria must be met before a protocol may be considered for an expedited review process:

- The activity must present no more than minimal risk to subjects. The regulatory definition of minimal risk is that the probability and magnitude of harm or discomfort anticipated in the research is 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.
- The research must fall within the categories of expedited research as identified in OHRP guidance on Categories of Research That May Be Reviewed by The Institutional Review Board (IRB) through an Expedited Review (See also 63 FR 60364-60367, November 9, 1998).
- The expedited review criteria cannot be used where the identification of subjects and/or their responses would reasonably place them at risk of criminal or civil liability; would be damaging to the subjects’ financial standing, employability, insurability or reputation; or would be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- The activity is a minor change (amendment) to approved research previously reviewed by the convened board. Refer to OM Part 3.III C.5(b).

2. Expedited Review Process

eResearch submissions qualifying for expedited review are accepted and reviewed by the IRB on a continuing basis, during University business hours, except during seasonal holidays when University administrative offices are closed. The IRB-Flint staff and reviewers make every attempt to review expedited applications without undue delay dependent upon the completeness of the application, the availability of reviewers and the number of other projects in process.

IRB staff conducts an administrative review of each application for completeness and adherence to regulatory requirements. An application that is not complete is returned to the PI via eResearch with instructions regarding necessary changes before the application can be submitted for regulatory review. Once the administrative review process is complete, the IRB staff assigns the application to the expediting reviewer.

Expedited review is conducted by a single reviewer. The IRB-Flint chair(s), IRB members, or qualified IRB staff may be appointed by the chair(s), may conduct expedited reviews under the regulations stated in 45 CFR 46.110. Prior to assignment, the IRB staff also makes an assessment to ensure that an application is not assigned to a conflicted expediting reviewer. If a previously unreported conflict is
identified in the course of reviewing an application, a new reviewer will be assigned to the application. Refer to SOP Part 8 for conflict of interest procedures.

If relevant expertise to review an application does not exist among the expediting reviewers, then the reviewer may request, via the IRB office, that an ad hoc consultant review the application and supporting materials. The outcome of this review is documented for the review and consideration by the expediting reviewer.

The application and supporting documents including informed consent documents, study protocols, survey instruments, and recruitment materials are forwarded to the reviewer via eResearch. Materials that cannot be provided via eResearch are set aside for review within the IRB Office. A regulatory checklist is also generated for the reviewer at the time of assignment, including comments provided by the IRB staff. In addition, the reviewer has access to all eResearch correspondence between the IRB staff and the study team. The assigned expedited reviewer examines the application and supporting materials for compliance with regulations and documents the review and determination using the reviewer checklist in eResearch.

3. Expedited Review Determinations
All expedited determinations, decisions, and contingencies issued by the IRB are recorded in eResearch and are available for review by the members of the IRB, the IRB staff, the investigator and study team. Investigators receive extensive detail regarding any changes required in order to achieve approval of the application.

a. Approve
The expediting reviewer may issue a determination to approve an application without imposing changes to the study or informed consent process if it meets all regulatory requirements for approval (refer to Section D, below). The reviewer must also identify the expedited review category used to approve the study.

The approval period begins on the date of the submission of expedited reviewer’s approval. The expiration date represents the last day of the approval period. For federally-supported research, the approval period shall not extend beyond one year (364 days). The IRB-Flint may approve an application for an interval of less than one year for reasons that include, but are not limited to, overall study risk level, proposed DSMP, research conducted in an international setting, or a study team that has demonstrated the need for additional oversight. Projects which qualify under IRB policies may be approved for a period of two years (729 days). (Refer to the HRPP Innovation and Demonstration Initiative Website).

For federally-supported research, the approval period shall not extend beyond one year (364 days).

b. Approve with Contingencies
The expedited reviewer may make approval contingent on the principal investigator making specified changes to the protocol, informed consent document(s), or other supporting materials. The investigator is notified of the study outcome via eResearch and is provided with detailed instructions regarding required changes to the application or study materials that must be completed before the application can receive final approval. The expediting reviewer may
indicate whether they wish to review and approve the response to contingencies or whether the IRB staff can perform that activity.

The IRB may, in its discretion, require that the investigator respond to required changes within a specified period and instruct that if the response is not received, the application will be considered withdrawn and may be administratively withdrawn.

The approval period begins on the date of the submission of the expedited reviewer’s approval with contingencies, regardless of when the specified changes are resubmitted to the IRB by the investigator.

c. Changes or Clarification Requested
For projects that require significant revision before approval can be granted, the expediting reviewer will request that the application be returned to the investigator using the Changes or Clarification Requested activity. The investigator will be provided with detailed instructions, via eResearch, of the materials needed or revisions to the application or study materials that must be submitted before reconsideration of the application by the expedited reviewer.

The Board may, in its discretion, require that the investigator respond to required changes within a specified period and instruct that if the response is not received, the application will be considered withdrawn and may be administratively terminated.

d. Request Review by Convened Board or Other Review Path
An expediting reviewer may return an application to the IRB-Flint staff with a request that the chair place the study on the agenda for the convened board, if the reviewer finds that the study does not meet the criteria for expedited review, or if the reviewer feels that the expertise of the full board would prove useful in the review. A study may also be referred to the convened board if the principal investigator disagrees with changes required by the expediting reviewer. Only the convened IRB can disapprove a study.

An expediting reviewer can also recommend that a study receive an exempt or not regulated determination.

B. Convened (Full) Board Review

1. Criteria for Convened Board Review
Projects requiring IRB-Flint oversight that do not meet the criteria for expedited review (see Categories of Research That May Be Reviewed by The Institutional Review Board (IRB) through an Expedited Review), are assigned to the convened IRB for review. Such projects include:

- Research involving more than minimal risk to subjects
- Projects referred to the convened board by the IRB chairs or at the request of an expediting reviewer
• Research involving vulnerable populations, sensitive topics, or complex
design elements that would benefit from review by the breadth of expertise
represented on the board

2. Convened Board Review Process
IRB-Flint meets monthly, according to a published schedule, to review assigned
applications. The IRB staff, in consultation with the IRB chair assigns a primary and
secondary reviewer from the IRB membership for each initial application. Scheduled
Continuing Reviews and Amendments may be assigned only a primary reviewer, or
a primary and secondary reviewer, depending on the complexity of the application.
The primary reviewer typically has relevant expertise or knowledge of the subject
matter. The secondary reviewer may represent a different field of expertise or
experience, and will be chosen from the membership at-large, including the non-
scientific and community members.

If relevant expertise to review the application does not exist among the IRB
membership, then the IRB chair, the primary or secondary reviewer, or the IRB staff,
may select an ad hoc consultant to review the application and supporting materials
and present the outcome of their review at the convened meeting. IRB staff
facilitates contact with the consultant and provides them with a copy of relevant
application materials and confidentiality statement. Consultants are typically used to
provide expertise in a specific subject area or about a particular subject population.

The application and supporting documents including informed consent documents,
study protocols, survey instruments, and recruitment materials are forwarded to the
primary and secondary reviewers via eResearch. Materials that cannot be provided
via eResearch are set aside for review within the IRB Office. A regulatory checklist
is also generated for each reviewer at the time of assignment, including comments
from the IRB staff. In addition to the assigned reviewers, IRB board members have
access to the full application and supporting materials for review prior to the meeting,
including all eResearch correspondence between the IRB staff and the study team.

a. Reporting of Expedited Reviews to the Convened Board
Expedited approvals for the time period between IRB meetings are reported and
acknowledged by the board at each meeting of the convened IRB through a
prepared report listing the activities. The board is given an opportunity to discuss
any of the applications. Expedited applications are available to any board
member, at any time, via eResearch.

3. Convened IRB-FLINT Determinations
All convened board determinations, decisions, and contingencies issued by the IRB
are recorded in eResearch and are available for review by the members of the IRB,
the IRB staff, the investigator and study team. Investigators receive extensive detail
regarding any modifications required in order to achieve approval of the application.

a. Approve
The convened board may vote to approve an application without imposing
changes to the study or informed consent process if it meets all regulatory
requirements for approval (refer to Section D, below).
The approval period begins on the date the submission is approved by the IRB and generally expires 364 days later unless the IRB issues a shorter approval period or the project qualifies for a two year approval (729 days) under the IRB-Flint policy. The expiration date represents the last day of the approval period.

b. Approve with Contingencies Pending
The IRB may vote to make approval contingent on specified changes to the protocol, informed consent document(s), or other supporting materials. The principal investigator is notified of the review outcome via eResearch and is provided with detailed instructions regarding required changes to the application or study materials that must be completed to the satisfaction of the IRB before the application can receive final approval. Contingent approval is granted only for changes that are not directly related to the regulatory determinations of the board required for approval under the regulations at 45 CFR 46.111. The IRB, in its vote, must indicate whether the response to contingencies can be reviewed and approved by the chair, a primary reviewer, or returned for review and approval by the convened board.

The date of the vote to approve with contingencies pending shall be deemed the date of approval by the convened IRB regardless of when the specified changes are submitted to IRB for final review and release of the contingent approval. Approval periods are issued according to the standards outlined in the preceding section.

The Board may, in its discretion, require that the investigator respond to required changes within a specified period and instruct that if the response is not received, the application will be considered withdrawn and may be administratively terminated.

c. Action Deferred
The IRB-Flint may vote to defer action on an application when a significant action on the part of the investigator or the convened board is required before the IRB can consider approval or disapproval. If the action involves the principal investigator, notification is provided via eResearch and includes detailed instructions regarding required changes to the application or study materials that must be completed to the satisfaction of the IRB before the application can receive additional consideration and possibly, final approval. If the required action involves the IRB, appropriate, designated individuals will undertake the necessary actions.

The Board may, in its discretion, require that the investigator respond to required changes within a specified period and instruct that if the response is not received, the application will be considered withdrawn and may be administratively terminated.

d. Disapproval
The IRB-Flint may vote to disapprove an application to conduct human subjects research when it determines that the study design does not provide, and is unlikely to be modified to provide, adequate protection to subjects. Disapproval of an application usually follows several attempts by the investigator, in
conjunction with the efforts of the IRB, to modify the study design to afford
protection to the subjects.

If the IRB disapproves a research activity, the PI will be notified of the decision in
writing. The notification will include a statement of the reasons for disapproval
and will provide instructions to the investigator regarding his/her right to respond
to the IRB in person or in writing.

Only the convened IRB can disapprove a study and this study-specific decision
may not be modified by any other agency or entity at the University of Michigan.
A principal investigator may submit a new study on the same research topic,
without prejudice, if the IRB’s reasons for disapproval in the first instance are fully
addressed.

4. **Appeal of Disapproval Determination**
   An investigator may submit an appeal to the IRB and may appear before the
   convened IRB to respond to a disapproval of research. After presentation by the PI,
   the IRB may decide to issue a final disapproval or it may choose to reverse its
disapproval if new facts are presented that were previously unknown or if the
investigator modifies the project to address the IRB’s concerns.

5. **Appeal of a Decision other than Disapproval**
   If an investigator wishes to appeal any other decision issued in conjunction with the
   review of a study, the investigator may contact the IRB for a full and considered
discussion of the concern. Examples of these decisions include the transfer of an
application to a different UM IRB for review and oversight or objection to a
contingency or change request within the application. Concerns will be addressed
by the IRB chair in consultation with the reviewing entity (convened board or
expediting reviewer).

6. **Institutional Approval**
   Research approved by IRB-Flint is still subject to disapproval by the VPR and, as
   applicable, other institutional officials. However, no institutional official, including the
   Vice President, is empowered to approve research previously disapproved by an
   IRB.

C. **Criteria for IRB Approval**

   All applications for research with human subjects, reviewed by a single expediting reviewer
   or by the convened board, are reviewed and approved in accordance with the requirements
   of 45 CFR 46.111. The IRB considers the following elements when evaluating and
   approving a research proposal:

1. **Scientific Merit and Feasibility**
   The IRB considers whether research procedures are consistent with sound research
design in order to yield the expected knowledge. Scientific merit is examined in
relationship to the risks and benefits of the research.

   For projects that have undergone a peer review process, the eResearch application
   asks the researcher to identify the organization that conducted the scientific review.
   All studies that receive federal support are subject to scientific review before award.
The grant application and related materials are uploaded into the eResearch system or accessed via a link into the UM Proposal Management system and are considered as part of the IRB review. For student applications, it is expected that the faculty advisor has reviewed the study for scientific merit before it is submitted to the IRB.

2. **Minimizing Risk**
   The Belmont principle of beneficence directs that studies involving human subjects should be designed so as to minimize possible harms and maximize possible benefits. The Belmont Report defines “risk” as the possibility that harm may occur, both in the chance (probability) of experiencing harm and the severity (magnitude) of the envisioned harm. Potential harms from research can include physical, psychological, reputational, financial, civil or criminal risks. The term “benefit” is used in the research context to refer to something of positive value related to health or welfare.

To approve research the IRB conducts a risk/benefit assessment, concerned with assessing probability and magnitude of possible harms in relation to anticipated benefits. Risks can extend beyond individual participants to include their families or to segments of society. Benefits of the research include those that may accrue to the individual subject or their family, or to society at large (or to certain subsets of society). While many studies do not offer the hope of any direct benefit to their participants, the risk/benefit calculus properly includes benefits that may be realized by others.

To approve research, IRB-Flint verifies that the research plan, including research design, methodology, and allocation of resources will not place participants at unnecessary risk. In order to make this determination, IRB-Flint must determine that risks to participants are minimized by evaluating the following:

- Procedures are consistent with sound research design and do not expose participants to unnecessary risk
- When appropriate, the research uses procedures already being performed on the participants for diagnostic or treatment purposes
- The time for the investigators to conduct and complete the research is adequate
- There are an adequate number of qualified staff
- The facilities where the research will be conducted are adequate
- The investigators have access to a population that will allow recruitment of the necessary number of subjects
- Medical or psychosocial resources that subjects may need as a consequence of the research are available.

3. **Risk/Benefit Analysis**
   All research studies, regardless of the type of review (initial or continuing review; convened board or expedited), undergo a risk/benefit assessment.

   A risk/benefit assessment is concerned with assessing probability and magnitude of possible harms in relation to anticipated benefits. Risks can extend beyond individual participants to include their families or to segments of society.
Benefits of the research include those that may accrue to the individual subject or their family, or to society at large (or to certain subsets of society). While many studies do not offer the hope of any direct benefit to their participants, the risk/benefit calculus properly includes benefits that may be realized by others.

The IRB will review the eResearch application to evaluate the risk/benefit balance of the study, using supporting documents and scientific references, as well as staff and reviewer checklists and opinions provided by consultants (as needed).

The initial step in evaluating a study for risk is to determine if the study meets the federal regulatory definition of minimal risk found at 45 CFR 46.102(i). Generally studies with a low probability of harm are considered to pose minimal risk to subjects.

In determining whether a study presents no greater than minimal risk to the subjects, the IRB considers the following:

- The PI’s assessment of the subjects’ risk level as presented in the eResearch application
- Whether the study procedures are consistent with sound research design
- An evaluation of the probability (likelihood) of harm occurring and the magnitude (potential severity) of possible harms
- An evaluation of whether the subjects are vulnerable in some way
- An evaluation of the steps taken, or planned, by the investigator to alleviate the potential harms (including the quality of the data safety monitoring plan (DSMP), if appropriate)
- The investigator’s history of compliance with research protocols and IRB procedures

Generally, studies with a low probability of harm are considered minimal risk.

If the study does not meet the federal definition of minimal risk, then the IRB evaluates the design of a proposed study to ensure that, consistent with fulfilling its scientific mission, risks are minimized and potential benefits of the research are maximized as much as possible within the confines of the research study.

In assessing the risks and benefits arising from a research proposal, the IRB only considers the risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). In addition, the possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) should not be assessed as a potential research risk by the IRB.

The IRB will rely upon the expertise of its membership to evaluate the risks and benefits of a research proposal. Alternatively, if physical risks are difficult to assess, or outside the scope of expertise of IRB, the protocol may be referred to another IRB according to the policies outlined in the OM Part 5.1.
4. **Qualifications of the Principal Investigator**

By University policy, the IRB recognizes only one PI for each application. This policy ensures that the PI assumes full responsibility for the project and for compliance with applicable laws, regulations and institutional policy. Only the PI can execute the command to submit an eResearch application (initial, continuing review, or amendment) to the IRB and by doing so, must attest to full knowledge and approval of the content of the submission and supporting documentation. OM Part 6.1 describes who may serve as principal investigator on an IRB application.

The PI must be qualified by training and experience to oversee all aspects of the proposed research. The PI, as well as key study personnel (co-investigators, faculty advisors, study coordinators), must complete PEERRS human subjects research training before their research can be granted IRB approval.

As an academic institution, the University of Michigan trains students to design, develop, and implement research studies. The IRB permits student trainees (undergraduate and graduate) to act as principal investigators, but requires that all such studies involve oversight from a faculty advisor with appropriate knowledge, training and expertise to oversee the conduct of the study and serve as a study team co-investigator. Faculty advisors attest to their oversight of and responsibility for the student researcher via acceptance of their role in the eResearch application. Students may not submit an application unless the faculty advisor has accepted their role. Undergraduate students are generally not permitted to conduct research involving greater than minimal risk to the subjects.

5. **Recruitment, Selection, and Enrollment of Subjects (Equitable Selection of Subjects)**

The process of inviting a person to participate in a research project involves presenting clear information that allows a knowledgeable decision to enter a study. Recruitment into a study must be free of coercion.

The IRB will evaluate each submission to ensure that the project provides for “equitable selection” of research subjects, paying particular attention to the subject inclusion and exclusion criteria and recruitment methodology.

Among the points IRB-Flint may consider in making its determination are whether:

- The research is grounded in appropriate current science; is of value to the subject, researcher or the field; and the setting is appropriate
- The burdens of participating in the research fall on those most likely to benefit
- The recruitment of subjects will avoid placing a disproportionate share of the burdens of research on any single group
- The nature of the research requires or justifies using the proposed population
- Any groups who might be more susceptible to the risks presented by the study ought to be excluded and whether procedures for identifying those groups are adequate
- The benefits and burdens are fairly distributed
- It is more appropriate to conduct the study with other, less vulnerable subjects
• The selection process, by design, will overprotect potential subjects who may be vulnerable so that they are denied equal opportunities to participate
• Vulnerable subjects will be adequately protected during recruitment

The IRB reviews all materials or methods intended to recruit prospective subjects. Recruitment materials are submitted as part of the eResearch application and are reviewed as part of the initial review or submitted as an amendment and must be approved prior to implementation, or are provided to the IRB in hard copy if the materials are in a format that cannot be uploaded into the application.

The IRB reviews both the information contained in the recruitment material, as well as the format of the material to ensure that the procedure for recruiting subjects is: 1) not coercive; and 2) does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

In the review of advertisements, the IRB will evaluate the following:

• The mode of its communication
• The final copy of printed advertisements
• The final audio or video taped advertisements

As part of their review, the IRB will ensure that these advertisements do not include exculpatory language, and do not promise “free treatment” when the intent is only to say that subjects will not be charged for taking part in the investigation. Recruitment materials should be limited to the information the prospective subjects need to determine their eligibility and interest. The following may also be included, though are not required:

• The name and address of the investigator and/or research facility
• The condition under study and/or the purpose of the research
• In summary form, the criteria that will be used to determine eligibility for the study
• A brief list of participation benefits, if any
• The time or other commitment required of the subjects
• The location of the research and the person or office to contact for further information
• Information about payment to subjects. As a practice, recruitment materials should not emphasize the amount to be paid, by such means as larger or bold type when studies involve greater than minimal risk.

6. Review of Payment Arrangements to Subjects
The IRB will review the arrangement for payments or other participation incentives offered to subjects. All information concerning payment, including the amount and schedule of payments is described in the consent document and reviewed by the IRB to assure consistency between information presented in the application and the consent document.

The IRB will assess:
• Whether the payments appear to be appropriate for the proposed research, particularly whether the payment might be coercive or provide undue influence based on the risk level of the study or the vulnerability of the subject population
• The plan for prorating payments in the event that a subject withdraws from the study prior to its conclusion. Where appropriate, credit for payment accrues as the study progresses and may not be contingent upon the subject completing the entire study
• Whether the payment is considered sufficient to take into account other costs to the subject for participating in research (e.g. travel, lodging)
• Any amount paid as a bonus for completion is reasonable and not so large as to unduly influence participants to stay in the study when they would otherwise have withdrawn
• Where academic credit is offered as an incentive for participation, the IRB will ensure that students are offered an alternative option for extra credit if they choose not to participate in research
• The plan for payment as it relates to the University’s Human Subject Incentive Program (HSIP) (refer to Standard Practice Guide (SPG) 501.07).

7. Data Safety Monitoring
Detailed information about DSMPs can be found in the OM Part 7.II. With respect to any research project or class of research projects, the IRB may impose additional conditions on the conduct of the research at any time prior to, concurrent with, or following approval, when in the judgment of the IRB such additional conditions are necessary or appropriate for the protection of human subjects.

a. Considerations for the Imposition of Special Monitoring Requirements
The IRB-Flint may, at its discretion, perform monitoring or request monitoring (via UMOR) of a project in addition to that accomplished through initial, amendment, and annual continuing reviews, and analyses of interim reports such as adverse event and audit reports. For example, the IRB may choose to undertake extra monitoring for research which presents greater than minimal risk or to gauge the progress of recruitment for vulnerable subjects or to follow the research progress on controversial subject matter. The IRB may also consider the frequency and nature of adverse events reported to-date.

The IRB may also choose to monitor one or more of the projects of a single investigator in consideration of the experience of the investigator or as follow-up to previous reports of complaints or non-compliance or prior IRB interactions with the individual.

b. Examples of Special Monitoring Requirements
Monitoring may include, but is not limited to:

• Shortened approval periods and/or interim, scheduled reports from the investigator during the approval period
• Site visits to research locations
• Interviews of subjects
• Third party witness to the informed consent process
• Review of research records
- Independent, third-party monitoring that no material changes in the study have occurred
- Independent Data Safety and Monitoring Board (DSMB)

The IRB shall communicate with investigators, as appropriate, regarding the outcomes of these additional monitoring efforts.

8. Protection of Subject Privacy and Data Confidentiality
The IRB will ensure that the research plan contains adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. OM Part 3.III.C.6 for a detailed description of points the IRB should consider in determining whether a protocol includes plans sufficient to address privacy and confidentiality concerns.

a. Privacy
The protection of subject privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. The IRB considers:

- Whether the research involves observation or intrusion in situations where the subjects have a reasonable expectation of privacy and whether reasonable people be offended by such an intrusion
- Whether the research could be redesigned to avoid the intrusion
- If privacy is to be invaded, whether the importance of the research objective justifies the intrusion, and if so, what if anything the subject will be told later

b. Confidentiality
Confidentiality relates to the protection of subject data that has been shared with the researcher in a relationship of trust with the expectation that it will be protected and disclosed as agreed upon in the consent process. The IRB evaluation of the data confidentiality plan presented in the eResearch application includes:

- Examination of the need for collecting sensitive information about individuals and whether adequate provisions have been made for protecting the confidentiality of the data through coding, destruction of identifying information, limiting access to the data, or other methods that may be appropriate to the study
- Examination as to whether the information obtained about subjects might interest law enforcement or other government agencies to the extent that they might demand personally identifiable information. The IRB will consider whether a certificate [grant] of confidentiality should be sought from a federal or state agency to protect the research data and the identity of the subjects from subpoena or other legal process.
- Evaluation of the disclosures to subjects about confidentiality plans and whether documentation of consent should be waived to protect confidentiality
- Evaluation of the sufficiency of the plan for data security
When needed, the IRB seeks guidance from the U-M Information Technology Services (ITS) regarding appropriate data security procedures for research under its oversight.

9. **Review of Informed Consent Process**  
*Throughout this section the term “consent” also refers to “parental permission.”*

IRB-Flint will review the informed consent process, including consent documents, for each submitted application to assure that subjects provide legally effective, voluntary, informed consent. Informed consent materials (including oral scripts), requests for waiver of informed consent, and waiver of documentation of informed consent are submitted to the IRB as part of the eResearch application. The IRB will assess applications and issue waivers of documentation or waivers of some or all of the elements of informed consent, where appropriate under regulatory guidance.

Except as otherwise approved by the IRB, no investigator may involve a human subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.

The IRB will evaluate the plans for obtaining face-to-face consent, as described in the eResearch application, by confirming the following:

- The consent process is facilitated by a person knowledgeable about the study, its enrollment criteria, and its risks, benefits, and alternatives (usually a principal investigator or co-investigator, though other study team members may also be qualified)
- The prospective subject will be provided with the materials in a location appropriate to the study and offering the privacy necessary to ask questions about the study before deciding to participate
- The information is presented in language understandable to the participant or representative.

In obtaining informed consent, the investigators will give the subject (or representative) sufficient opportunity, commensurate with the risk level of the research, to consider whether or not to participate. Time should be allowed for questions and full discussion. Information about the study is presented in a neutral, non-coercive manner and in a language readily understandable by the subject.

The discussion may be supplemented with additional information (e.g., video tape, written material), provided that the materials are approved in advance by the IRB.

a. **Regulatory Elements of Informed Consent**

Except as otherwise approved by the IRB, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject’s legally authorized representative. A copy shall be given to the person signing the form. A consent document is valid only after its approval by the convened board or expediting reviewer/s.

In its review of informed consent documents, IRB will ensure that all of the basic elements of informed consent are included (45 CFR 46.116) and the materials do not contain any exculpatory statements suggesting that any of the subject’s legal
rights are being waived, or that the investigator, sponsor or the University of Michigan is being released from liability for negligence. For projects involving greater than minimal risk to participants, the informed consent process must include information regarding compensation or treatment that will be provided to an injured subject. Refer to OM Part 7.V for more information.

A detailed explanation of the elements of informed consent, including templates and suggested wording is posted at the IRB website.

b. Waivers of Documentation of Informed Consent
The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all of the subjects if the requirements of 45 CFR 46.117(c) are satisfied.

Situations justifying a waiver of documentation of informed consent may include:

- Telephone, web-based, or self-administered mail surveys
- Research involving deviant or illegal behavior
- Research involving socially sensitive issues such as HIV status

When the IRB waives the requirement for documentation of informed consent, it will determine whether investigators should provide subjects with a written or oral (e.g., in cases of phone interviews) statement explaining the nature, benefits, and risks of the research. The text of any written or oral script or statement must be reviewed and approved by the IRB before its use.

c. Waivers of Informed Consent
The IRB may approve a consent procedure which does not include or which alters some or all of the basic elements of informed consent or waives the requirement to obtain informed consent if the IRB finds that appropriate conditions of 45 CFR 46.116(c) or (d) are satisfied. Projects involving the use of deception in the consent process must meet the criteria for waiver of informed consent.

Researchers occasionally request the use of a “passive” or “implied” consent process. The use of such a process requires that the IRB-Flint to waive or alter the informed consent, meaning that the project must meet the regulatory requirements of 45 CFR 46.116(c) or (d).

d. Short Form, Comprehensive Oral Script, and Witness
The IRB may approve a short form consent process that documents that the elements of informed consent required by HHS have been presented orally to the subject or the subject’s legally authorized representative and must be signed by a witness. This consent process is used in populations whose members cannot read the consent document (see 45 CFR 46.117(2) and OM Part 3.III.C.6 (e). This consent process is rarely used in projects overseen by IRB-Flint.

D. Special Review Considerations for Projects Involving Vulnerable Populations
Research may, by design or by random recruitment, involve subject populations that may be vulnerable to coercion or undue influence. In order to protect the rights and welfare of these subjects, the IRB will consider additional safeguards to protect these individuals.

Subparts B, C and D of 45 CFR 46 include additional IRB review requirements which apply to research supported by DHHS and other federal agencies adopting these standards:

- Pregnant women, human fetuses and neonates (Subpart B) (Rarely utilized by IRB-Flint, this mainly applies to clinical research involving these populations.)
- Prisoners (Subpart C) Note: all IRB-Flint research involving prisoners as subjects will be referred to IRB-HSBS for review.
- Children (Subpart D) (In Michigan, the legal age to consent to the treatments or procedures involved in the research is 18.)

For research that is not federally-supported or is supported by federal agencies that have not adopted 45 CFR 46 subparts B-D, U-M institutional policies found at OM Part 7.IV provide equivalent protections for vulnerable populations as research subjects.

When individuals from these populations participate in research, as well as other vulnerable populations such as adults with cognitive impairment or otherwise impaired decision-making capacity, educationally or economically disadvantaged persons, students or employees in some research settings, participate in research, the IRB shall require investigators to specify what additional protections, if any, will be provided to protect their rights and welfare and minimize risks unique to these participants.

If available, an IRB reviewer with expertise in the vulnerable population will review the application. If appropriate expertise is not represented by the IRB membership, a consultant will be engaged and invited to review the application and present a report.

For projects supported by the U.S. Department of Education National Institute on Disability and Rehabilitation Research (NIDRR) that target children with disabilities or individuals with mental disabilities as subjects of the research, the IRB-Flint must include at least one member who is primarily concerned with the welfare of the research subjects (refer to 34 CFR 350 and 34 CFR 356).

The IRB-Flint applies additional scrutiny in reviewing the informed consent process for vulnerable populations. Emphasis is directed toward assessing the autonomy, cognitive capacity, and/or potential coercion of the prospective subjects during the informed consent process. The informed consent process assumes special importance in certain populations, including children, pregnant women, prisoners, students, and persons with diminished decision-making capacity. The principle of autonomy, or respect for persons, includes those unable to make fully autonomous decisions. In the case of a research subject with diminished autonomy, beneficence is enhanced through protections proportional to risks. It is the responsibility of the person obtaining the subject’s consent to determine that the person has sufficient capacity to give it. Unless the requirement is waived by the IRB, each prospective subject or a legally authorized representative must provide a legally effective informed consent to participate in the project.

Laws governing vulnerable populations, including who may consent on behalf of cognitively-impaired or incapacitated adults vary from state to state. Refer to OM Part 11.II.A.2 for a
detailed description of Michigan requirements and guidance for determining requirements for research outside of Michigan.

1. **Research Involving Pregnant Women, Human Fetuses and Neonates (subpart B: 45 CFR 46.201-207)**

When reviewing research involving pregnant women, human fetuses, and neonates, the IRB considers additional assessments in order to ascertain whether the subjects are vulnerable to coercion or undue influence and whether these risks have been minimized.

The IRB will, as it deems necessary, seek the additional expertise of consultants to assist in fully evaluating the research proposal. The IRB may also choose to refer these applications to another University of Michigan IRB according to the policies outlined in the OM Part 5.I.

In order to approve HHS-supported research involving pregnant women, fetuses, and neonates, IRB must apply the regulatory components of subpart B and satisfy the conditions of 45 CFR 46.201-207. For research not supported by HHS, the IRB considers the substantive elements of Subpart B in its deliberations, but may also utilize other comparable ethical guidelines, polices or procedures. Refer OM Part 7.IV for further details.

2. **Research Involving Prisoners (Subpart C: 45 CFR 46.301-306)**

A “prisoner” means any individual involuntarily confined or detained in a penal institution such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. The term is also intended to encompass individuals sentenced to such an institution under a criminal or civil statute, detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution and individuals detained pending arraignment, trial or sentencing. The OM Part 7.IV.B.1 includes several examples of individuals who are considered to be prisoners.

By practice, research involving prisoners is reviewed by the convened IRB board or another University of Michigan IRB. The convened IRB will include, as a member of the voting quorum, a prisoner representative.

When an enrolled participant becomes incarcerated during the course of a study where there was no intent to recruit prisoners as a subject group, researchers are directed to contact the IRB for guidance. The IRB may direct the PI to withdraw the participant or may require an amendment to take into consideration the required protections for prisoner subjects.

For more information about prisoner research consult OHRP guidance.

3. **Research Involving Children (Subpart D: 45 CFR 46.401-409)**

A child is defined under federal research regulations as an individual who has not yet reached “the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted” (45 CFR 46.402(a)). Detailed guidance on who is considered a “child” for purposes of human research conducted at U-M is provided in OM Part 11.II.A.2.
When reviewing research involving children, the IRB-Flint will, when necessary, seek additional expertise from consultants.

The IRB will assess recruitment strategies, the environment for assenting, additional resources to assist in the process (e.g., videos, books, pictures, etc.), and the age of the subjects in evaluating the capacity of the child to understand the nature of the research.

The IRB will determine whether the investigator has outlined adequate provisions for obtaining any necessary assent for the children and permission from parents/guardians according to 45 CFR 46.408. Research conducted in public schools may be subject to additional regulatory consent requirements such as PPRA (Protection of Pupil Rights Amendment) and FERPA (Family Educational Rights and Privacy Act) (refer to 34 CFR 98, 20 USC 1232g, 34 CFR 99, OM Part 11.I.A.6, OM Part 11.II.B.3 and HRPP Guidelines for Federally Sponsored Research).

The IRB will assess the adequacy of plans to obtain the permission of the parent(s)/guardian according to 45 CFR 46.408(b) and (c), including the instances in which both parents must provide permission and instances in which the requirement to obtain permission should be waived in order to protect the subject.

In order to approve HHS-supported research involving children as subjects, the IRB-Flint must apply the regulatory components of Subpart D. For research not supported by HHS, the IRB complies with Subpart D in its deliberations, but may also utilize other comparable ethical guidelines, polices or procedures as defined in OM Part 7.IV.C.

a. Evaluation of Assent

Assent is defined in 45 CFR 46.402(b) as: “...a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.”

The IRB-Flint uses its best judgment, on a study specific basis, to ensure that the assent is tailored to the level of comprehension of the prospective participants:

- Under age 4, assent is not generally sought
- Ages 4-7, verbal assent
- Ages 8-12, simple written assent
- Over age 12, full written assent, mirroring the parental permission document may be appropriate

The IRB compares the assent materials to the study protocol or application to determine the correctness of the information.

The IRB evaluates the procedures for obtaining assent, including the individual who will conduct the assent process. The IRB is granted wide discretion in determining whether a child is capable of assenting and can waive the requirement for assent if the child is not capable of providing it. Federal regulations do not specify any specific elements of assent or an age above which assent should be possible. The IRB can grant waivers of child assent or
documentation of assent. The IRB-Flint will make an assent determination for each protocol that includes children, including whether assent must be documented.

b. Evaluation of Parental Permission
Generally, a parent (the child’s biological or adoptive parent) or guardian (an individual who is authorized under applicable state or local law to consent on behalf of the child) must agree to the child’s participation in the research.

IRB-Flint assesses the procedures and appropriateness of the parental permission process. The IRB can grant waivers of parental permission or documentation of parental permission if the research meets the regulatory criteria set forth in 45 CFR 46.116 and 46.117. 45 CFR 408(c) also includes provisions for waiving parental permission in research that is designed for conditions or a subject population where parental or guardian permission is not a reasonable requirement to protect subjects (e.g., research on neglected or abused children).

The specific requirements for obtaining parental permission for HHS conducted or supported studies are found at 45 CFR 46.406 and 407.

c. Wards
Special requirements exist for more than minimal risk research involving children who are wards of the state or another agency if that research falls under at 45 CFR 46.406 and 407. Wards may participate in such research only if it meets the provisions of 45 CFR 46.409(a). In such cases, the IRB will require an advocate to be appointed for each child. For additional guidance, see IRBMED Guidance on Research Involving Children who are Wards.

4. Research Involving Other Vulnerable Populations
IRB-Flint considers certain other individuals or groups to be vulnerable to the possibility of coercion or undue influence. When a member of any vulnerable population participates in research, the IRB shall require investigators to specify what additional protections, if any, will be provided to protect their rights and welfare and minimize risks unique to these groups or an individual. Some additional vulnerable populations include, but are not limited to:

- Cognitively impaired adults
- Economically or educationally disadvantaged persons
- Employees or students of investigators conducting the study
- Patients of physician/dentist-investigators
- College students
- Individuals who are illiterate
- Individuals who are not fluent in English

a. Informed Consent in Special, Vulnerable Populations
The IRB applies additional scrutiny in reviewing the informed consent process for vulnerable populations. Emphasis is directed toward assessing the autonomy, cognitive capacity, and/or potential coercion of the prospective subjects during the informed consent process. The informed consent process assumes special importance in certain populations, including children, pregnant women, prisoners,
students, and persons with diminished decision-making capacity. The principle of autonomy, or respect for persons, includes those unable to make fully autonomous decisions. In the case of a research subject with diminished autonomy, beneficence is enhanced through protections proportional to risks. It is the responsibility of the person obtaining the subject’s consent, with the oversight of the IRB, to determine that the person has sufficient capacity to give it.

Unless the requirement is waived by the IRB, each prospective subject or a legally authorized representative must provide a legally effective informed consent to participate in the project.

When the IRB regularly reviews research conducted with human subjects representing specific populations, the IRB will add representation to the board to represent that specific population, when possible. The representative will guide the IRB through a focused assessment of the informed consent process as outlined by the investigator and offer input as to any special considerations or circumstances which may contribute to a potential alteration or waiver of the consent process.

When the IRB reviews research for subject populations not otherwise covered in policies, procedures, or represented by a member of the IRB, the IRB will utilize a consultant to assist in providing a focused evaluation of the informed consent process and any other special considerations for the vulnerable population.

b. Informed Consent Involving Adults with Decisional Impairment

When reviewing the informed consent process for research involving decisionally-impaired adults, the IRB considers additional assessments in order to ascertain whether the subjects are vulnerable to coercion or undue influence and whether these risks have been minimized. Adults may have decisional impairment due to conditions such as stroke, brain injury, or mental illness such as schizophrenia or depression. Decisional impairment is reflected in a diminished ability to reason and make sound choices. This impacts the subjects’ capacity to provide full, effective informed consent. Some decisional impairments may be transient, others are permanent. Individuals with transient impairments may be able to provide consent during lucid intervals but those intervals may not coincide with the conduct of the research. Lesser degrees of impairment may also allow some prospective subjects to consent to participation while individuals with a more severe degree of impairment are not competent to consent. Before these individuals are allowed to participate in any study consent must be secured from competent and legally sanctioned guardians. In these circumstances, the impaired individual must routinely provide assent even if they are unable to provide consent. Consult OM Part 7.IV.D.

In addition to the usual requirements, the IRB assesses the informed consent document and process as outlined by the investigator to assure that:

- The informed consent documents accurately and fairly represent the actual nature and potential risks of the proposed study
- Adequate assurances are in place to assess the prospective subject’s understanding of the research
• The consent document is written at a language/readability level appropriate to the subject
• If the subject is likely to be unable to read, that there are provisions, compliant with informed consent requirements, to provide for an oral presentation of the informed consent materials

The IRB may consider the following to provide additional assurances to the integrity of the informed consent process:

• Monitoring of the informed consent process by a third party
• Obtaining an independent assessment of the prospective subject’s cognitive capacity
• If the subject is unable to provide legally effective informed consent, the investigator should outline a plan to obtain assent from the subject and informed consent from a legally authorized representative
• Using open-ended questions to assess the individual’s understanding of the goals of the study and its risks and benefits

c. Legally Authorized Representatives
The IRB will review the study procedures to assure that the investigator has a plan to inform the legally authorized representative about the study, its implications for the subject, and the legally authorized representative’s role in providing initial and ongoing consent.

If subjects are initially capable of providing informed consent, but it is likely that they will lose this capacity during the conduct of the research study, they should be encouraged to appoint a legally authorized representative while the subjects are capable. Once the legally authorized representative’s appointment becomes legally effective, the representative will re-consent to continued participation, amendments to the study, or may decide to end the subject’s participation in the research. The subject always has the right to discontinue participation in the research.

Michigan law describes who is authorized to consent for particular medical interventions. For a detailed discussion of who may consent for whom under various circumstances, consult OM Part 11.II.A.

E. International Research

Generally, the IRB-Flint reviews all international human subject research projects conducted by UM investigators under its jurisdiction, rather than deferring review to a collaborating international institution. When an international site is engaged in the conduct of a UM research project and the research is federally supported by a Common Rule agency, the regulatory requirements of the Common Rule are applied and local IRB or ethics committee review is required. An FWA may be required by the supporting agency. For international research that is not federally supported, the IRB may apply the same or equivalent protections as those described in the Common Rule and UM institutional policy. The IRB may require local IRB review, particularly for those involving more than minimal risk to participants. Where the international research site is not engaged in the conduct of the
research, the IRB may request a letter of collaboration from an appropriate official agreeing to the conduct of the research. Refer to OM Part 11.I.C.

The IRB-Flint will consider local research context when reviewing research conducted in international settings. Elements of consideration include laws and regulations, local customs and cultural norms, political and socio-economic conditions, and language and literacy issues. The eResearch application elicits information from the study team regarding their experience with and knowledge of the community and culture in which the research will take place. When IRB members do not possess the appropriate cultural knowledge to review research in a particular country or region, the IRB will seek guidance from consultants with cultural expertise to assist with the review. The IRB may also request that the investigator seek cultural review by an IRB or ethics committee review or from a government agency in the region. For exempt research, the IRB does not require documentation of IRB review or other approvals from international sites.

Projects conducted in international settings are subject to the same IRB requirements for review and approval of initial applications, scheduled continuing review and review of modifications as projects conducted domestically. A key element of the review process is the assessment of the informed consent process and documents. The IRB evaluates the consent process to ensure that it is culturally sensitive and in a local language that is understandable to the subject, and that the complexity of the information is appropriate for the research population. Consent documents and other study materials must be provided to the IRB in the languages in which they will be offered, as well as in English.

Post approval monitoring, such as project reports to the IRB by the PI, may be imposed when necessary. As with domestic projects, investigators are obligated to report subject complaints, unanticipated problems involving risk to subjects or others and other reports of potential non-compliance to the IRB-Flint. Research participants are provided with the IRB email address and international phone number as part of the consent process.

F. Other Special Review Considerations – Research in Schools and Universities

Research conducted in schools receiving U.S. Department of Education (ED) funds may be subject to additional regulations. The IRB will advise researchers when these regulations may apply to a research proposal. In addition, schools granting access to researchers may impose additional requirements of researchers, such as particular consent processes or district approval processes that would not be required by the IRB.

1. The Family Educational Rights and Privacy Act (FERPA) (34 CFR 99)
FERPA applies to research involving student education records for any institution receiving Department of Education (ED) support, meaning that it applies to most public and private K-12 schools as well as public and private universities. Access to identifiable student records requires written permission from the parent (for children) or the adult student unless certain exceptions apply. Questions regarding FERPA applicability and exceptions may be referred to the Office of General Counsel (refer to OM Part 11.B.3.)

2. The Protection of Pupil Rights Amendment (PPRA) (34 CFR 98)
The PPRA was created by the No Child Left Behind Act and applies to survey research conducted in elementary and secondary schools receiving funds under Department of Education programs. The provisions of PPRA apply to surveys that
involve specific sensitive topics. The PPRA includes requirements for parental permission as well as for making the survey questions available for review. The PPRA also applies to ED conducted or supported research that is exempt from the Common Rule. Questions regarding PPRA applicability and exceptions may be referred to the Office of General Counsel (refer to OM Part 11.1.A.6).

G. Studies Subject to Health Insurance Portability and Accountability (HIPAA) Regulations

IRB-Flint serves as the Privacy Board for research not subject to IRBMED oversight and involving Protected Health Information (PHI) from the Flint Urban Health and Wellness Center. The IRB is authorized to review and approve the following:

- Waiver of authorization for research not subject to the Common Rule, or exempt from IRB-Flint oversight under the Common Rule
- Investigator certifications for reviews of PHI preparatory to research submitted in the eResearch application
- Investigator certifications for research involving decedents’ information submitted in the eResearch application
- In consultation with other units (e.g., ORSP) any use or disclosure of limited data sets under data use agreements

Only a small number of projects involving U-M PHI are reviewed and approved by the IRB-Flint. The IRB-Flint is most often is asked to waive the requirements under HIPAA for written authorization for release of PHI to be collected, used or disclosed for the study. In these instances, the IRB must find and document in the eResearch application that the use or disclosure of PHI involves no more than minimal risk to subjects’ privacy, as demonstrated by:

- An adequate plan to protect identifiers from unauthorized use or disclosure;
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (unless there is a health or research justification for retaining the identifiers, or retention if required by law); and
- The research could not practicably be conducted without access to and use of the protected health information

On occasion, the IRB-Flint may also be asked to serve as the Privacy Board for external institutions, such as small clinical practices, that are providing access to PHI for research purposes but that do not have an internal Privacy Board.

Refer to OM Part 11.II.B.2 for more on HIPAA.

H. Studies Subject to Other Legal and Regulatory Requirements

Research involving the Department of Defense (DOD), Department of Justice DOJ, and the Environmental Protection Agency (EPA), Department of Energy (DOE) requires special consideration in during IRB review. The IRB-Flint will conduct its review following the policies described in OM Part 11.1.A and HRPP Guidelines for Federally Sponsored Research when reviewing research sponsored by these agencies.
I. IRB Meetings

1. Standard Schedule
   Convened IRB-Flint meetings are scheduled once each month throughout the
   Academic year and on an as needed basis in the summer months. The schedule,
   including the deadline date for submission of applications for each meeting, is
   published on the Flint Institutional Review Board- Human Subjects Protection
   webpage. Any scheduled meeting may be canceled if there are no agenda items for
   consideration.

   IRB members are reminded of a scheduled meeting approximately 10-14 days prior
   to the meeting in order to determine the ability to meet quorum. Approximately one
   week before the scheduled meeting, IRB members are provided, via eResearch, the
   agenda and copies of all applications referred to the full board for review.

2. Agendas
   Agendas are prepared by IRB-Flint staff via eResearch. In order to assure timely
   review, applications are assigned to scheduled meetings according to a triage
   scheme which takes into account the expiration dates of renewing studies, the need
   for review to meet funding obligations, application submission prior to the published
   deadline, the availability of reviewer expertise and the volume of applications
   awaiting review. IRB-Flint does not limit the number of items that may be reviewed
   at a meeting.

   The IRB makes every effort to facilitate timely review of applications. IRB staff
   communicates with the investigator to inform them of the date their application is
   scheduled for full board review.

3. Meeting Procedures
   a. Meeting Chair
      The appointed IRB chair will preside over each meeting.

   b. Quorum
      A quorum is defined as more than half the number of regular or alternate voting
      members of the IRB and must include at least one non-scientist. A quorum must
      be present for each formal vote. Alternate members are included in the quorum
      vote only if they are replacing a regular member at the meeting. Initial
      applications, modifications, or scheduled continuing review applications may be
      approved or disapproved by a majority vote of the voting members present.

   c. Alternate Meeting Format (Electronically Assisted)
      In the event that not all necessary IRB members are able to be physically present
      to convene a scheduled meeting, the IRB may utilize electronic technology (e.g.,
      teleconference, videoconference) to facilitate the participation of the members.
      All application materials are available, via eResearch or if required hard copies,
      to the remote member in advance of the meeting and throughout the meeting.
      The chair of a meeting utilizing these alternative technologies will facilitate the
      active and equal participation of the remote members. Minutes of meetings
      utilizing assistive technology must document that these two additional conditions
      have been satisfied.
d. **Conflicts of Interest**
Prior to each convened IRB-Flint meeting, the full board administrator will determine if any conflicts of interest exist on any applications that are to be reviewed and will note the conflict on the agenda. No IRB member, including the chair(s), shall be present for, nor participate in, the deliberations or vote on the disposition of an application in which the member has a conflict as described above. The member may, however, be invited by the IRB-Flint to provide information relevant to the board’s consideration of the application.

The IRB-Flint chair and staff will ensure that all identified, conflicted IRB members are:

- Excused from discussion except to provide information requested by the IRB
- Excused (absent from the room) during voting
- Not counted towards quorum
- Documented appropriately in the meeting minutes

To facilitate the identification of any previously unreported conflicts, the IRB Chair shall, at each meeting, inquire as to whether any member should excuse themselves from discussion and voting as outlined above.

e. **Review of Expedited Studies**
A list of the expedited reviews completed in the period between convened meetings is generated in eResearch by IRB-Flint staff and a link to the list is located with the materials for members under the eResearch tab for each meeting. At the convened meeting the list is displayed for members and is reviewed. Members have the opportunity to comment and ask questions.

f. **Presentation of Reviews**
Assigned primary and secondary reviewers present their reviews at the convened meeting. If a reviewer is unexpectedly absent, their written reviews may be presented by another board member.

Primary reviewers are expected to provide a summary overview of the project and detail specific concerns relative to the conduct of the study or the human subjects involved.

Secondary reviewers are expected to present concerns or discuss elements of the application, especially where there may be a difference of opinion with regard to information presented by the primary reviewer.

An ad hoc consultant may attend a meeting to present his/her review or may submit a written review that is assigned to an IRB member (usually another reviewer or the chair) for presentation.

g. **Board Action**
The convened IRB-Flint may vote to take any of the actions described in IRB Determinations (SOP Part 4. IV. B) with respect to an application for initial
review, scheduled continuing review, or an application for modification. All determinations, decisions, and contingencies issued by the IRB are recorded in eResearch and are available for review by the members of the IRB, the IRB staff, the investigator and study team. Investigators receive extensive detail regarding any changes required in order to achieve approval of the application.

h. Notification of Decisions
Following a convened IRB-Flint meeting, staff shall prepare written and/or electronic notification to inform the PI of the outcome of IRB review. The notification shall include at least the following information:

- The IRB-Flint’s decision and date it was reached
- For an approved project, the approval expiration date and notification of any interim reporting requirements
- For a project approved contingent on specified changes being made to the protocol, informed consent documents, or otherwise, a description of the specific modifications necessary to secure approval. The IRB may, in its discretion, require that the PI respond to required changes within a specified period and instruct that if the response is not received, the application will be considered withdrawn or reassigned to deferred status
- For a disapproved, suspended, or terminated project, the reasons for the IRB’s decision and notice of the PI’s right to respond in person or in writing
- Approved documents, including the informed consent, survey instruments and recruitment materials are contained within the eResearch application

Documentation of all IRB-Flint determinations is available within eResearch for review by IRB-Flint members, UMOR and other authorized persons. A copy of any notification of an IRB suspension or termination of a project shall be delivered under cover letter to UMOR for additional disposition and notification, as necessary, to other interested parties, such as government authorities with jurisdiction (e.g., OHRP or FDA) and, in the case of a sponsored project, the Office of Research and Sponsored Projects (ORSP).

i. Minutes
IRB-Flint will prepare and retain minutes of IRB meetings which shall be in sufficient detail to show:

- Attendance for each action including verification that quorum was met and maintained throughout the meeting (majority and nonscientist present)
- Attendance at the meeting including when an alternate member replaces a primary board member
- The names of IRB-Flint members who leave the meeting because of a conflict of interest for the study being discussed
- For each protocol reviewed, any votes or other actions taken and the vote on that action (including number of members voting for, against, or abstaining, and the names of any abstaining members)
Verification and summary showing the IRB-Flint considered and found all required determinations (45 CFR 46.111) for protocol and informed consent approvals

- Protocol-specific information supporting any waiver of informed consent or documentation of consent (45 CFR 46.116(c),(d)) or the inclusion of vulnerable subjects in the research (45 CFR 46 subparts B, C, D)
- The basis for requiring changes in or disapproving research
- A written summary of controverted issues and their resolution
- For initial and continuing review, the approval period
- Documentation of any continuing education provided to board members
- Documentation that the IRB was informed of all expedited review activity since the last IRB meeting as required by 45 CFR 46.110(c)

Following a convened IRB meeting, the IRB staff shall prepare minutes consisting of the information described above. The minutes will be distributed for review by IRB members, who will vote to approve or modify them, normally at the next convened meeting. The ratified minutes will be maintained by the IRB in accordance with applicable legal requirements and the data storage policies of the University and the IRB. Within eResearch, the approved minutes as a Word document are uploaded into the meeting workspace and considered the official version of the minutes.

4. Records and Reports
The IRB-Flint office maintains records and documents associated with its oversight of research and the administration of the boards. These materials include, but are not limited to the following:

- A roster of the current IRB-Flint members and their qualifications (degrees earned, area of expertise, etc.) sufficient to describe each member’s anticipated contribution to IRB-Flint deliberations and any employment relationship between the members and the University of Michigan
- Written Standard Operating Procedures (SOPs)
- All documentation related to specific research studies are stored within the eResearch system, including study protocols, informed consent documents, recruitment materials, and data collection instruments. eResearch retains records for continuing reviews, amendments and for adverse events and ORIOs reported on each study. For studies approved via the expedited procedure, the eResearch record includes the applicable expedited criteria used to approve the submission. For projects receiving an exempt determination, the eResearch record includes the applicable exemption category.
- Documentation for projects reviewed and approved by IRB-Flint prior to the implementation of the eResearch system. These are filed in a secure manner at the IRB-Flint office or are stored offsite in U-M storage. Records are retained for 6 years after the conclusion of the study and may then be destroyed.
- Agendas and minutes of IRB-Flint meetings, sufficiently detailed to show attendance at meetings, actions taken by the IRB-Flint, the votes on these actions (including the number of members voting for, against, and abstaining), the basis for requiring changes in or disapproving research, a
written summary of the discussion of controverted issues and their resolution, and the presence of any alternates (consistent with the IRB-Flint’s SOPs for alternates) for any substitution

- Copies of official correspondence between IRB-Flint and PI
- Documentation of IRB Authorization, Individual Investigator, and Collaborating Institution Agreements

Paper and electronic documents will be made accessible for inspection and copying by authorized representatives of the University, relevant sponsors, and government authorities with jurisdiction (such as OHRP and NIH) at reasonable times and in a reasonable manner.

Refer to OM Part 3.III.D.4 for additional guidance on record and report retention.
PART 5 - IRB JURISDICTION AND COOPERATIVE RESEARCH

I. Determining which University of Michigan IRB Should Oversee the Research

The University has nine IRBs registered under its Federalwide Assurance with the U.S. Department of Health and Human Services. IRB-HSBS is under the oversight of UMOR and reviews health, behavioral, and social science research occurring at the Ann Arbor campus (excluding the Health System and Medical School). Five IRBs (collectively referred to as IRBMED) review research from the University of Michigan Health System and the Medical School and any FDA-regulated clinical trials including those involving investigational new drugs (INDs) or investigational device exemptions (IDEs) and other agreed upon categories of research that would otherwise fall under the oversight of IRB-Flint. IRB-Dearborn reviews research from the UM-Dearborn campus.

The IRBs serve the institution as a whole. Approval by one IRB constitutes approval under the University’s HRPP. The IRBs are specialized to reflect the types of studies each regularly reviews. The membership of each committee is diverse and promotes a complete, adequate, fair and balanced review of research activities commonly conducted within its associated segment or discipline of the University.

Refer to OM Part 5.I for additional information.

II. Cooperative Research

Researchers at the University of Michigan frequently work with entities or individuals outside the University. The University and its researchers have differing regulatory obligations and alternatives for addressing these interactions depending on if the outside entity or individual is engaged in human subjects research (refer to OM Part 4.III). The IO has implemented the policies described in OM Part 5.III to ensure that the University can fulfill its obligation to assure appropriate oversight of research in which the University is engaged and also, under certain circumstances, of other engaged entities associated with University research.

If, during a review of an eResearch application, IRB-Flint staff members or reviewers determine that an outside entity or individual is engaged in research, they work with the IRB director other designated staff member to determine the appropriate oversight mechanism such IRB approval, IRB Authorization Agreement (IAA), as an Individual Investigator Agreement (IIA), or Collaborating Institution Agreement (CIA) for the outside entities. Refer to SOP Part 5.III and IV, below.

III. Coordinated or Joint Review

For federally supported research, an institution with an FWA that is participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. The University permits similar arrangements for non-federally-supported research. In either case, the IO or designee must approve the arrangement for either individual studies or for a category of research.). Any coordinated or joint review effort requires a written agreement among the involved institutions, regardless of whether they maintain FWAs. The IRB director or designated staff member will coordinate with UMOR to determine the best type of agreement for coordinated review. Refer to the OM Part 5.IV.
Even when the University or another institution serves as IRB-of-Record for multi-site research, each organization remains responsible for maintaining a system to protect human research participants. The ceding institution retains ultimate responsibility for safeguarding the rights and welfare of human research subjects involved at its performance site and for educating members of its research community to establish and maintain a culture of compliance with applicable laws and regulations and with institutional policies relevant to the protection of human research participants. The ceding institution also remains responsible for implementing appropriate oversight mechanisms to ensure compliance with the determination of the reviewing IRB. As part of this responsibility, each site must be aware of the reporting requirement for unanticipated problems involving risks to participants or others, reporting interim results and protocol modifications and scheduled continuing reviews.

**IV. Unaffiliated Investigators**

Researchers engaged in federally-supported research, University-initiated or University-centered research who are not employees of the University (unaffiliated) and not agents of an outside entity able to provide IRB review, must assure that they understand obligations associated with conducting human research. This is typically accomplished via an Individual Investigator Agreement (IIA). The IRB-Flint may choose to employ different formats for an IIA depending on literacy or technology constraints of the investigator.

For the non-federally-supported research, the IRB may choose to enter into an Individual Investigator Agreement or may choose an alternative method of oversight for the individual investigator, depending on the risk level of the study as well as literacy or technology constraints for the individual investigator.

The IRB-Flint staff member will alert the IRB-HSBS director or designated staff member to the potential need for an IIA and will coordinate the agreement process with UMOR (for federally-sponsored research) or with the IRB chair (for other research). Refer to OM Part 5.IV.

For non-federally-supported projects involving a collaborating organization that does not hold an FWA, the IRB-Flint may enter into a Collaborating Institution Agreement (CIA) with a responsible representative of the organization. Similar to the IIA, that representative certifies that affiliates of the organization will follow the requirements for the conduct of ethical human subjects research and serves as the responsible party for the organization.
PART 6 – ROLES AND RESPONSIBILITIES OF INVESTIGATORS AND RESEARCH STAFF

I. Eligibility to Perform Research at the University of Michigan

A. Who May Apply to Serve as Principal Investigator on IRB Applications

The following individuals are eligible to serve as PI on University research projects and submit applications to University IRBs and other oversight committees:

- Non-temporary members of the University’s faculty and staff
- Trainees, including undergraduates, graduates, medical students, residents/interns, clinical and postdoctoral fellows – but only if an eligible mentor (faculty advisor) sponsors the application and accepts all of the responsibilities of a PI
- Other individuals whose applications are sponsored by University faculty or staff members who accept all of the responsibilities of a PI

Exceptions to these requirements are at the discretion of the IO or designee.

B. Other Key Personnel

Key personnel include the principal investigator, co-investigators, faculty advisor and other individuals who contribute to the scientific development or execution of a study in a substantive, measurable way. Research fellows, residents, associates and consultants may be key personnel.

Co-investigators (Co-Is) are a subset of key personnel and have special responsibilities on research projects. While the PI has ultimate responsibility for the conduct of a research project, Co-Is are also obligated to ensure the project is designed and conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of human subjects research. The Co-I must be qualified by training and experience to conduct his or her responsibilities on the research project. Only the following individuals may serve as co-investigators on IRB applications:

- University faculty and staff, including those with temporary U-M appointments, such as visiting professors
- Trainees, including undergraduates, graduates, medical students, residents/interns, clinical and postdoctoral fellows
- Individuals who are not U-M faculty, trainees or staff, provided they meet the other qualifications defined above

Exceptions to these requirements are at the discretion of the Vice President for Research or designee.

Refer to OM Part 6.I for additional information

II. Roles and Responsibilities of Investigators and Research Staff

For a full description of the roles and responsibilities of investigators and research staff consult OM Part 6.II.
III. Education

IRB-Flint provides educational opportunities for researchers. Workshops, conferences, and consults are provided on regulations, research ethics, institutional policies, and the eResearch application. Additional information is available on the IRB-Flint website.

See also OM Part 13.
PART 7 - PARTICIPANT PROTECTION

I. HRPP Protection Extends to All Subjects

The HRPP protects the rights and welfare of all individuals who participate in University research as human subjects, regardless of funding source or whether they are intended “primary” subjects of the research or their participation is ancillary to the main study intervention.

Refer to OM Part 7.I for additional information.

II. Data and Safety Monitoring Plans (DSMPs)

The IRB-Flint considers the plans for safeguarding the health and safety of subjects as well as for the protection of subject privacy and data confidentiality for all research under its oversight. Information provided in eResearch by the investigators, is used to assess the sufficiency of the protections. Formal DSMPs may be required depending on study design, but are generally not required for minimal risk research.

Refer to IRB-Flint SOPs Part 4.II.E and OM Part 7.II for additional information.

III. Payments to Research Subjects

The IRB-Flint recognizes the importance of encouraging individuals to participate in research as human subjects and values the contributions of subjects to University research efforts. In its review of research, the IRB-Flint evaluates plans for subject compensation.

Refer to IRB-Flint SOPs Part 4.IV.C.6 and OM Part 7.III for additional information.

IV. Vulnerable Subjects

Special rules apply to research involving vulnerable populations. The IRB-Flint considers additional safeguards to protect the rights and welfare of these subjects in research.

Subparts B, C and D of 45 CFR 46 include additional IRB review requirements which apply to research supported by DHHS and other federal agencies adopting these standards:

- Pregnant women, human fetuses and neonates (Subpart B) (Rarely utilized by IRB-Flint, this mainly applies to clinical interventions involving these populations.)
- Prisoners (Subpart C) (All research with prisoners is referred IRB-HSBS for review.)
- Children (Subpart D) (In Michigan, the legal age to consent to the treatments or procedures involved in the research is 18.)

For research that is not supported by federal agencies that have adopted 45 CFR 46 Subparts B-D, U-M institutional policies found at OM Part 7.IV provide equivalent protections for vulnerable populations as research subjects.

Refer to IRB-Flint SOPs Part 4.IV.D and OM Part 7.IV for additional information.
V. Compensation for Injuries

Refer to OM Part 7.V for additional information.
PART 8 – USE OF TEST ARTICLES

IRB-Flint defers to IRBMED the oversight of any FDA-regulated clinical investigations including those involving investigational new drugs (INDs) or investigational device exemptions (IDEs) that would otherwise fall under the oversight of IRB-Flint.

Refer to IRBMED SOPs and OM Part 8.
PART 9 - CONFLICTS OF INTEREST

I. Conflict of Interest Policies

The OM Part 9 contains detailed information regarding the University’s conflict of interest policies.

II. Conflicts of Interest of Investigators and Research Staff

Refer to OM Part 9.II for additional information

III. Conflicts of Interest of IRB Members, Consultants and Staff

Real or perceived conflicts of interest on the part of any individual associated with the use and the protection of human subjects in research can seriously undermine the credibility of the process and must be avoided. The IRB-Flint strives to avoid conflicts of interest in performing its obligations. A conflict of interest may take many forms, but arises when an IRB member, staff member, or consultant, in relationship to an outside organization, is in a position to influence the university’s business, research, or other decisions in ways that could lead directly or indirectly to financial or other gain for the IRB member, IRB staff, or consultant (or their families) or give improper advantage to others, to the detriment of the University.

A. IRB Members

No IRB member, including the chair, shall be assigned to review an eResearch application if the member or a member of his or her immediate family has a conflict of interest as detailed in OM Part 9.III.

No member, including the chair, shall participate in the investigation of actual or alleged noncompliance or other misconduct (other than to cooperate with the investigation) if the member has a conflict as described above.

UM legal counsel is available to IRB-Flint to discuss a conflict of interest situation.

1. Convened Board Procedures

At the start of each convened IRB-Flint meeting, the IRB administrative staff in consultation with the IRB Chair will determine if any conflicts of interest exist on any applications that are to be reviewed and will note the conflict on the agenda. No IRB member, including the chair, shall be present for, nor participate in, the deliberations or vote on the disposition of an application in which the member has a conflict as described above. The member may, however, be invited by the IRB to provide information relevant to the board’s consideration of the application.

IRB chair and staff will ensure that all identified, conflicted IRB members are:

- Excused from discussion except to provide information requested by the IRB
- Excused (absent from the room) during voting
- Not counted towards quorum
- Documented appropriately in the meeting minutes
To facilitate the identification of any previously unreported conflicts, the IRB staff or chair shall, at each meeting, inquire as to whether any member should excuse themselves from discussion and voting as outlined above.

2. **Expedited and Exempt Review Procedures**

Prior to assignment, the IRB staff also makes an assessment to ensure that an application is not assigned to a conflicted expediting or exempting reviewer. If a previously unreported conflict is identified in the course of reviewing an application, a new reviewer will be assigned to the application.

**B. IRB Consultants**

When a consultant is identified as a potential reviewer, they will be asked to verify that they have no conflict with the research content of application or the principal investigator.

Conflicts of interest involving consultants will be evaluated according to the same definition as IRB members (Flint SOP 9.III A).

If a conflict is identified by the consultant, but review of the application by the consultant is deemed necessary because of their special, qualified expertise, the IRB-Flint chair will contact the consultant. Through an examination of the application content and the nature of the conflict, the chair will evaluate whether it is possible for the consultant to provide an objective assessment of the research study. If the chair believes the conflict does not preclude an objective review, the conflict will be disclosed to the board at the convened meeting or to the expediting reviewer and the consultant may present their review.

**C. IRB Staff**

Prior to administrative review of an eResearch application, IRB-Flint staff will conduct a preliminary assessment to determine if they have an actual or potential conflict of interest with any aspect of the application (as defined in OM Part 9.III) including: research content, principal investigator or study team member. IRB staff should notify the IRB chair to discuss the potential or actual conflict. If a conflict is identified, the staff member will be excused from any IRB duties directly relating to the processing, review, or outcome determination of the application, as applicable.

**IV. Institutional Conflicts of Interest**

Refer to OM Part 9.IV.
PART 10 – SPONSORED RESEARCH

I. General Information

Refer to OM Part 10 for additional information.

II. Additional Points for U-M Demonstrations

IRB-Flint considers funding sources or other sponsor contractual agreements as part of its review in determining whether a research project is eligible under U-M demonstration projects policy for two year approval or the exemption for analysis of identifiable information (Refer to HRPP Innovation and Demonstration Initiative Website). Projects that are federally supported or that have sponsor contractual requirements for annual review do not qualify under the demonstration projects policy.
PART 11 – STANDARDS AND COMPLIANCE

I. Legal and Regulatory Bodies

Refer to the OM Part 11.I for additional information.

II. Laws, Regulations and Standards Commonly Applicable to Research

Refer to the OM Part 11.II for additional information.

III. Access to Legal Counsel

Refer to the OM Part 11.III for additional information.
PART 12 - INVESTIGATION OF COMPLAINTS, ALLEGATIONS OF NONCOMPLIANCE, AND UNANTICIPATED PROBLEMS

I. Quality Assessment, Improvement, and Assurance

In conjunction with UMOR and the HRPP, IRB-Flint monitors the quality of the regulatory process and strives to improve its operations. For procedures related to the QA/QI process, refer to OM Part 12.

II. Compliance Oversight

The Human Research Protection Program (HRPP) promotes an organizational culture that encourages a commitment to compliance with the legal, regulatory, and ethical principles that govern human subjects research. The program relies on a system of self-regulation and integrated oversight to accomplish this objective. The OM Part 12.II describes the circumstances under which allegations of noncompliance and complaints may and must be reported and the process for reporting, protection for individuals who make reports and the process for investigating and responding to reports. Although all complaints and concerns related to the HRPP or conduct of individual studies are reviewed, not all of them involve noncompliance.

A. Response to Complaints or Allegations of Non Compliance

If information brought to the attention of the IRB, through any source, indicates the possibility that research subjects or others are exposed to unnecessary or excessive risks, or the requirements of the IRB are not being met, the IRB shall collect any additional information necessary to evaluate the credibility or accuracy of the information and determine whether further action (such as education of the investigator and/or investigator’s research staff and/or suspension or termination of the project) appears necessary.

The IRB shall promptly report the following to the UMOR Deputy Institutional Official (DIO) and the Senior Vice Provost (SVP) or other appropriate institutional officials:

1. Any unanticipated problems involving risks to subjects or others (see below for detailed procedures on reporting unanticipated problems)
2. Any serious or continuing noncompliance with federal regulations, institutional policy or IRB requirements
3. Any suspension or termination of IRB approval

B. Noncompliance Review Procedures

Refer to OM Part 12.II.B for additional information.

C. How Compliance Concerns are Brought Forward

Refer to OM Part 12.II for additional information.

D. Receipt and Initial Handling of Allegations of Noncompliance

When IRB-Flint receives an allegation of noncompliance, the IRB follows the procedures outlined in the OM Part 12.II.D. The IRB office staff, with direction from the IRB director(s),
will undertake a preliminary fact-finding in order to frame the allegations of noncompliance and determine key elements upon which to proceed. This information is forwarded to the IRB director(s) for additional examination and triage.

**E. Serious or Continuing Noncompliance**

If the IRB staff believes that serious noncompliance has occurred or that subjects are at risk of harm, the allegations are promptly forwarded to the IRB chair for review. Where serious or continuing noncompliance is a possibility, and subjects are not at risk of imminent harm, the IRB office should forward materials to the chair for review not later than two weeks after receipt. Exceptions to these timeframes are possible where extenuating circumstances have prevented the IRB from conducting its fact-finding (e.g., the unavailability of the principal investigator).

**F. Suspension or Termination of IRB Approval**

The IRB-Flint may suspend or terminate approval of research if it determines any of the following, after appropriate review and deliberations:

- The research is not being conducted in accordance with IRB-Flint requirements
- The research has been associated with unexpected harm to subjects, or
- The research design cannot minimize risks to subjects or maintain a favorable risk-benefit ratio

Any suspension or termination of approval under this provision shall include a statement of the reasons for the action and shall inform the principal investigator of institutional notification and reporting requirements. IRB-Flint will report any suspension or terminations to UMOR and UMOR will take additional action, as appropriate.

Refer to OM Part 12.II.E for additional information.

**G. Chair and Board Considerations and Determinations**

Refer to OM Part 12.II.E for additional information.

**H. Detailed Procedures for Investigating Allegations of Noncompliance**

Refer to OM Part 12.II.D. for additional information.

**I. Response to Determinations of Noncompliance**

Refer to OM Part 12.II.G for additional information.

**J. Institutional Notification and Reporting Requirements**

Refer to OM Part 12.II.H for additional information.
III. Procedures for Review and Reporting of Unanticipated Problems Involving Risks to Subjects or Others

A. Background

Refer to OM Part 12.III.A for additional information.

C. Roles and Responsibilities

The principal investigator of any research project is responsible for reporting to the IRB-Flint, any adverse events (AEs) and other reportable information or occurrences (ORIOs) as required by the IRB. These include unanticipated problems involving risk to research subjects or others (referred to as “unanticipated problems”). IRB-Flint has adopted the IRBMED guidelines for reporting of unanticipated problems, adverse events and other reportable information (refer to Adverse Events (AEs), Other Reportable Information and Occurrences (ORIOs), and Unanticipated Problems Involving Risks to Subjects or Others (UaPs) and is also referenced within the Help feature in the eResearch system). The IRBMED guidelines include examples of unanticipated problems.

Examples of problems that should be reported include (but are not limited to):

- Internal adverse events that are unexpected, involve new or increased risks, and are related to the research
- External adverse events that are unanticipated problems involving risks to participants or others
- Changes made to the research without prior IRB or EC approval in order to eliminate apparent immediate harm
- Other unanticipated information that is related to the research and indicates that participants or others might be at increased risk of harm

Unanticipated Problems (UaPs) involving risks to subjects or others include events that:

- Are unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Are related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Problems that require reporting in accordance with the above definition include:

- Internal adverse events that are unexpected, involve new or increased risks and are related to the research
- External adverse events that are unanticipated problems involving risks to subjects or others
- Changes made to the research without prior IRB approval in order to eliminate
apparent immediate harm

- Other unanticipated information that is related to the research and indicates that subjects or others might be at increased risk of harm, or which indicates a change to the risks or potential benefits of the research including:
  
  - An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB
  - A paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB
  - A breach of confidentiality
  - Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol
  - Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research subject
  - Incarceration of a subject in a protocol not approved to enroll prisoners
  - Event that requires prompt reporting to the sponsor
  - Sponsor imposed suspension for risk
  - Complaint of a subject when the complaint indicates unexpected risks or cannot be resolved by the research team
  - Protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed subjects or others or that indicates subjects or others may be at increased risk of harm

Investigators must report serious and non-serious UaPs occurring in or related to studies under the direction of University faculty, staff or students. Serious UaPs must be reported to the IRB within seven (7) days and non-serious UaPs within fourteen (14) days of their occurrence or notice to the investigator.

IRB-Flint staff reviews the eResearch inbox each business day to monitor if any UaPs have been submitted. IRB staff conducts an initial review of the submission for completeness; assesses the submissions to determine if they represent a UaP, and routes serious UaPs and serious, unexpected, and related adverse events for prompt review.

If the chair determines the report is serious, it will be placed on the agenda of the next IRB meeting for review. Non-urgent reports will receive a standard assignment to a full board meeting based on availability on the agenda. Information about the report will be presented to the convened board by a primary reviewer (usually the IRB chair). All documents related to the review of the unanticipated problem (approved research application, approved informed consent, AE/ORIO report, any other supplemental material) are made available to the primary reviewer and the convened IRB members.

The IRB chair is authorized to take immediate action to protect the health and safety of research subjects. Such action may take the form of:

- Asking the investigator to voluntarily impose a hold on the recruitment of subjects to facilitate additional inquiry by the IRB and/or institutional officials
- Asking the investigator to voluntarily impose a hold on the recruitment and research intervention to facilitate additional inquiry by the IRB and/or institutional officials
• Suspending recruitment or enrollment
• Altering or suspending current interventions
• Suspending the project

Any such action by the IRB chair will be documented in the eResearch record immediately. If the IRB chair imposes a partial or complete suspension, the IRB chair will immediately report the suspension to UMOR Deputy Institution Official (DIO). The IRB chair shall report any such action taken to the convened IRB at its next regularly scheduled meeting.

If subjects are not at immediate risk of harm, a convened board will review serious and non-serious UaPs occurring on studies under the direct oversight of IRB-Flint, and external serious UaPs. The IRB may endorse interim action by the chair, if any, or may take a different action or additional actions.

If a majority of IRB-Flint members vote that a submitted report is an unanticipated problem, the following steps will be taken:

• The chair or chair’s designee will notify the DIO and the SVP
• The board will vote on additional actions. Possible actions to be considered include:
  o Suspension of the research
  o Termination of the research
  o Notification of current participants when such information may relate to participants’ willingness to continue to take part in the research
  o Modification of the protocol
  o Modification of the information disclosed during the consent process
  o Providing additional information to past participants
  o Requiring current participants to re-consent to participation
  o Modification of the continuing review schedule
  o Monitoring of the research
  o Monitoring of the consent process
  o Referral to other organization entities.

• The investigator will be notified
• The study records and IRB-Flint minutes will document the findings and actions of the board

The DIO and SVP shall receive notification of any research suspended or terminated for cause and shall make or direct any necessary reports to the Institutional Official or designee, who will make outside reports as needed.

IV. Board Considerations and Determinations Regarding Noncompliance and UaPs

A. Voluntary Hold

In order to initiate a period of fact-finding and evaluation, the IRB may approve a request by an investigator to place a voluntarily “hold” whereby the investigator may not accrue
new subjects and/or conduct research-related interventions during the fact-finding period.

A voluntary hold does not constitute a suspension for purposes of these procedures.

**B. Suspension or Termination**

The convened IRB-Flint may suspend or terminate approval of research that it determines (after appropriate review and deliberation):

1. Is not being conducted in accordance with IRB requirements
2. Has been associated with unexpected serious harm to subjects or
3. Cannot minimize risks to subjects or maintain a favorable risk-benefit ratio

**Key Definitions:**

- **Suspension of Research Activity** – Suspension is the temporary closing of a human subject research project or discontinuing a PI’s privilege to conduct human subject research. The suspension may be partial, in that certain activities may continue while others may stop, or it may be complete, in that no activity related to the research may proceed.

- **Termination of Approval** – Termination is the ending of all activities related to a human research project or a PI’s privilege of conducting human subject research at the University of Michigan except for the continuation of follow-up activities necessary to protect human subject safety.

Only the convened board is authorized to suspend or terminate a research study, unless subjects are immediately at risk and the study must be suspended immediately. In such cases, the IRB chair may suspend the research study and the action is then reported to the convened board at the next meeting.

When study approval is suspended or terminated, the IRB (or chair in the case of urgent suspensions) should:

- Consider actions to protect the rights and welfare of currently enrolled subjects
- Consider whether procedures for withdrawal of enrolled subjects take into account their rights and welfare (e.g., making arrangements for medical care outside of a research study, transfer to another investigator or continuation in the research under independent monitoring)
- Consider informing current subjects of the termination or suspension
- Have any adverse event or outcome reported to the IRBs.

Any suspension or termination of approval under this provision shall include a written statement of the reasons for the action and inform the principal investigator of an opportunity to respond to the IRB. The DIO and SVP shall receive notification of any research suspended or terminated for cause and shall make or direct any necessary reports to the Institutional Official or designee.
C. Notification of Participants on a Terminated Study

If study approval is terminated by IRB-Flint, any subjects currently participating should be notified of the termination. The principal investigator will provide the notification unless otherwise directed by the IRB or institutional officials.

Any withdrawal of subjects currently enrolled in the study should take into account the rights and welfare of the subjects.

If follow-up of subjects for safety reasons is permitted/required by the IRB, the subjects should be so informed and any adverse events/outcomes should be reported to the IRB and the sponsor.

V. Reporting Requirements

A. IRB Reporting

If an examination of the issues leads to a potential finding of serious or continuing noncompliance, the findings to-date will be presented to the convened board. If the convened board agrees (by majority vote) with the preliminary finding of serious or continuing noncompliance, they will affirm the finding and request that the materials associated with the investigation and the outcome of their assessment be forwarded to the DIO for further examination and investigation, as necessary.

If the incident of noncompliance requires termination or suspension of research, the IRB must report this to the DIO immediately, so that the DIO may make the required external reports. In certain cases, the IRB may choose to provide an ‘early report’ of a case to the DIO. Upon evaluation of the IRB’s report, the DIO may choose to investigate the matter with additional University resources, including the Office for Human Research Compliance Review (OHRCR). For situations reported to the SVP for additional review, the SVP makes and reports the institutional conclusions to the Vice President for Research and imposes any institutional sanctions or remediation requirements.

Summaries of non-serious concerns are reported by the IRB to the DIO on a quarterly basis as a way of monitoring the need for attention to policy or to education.

B. Institutional Reports

The UM HRPP OM Part 12.III.2 fully describes the obligations of the University to make additional reports outside the institution to sponsors and government authorities with jurisdiction.
PART 13 – EDUCATION AND TRAINING

I. Education in General

The University of Michigan (U-M) and its faculty, staff, and trainees are committed to complying with the laws and regulations that govern the review and conduct of human research and to upholding the highest ethical standards. To help achieve this and ensure protection of research participants, the University requires a basic level of human subject protection education, and provides a variety of educational activities designed to enhance the understanding of human subjects protection at all levels including leadership, IRB members and staff, investigators, research staff, and study participants and their communities. (Refer to OM Part 13.)

II. Required Human Subjects Training

U-M has developed an online Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS) required for designated to all University faculty and staff, students, and collaborators involved in human research. PEERRS offers two courses that fulfill regulatory requirements for training in the protection of human subjects in research. Completion of at least one of these courses is a requirement for IRB approval. The two courses are:

- Human Subjects Protection – Biomedical & Health
- Human Subjects Protection – Social & Behavioral

These courses are modeled on the Collaborative Institutional Training Initiative (CITI) human subjects protection modules and provide training required per university, state, and federal regulations.

PEERR certification is obtained by passing a short quiz for each required topic area. Certification in a module is granted for three years from the last date the user passes a certification test. Certification status is visible in the linked to eResearch IRB application. The IRBs will not release initial study approval until all required individuals have completed the training. Individuals may not conduct research with human subjects research until the training is completed.

In addition to PEERRS, individuals may be required to complete additional training depending on the scope and nature of the specific research.

III. Supplemental Educational Activities

To complement the required PEERRS training, the IRBs and other components of the HRPP offer a wide range of educational opportunities for the research community. Information about IRB-Flint educational offerings for the research community is found on the IRB-Flint website.