



**HEALTH SCIENCES &
BEHAVIORAL SCIENCES IRB**
UNIVERSITY OF MICHIGAN

**Institutional Review Board Health Sciences and Behavioral Sciences
(IRB-HSBS)**

Standard Operating Procedures

June 2015

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PART 1 – INTRODUCTION, PURPOSE, AND ETHICAL PRINCIPLES

I. The Human Research Protection Program (HRPP)

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 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; research review units, including institutional review boards (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 [HRPP Operations Manual](#) (OM) is designed to illuminate the system and its overarching governing rules and to serve as a reference for investigators, IRBs, administrators, and others. The Standard Operating Procedures (SOPs) serve as the method by which the IRBs implement that policy.

Additional resources:

[HRPP Operations Manual Parts I, II, III, IV](#)
[45 CFR 46](#)

II. The Institutional Review Boards (IRBs)

The University of Michigan IRBs review and oversee research conducted by the University to assure that it meets ethical principles articulated in the Belmont Report, and complies with federal regulations that pertain to human subject protection at [45 CFR 46](#) and other pertinent regulations, policies and guidance.

The Institutional Review Board's first and most important function is to protect the rights and welfare of human research subjects. Secondly, 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. IRB members and staff, as well as researchers submitting applications to the IRB, must be informed of and understand this obligation.

All human subject research conducted by the University must be approved by an Institutional Review Board or granted an exemption by a University IRB (through its members or staff) or the IO as specified in the IRBs Standard Operating Procedures. 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 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, divisions 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.

PART 2 – ORGANIZATION OF THE IRB-HSBS

I. Administrative Structure for IRB-HSBS

IRB Health Sciences and Behavioral Sciences (IRB-HSBS) is supported by a single administrative office and consists of two separately constituted IRBs registered with the Office for Human Research Protections (OHRP). To distinguish between the IRBs, they are sub-named IRB-HSBS Maize and IRB-HSBS Blue. Each IRB meets once per month. By agreement and collaboration via the chair(s) and core member(s) appointed to attend both IRB meetings, the IRBs work together in order to expand the available expertise pool and facilitate the review of time-sensitive applications.

The U-M Office of Research (UMOR) provides administrative and compliance support for IRB-HSBS.

The IRB-HSBS Advisory Committee, an executive committee comprised of Associate Vice Presidents (AVPs) (or designees), IRB-HSBS chair(s) and vice chairs, IRB-HSBS representatives, including the IRB director and IRB members, faculty-at-large representatives with research experience, and others, meet periodically to review IRB workflow metrics, consider guideline/SOP/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-HSBS is under the direction of the IRB director and the assistant director (collectively referred to within these SOPs as director(s)).

Additional resources:

Additional information about IRB-HSBS, resources and available educational and guidance materials can be found on the [IRB-HSBS website](#).

II. Organizational Entities That Support IRB-HSBS

Numerous additional organizational entities contribute to the operation of the IRB-HSBS and the HRPP. These include:

- The Office of Research and Sponsored Projects (ORSP), 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
- Other support units and committees, such the Research Administrators' Network (RAN)
- Key executive and administrative offices and functions including the Office of the Provost and Executive Vice President for Academic Affairs, and Office of General Counsel

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Additional resources:

Refer to the [OM Part 2.II](#) for a detailed description of each of these entities.

PART 3 - IRB-HSBS POLICIES

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 Vice President for Research, 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) and to the HRPP Director. 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 [University of Michigan Standard Practice Guide \(SPG\) 303.05](#).

II. The Operations Manual (OM)

The [HRPP Operations Manual](#) 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).

UMOR initiates periodic comprehensive review of the OM. However, revisions may be made at any time in response to changes in laws, ethical standards, institutional policies, quality assurance activities, or other considerations. Nonsubstantive 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-HSBS Standard Operating Procedures and Policies (SOPs)

A. General Provisions

IRB-HSBS, to which these SOPs refer, is mandated by and follows Federal regulations and OHRP guidance, and operates under the authority and oversight of the University's Vice President for Research. Refer to [OM Part 3](#) for detailed information.

Generally, IRB-HSBS has oversight for human subject research conducted by the schools, colleges, and units of the University that comprise the Ann Arbor campus but are not part of the Medical School. Exceptions to the policy are allowed by agreements between IRBMED and IRB-HSBS under guidance from UMOR. For example, clinical and FDA-regulated research projects from the School of Dentistry, certain fMRI research from Psychology, and some clinically-oriented or invasive research from Kinesiology and the Center for Human Growth and Development are under the oversight of IRBMED. For a more detailed description of IRB jurisdiction on the Ann Arbor campus, see [OM Part 5](#).

The IRB-HSBS assures that where applicable, research complies with state and local laws, regulations, and University policies that relate to research involving human subjects. Additionally, IRB-HSBS 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-HSBS may, in its discretion, consider ethical guidelines in addition to the Belmont Report, 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-HSBS cooperates with UMOR to establish, review, and revise these SOPs. These SOPs and any substantive revisions 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 (i.e., contact, resources, etc.) is not considered a substantive revision. Standard forms, guidance documents, and similar information developed by IRB-HSBS do not require additional review or approval by UMOR. IRB-HSBS guidance materials, depending on their intended use, may be created with input from and reviewed by stakeholders of the process including the IRB-HSBS Advisory Committee, IRB-HSBS membership, and individual faculty members with special expertise.

IV. IRB-HSBS Organization and Personnel

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

A. Qualification and Appointment of Chair(s) and Reviewers

1. Chair(s) and Vice Chair(s) *(Note: These SOPs may reference the chair role in either a singular or plural form)*

IRB-HSBS has one or more chair(s) appointed by the IO in consultation with the DIO, HRPP Director, and IRB directors. Each chair serves at the will of the IO and is a respected faculty member of, and has an appointment in, one of the units under IRB-HSBS jurisdiction. Exceptions to these parameters must be approved by the IO. A 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.

A chair may also 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-HSBS jurisdiction.

One or more members of the IRB may be designated as vice chair(s) to serve in the event that the chair is absent and not able to convene an IRB-HSBS meeting or perform other duties of the chair. A member may be designated as an acting chair in the case where the chair or vice chairs are not available to convene an IRB-HSBS meeting. A 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

Experienced full and alternate members of the IRB-HSBS may be appointed by the chair with the concurrence of the HRPP Director as expediting reviewers. Expediting reviewers are selected based on their knowledge of pertinent content areas, knowledge of human subject regulations, and concern for human rights and ethical issues. Per U-M policy, a member is deemed experienced if he or she has completed all education requirements for IRB members and has served on an IRB for a minimum of six months or has equivalent experience. Equivalent experience may include service on other research oversight or scientific review committees, previous IRB experience, or participation in other activities that reflect consideration of issues involving the protection of human subjects in research. Expediting reviewers have authority to review and approve expedited and exempt applications or refer them to the convened board, as necessary. Given the breadth of academic disciplines under oversight of IRB-HSBS, social and behavioral scientists serving as expediting reviewers may use their academic training and experience to review research applications from multiple disciplines where they have familiarity with the primary research activity.

Expediting reviewers receive additional training pertinent to the federal expedited review categories, other relevant federal regulations, and U-M flexibility initiatives. They also receive training in the use of eResearch to conduct their reviews.

IRB-HSBS 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. They may review and approve scheduled continuing reviews according to criteria set by IRB procedures. 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-HSBS staff may conduct exempt reviews and issue determinations. Refer to [OM Part 4.VI.C](#).

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

IRB staff members appointed as exempt reviewers must be qualified through academic or research experience and expertise, IRB employment or other IRB experience leading to familiarity with regulations and institutional policy relevant to the use of human subjects in research. IRB directors and the IRB chair will jointly assess the readiness of staff to conduct autonomous exempt reviews and issue determinations based on previous education, 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-HSBS Members

1. Regular Members

IRB-HSBS Maize and Blue each have at least five voting members, including chairs or vice-chairs. Representatives from the primary academic units under IRB-HSBS jurisdiction (one of whom must be a scientist), at least one community member not affiliated with the University of Michigan, and one non-scientist will be appointed to serve as full members for each board. The IRB will not consist entirely of men or entirely of women. In order to facilitate collaboration between the IRBs, members may agree to be appointed as core members to serve on both IRBs.

Membership shall be sufficiently diverse (including consideration of race, gender, cultural background, and sensitivity to such issues as community attitudes) in order to evaluate categories of research presented to the IRB-HSBS. IRB members must have knowledge of the specific scientific disciplines relevant to the research that it reviews. In addition to possessing the professional competence to review specific research activities, the IRB membership must be able to determine the acceptability of proposed research in terms of institutional commitments and policies, applicable laws and regulations, and standards of professional conduct and practice. 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, research context, or legal issues as related to a specific project, consultants may be used to supplement IRB-HSBS review (refer to SOP Part 3. IV.E). If the IRB regularly reviews research involving vulnerable populations (as identified by regulation or institutional policy), the IRB will secure members experienced in working with such populations.

Scientist members have credentials, training, background and occupations that would incline them to view scientific activities from the standpoint of someone within a social, behavioral, or biomedical research discipline. Scientist members are recruited from among active and emeritus members of the university faculty and staff.

Non-scientist members are members whose credentials, training, background, and occupations would incline them to review research activities from the perspective of

someone outside of any social, behavioral or biomedical scientific discipline. Non-scientist members may be recruited from among active and emeritus members of the university faculty and staff and also from the community.

Community representatives may be scientists or non-scientists. Community members are individuals who represent the general perspective of participants, are sensitive to community attitudes in promoting respect of research participants regardless of race, gender and cultural background, and safeguard the rights and welfare of human subjects. To be eligible for participation on IRB-HSBS as a community representative, neither the member nor any member of his/her immediate family may otherwise have a direct affiliation with the U-M Ann Arbor (e.g., employee, contractor, student in a degree program, volunteer at the institution or business unrelated to the IRB, or active emeritus faculty member) with the University. 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 constitute a direct affiliation.

A copy of the current membership roster is on file in the IRB-HSBS office and posted to the IRB website. The roster is updated as necessary and provided to UMOR at least quarterly. UMOR is responsible for providing required updates of membership changes to OHRP.

Members are expected to attend, actively participate in, and vote at monthly meetings of the IRB-HSBS and to serve as reviewers of assigned applications. Poor attendance by members will be addressed by the IRB-HSBS chair and directors on a case-by-case basis.

2. Alternate Members

IRB members from the each board serve as alternate members to the other board (i.e. a full member on Blue serves as an alternate for a member of Maize). Alternate members may also be chosen for, among other qualifications, their ability to expand the expertise and/or diversity of the IRB-HSBS. Alternate members are appointed from the academic units that are subject to the jurisdiction of the IRB-HSBS. Alternates may also be appointed for community and non-scientist members. Alternate voting members are designated to serve for specific regular voting members based on expertise (e.g., social scientist for social scientist). The roster identifies specific alternates for each member of the board. IRB-HSBS staff members may also be appointed as alternate members, depending on their qualifications.

Alternate members may attend all IRB meetings and participate in the discussion, 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).

3. Appointment

Individuals affiliated with the University may nominate themselves for service on the IRB, or may be identified by the IRB-HSBS chair, members, IRB directors or staff, or by an academic unit under the jurisdiction of IRB-HSBS. Community and/or non-scientist members who are not affiliated with the University may self-nominate or be recommended for nomination by third parties.

The IRB-HSBS chair and designated staff will evaluate each potential candidate for membership. Candidates for membership meet with the IRB-HSBS chair and director. Candidates are asked to provide a curriculum vitae or a resume summarizing previous educational, professional, and/or personal experiences which may contribute to the expertise of the IRB.

The IRB-HSBS chair recommends appropriately qualified candidates to the HRPP Director for appointment. Upon agreement with the recommendation, the HRPP Director will issue a letter of appointment indicating the term and status of the candidate's appointment as an alternate or full member. The IRB-HSBS chair or the HRPP Director may approve changes in appointment status and may issue a new letter of appointment, when appropriate (e.g., a full member's status is changed to an alternate member during a leave from the university). Members and alternate members are appointed for two years.

4. Evaluation of Membership and Reappointment

a. Chair(s)

Prior to the end of the term, the chair(s) are evaluated by the DIO, the HRPP Director, IRB director(s), and IRB membership, with input from the IRB-HSBS Advisory Committee, as appropriate. Chair(s) are 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 HRPP Director, the IO may choose to reappoint chair(s). Retiring chair(s) desiring to continue IRB-HSBS service at the end of their term as chair may be reappointed as a full or alternate member of the IRB.

b. Members

Prior to the end of their term, IRB members may be recommended for reappointment as regular or alternate members, or the IRB may choose not to renew their appointment. IRB members are assessed based upon the continuing interest and availability and given feedback by the IRB chair and IRB directors as part of their reappointment process. 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 (when necessary). 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).

C. Terms of Appointment

1. Term of Service

IRB-HSBS chair(s) and vice chairs serve two-year terms and may be reappointed based on recommendations by UMOR, IRB-HSBS directors and staff, and mutual agreement by the nominee.

2. Termination of Appointment

IRB-HSBS chairs and members serve at the pleasure of the IO and their appointment can be terminated by the IO. If it becomes necessary to terminate a regular or alternate member before expiration of their appointment, the DIO, on the advice of the IRB-HSBS chair, will effect termination.

Reasons for early termination include but are not limited to: failure to attend meetings, failure to prepare for or participate at meetings, failure to uphold the central tenets of the Belmont Report or other applicable policies or ethical principles, or engaging in activities deemed inappropriate or incompatible with IRB membership.

3. Compensation of Chairs and Members

The rates of any compensation for the roles of chair and expediting reviewer are determined by UMOR in consultation with the academic units, if necessary. Rates of compensation for community members are determined by the HRPP Director in consultation with the IRB director and the IRB chair.

4. Liability Coverage

Liability coverage for members of the IRB is a matter of institutional policy and is further described in [OM Part 3.III.B.5](#).

D. Periodic Review of Membership and Composition

The membership and composition of the IRB-HSBS Maize and Blue boards is reviewed at least annually with the IRB chair(s) and IRB directors, and may be considered by the IRB-HSBS Advisory Committee. Changes are made to the membership or composition of the board to meet regulatory, expertise, or organizational requirements as needed.

E. Consultants, Advisors, and Ad-Hoc Reviewers

1. Selection

The IRB-HSBS membership 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(s), 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, data security experts, 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.

A consultant who is unable to attend the convened board meeting or meet directly with an expediting reviewer will send a written review for consideration. Information presented by the consultant is documented in the eResearch study record.

Consultants are asked to sign a confidentiality agreement and to follow IRB-HSBS conflict of interest procedures.

F. IRB-HSBS Staff

1. Support and Supervision

The IRB-HSBS is supported by a professional staff who report to the DIO and the HRPP Director. Day-to-day supervision is provided by the IRB director and/or the IRB assistant director.

2. Hiring

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

3. Duties

The IRB-HSBS staff is responsible for facilitating IRB operations (e.g., protocol review, documentation and record retention, fact-finding, creation of informational resources and educational activities) in such a manner as to maintain compliance with applicable regulations and University policies. IRB staff may also perform additional projects and assignments, as directed. IRB staff members 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.

4. Staff Evaluation

IRB-HSBS staff members are evaluated as part of UMOR's annual performance evaluation process as well as an informal evaluation at the midyear. The performance appraisal is performed by the staff member's direct supervisor and/or the IRB director. If circumstances dictate, staff is evaluated more often. The IRB director is evaluated annually by the HRPP Director. In addition, regular quality assurance assessments of staff reviews are conducted and feedback is provided to the staff member.

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

IRB-HSBS 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-HSBS Membership

a. New Member Orientation

New IRB-HSBS members must complete a detailed orientation and training program designed to prepare them to effectively discharge their duties. The orientation includes a series of educational sessions with members of the IRB-HSBS staff.

New member orientation and training occurs prior to the start of the member's formal appointment to the board and includes:

- Attendance at one or more convened IRB-HSBS meetings as a non-voting guest
- Review of essential resource materials, including historical background regarding human subjects in research, federal regulations, the Belmont Report, OHRP information and guidance, institutional policies and SOPs
- Completion of appropriate modules of the U-M Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS)
- In-depth review of [45 CFR 46](#) and application to case study scenarios

- In-depth practical training in the use of the eResearch system in order to review applications presented for full committee or expedited review (refer to SOP Part 3.V.A)
- Overview of full board operations and processes, meeting roles, and review presentation guidelines

b. Current Member Continuing Education

Educational activities are conducted at convened meetings unless the number of agenda items is prohibitive. Topics include current developments in human subject regulations or U-M policies, changes to the eResearch application, and focused presentations on specific regulatory issues. Invited speakers on special topics are periodically scheduled.

IRB-HSBS members are kept informed of opportunities for continuing education. IRB members are encouraged to attend local presentations from other units of the University or other locally available educational opportunities, and webinars such as those offered by 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 may be available for members to pursue other educational opportunities such as national meetings sponsored by PRIM&R or OHRP.

IRB members are also encouraged to obtain membership in the IRB Forum in order to monitor the dialogue on current topics in human subjects research.

c. Expedited Reviewer and Exempt Reviewer Education

Full or alternate members appointed as expediting and/or exempt reviewers receive additional training on the regulatory categories used to make these determinations as well as on the use of eResearch to conduct the reviews.

2. IRB-HSBS Staff

a. New Staff Orientation

New staff members receive an orientation to IRB-HSBS office policies, procedures and practices. Basic resource materials are distributed (including copies of pertinent federal regulations, the Belmont Report, OHRP information, guidelines, policies and SOPs) and additional information sources are provided. New employees are also assigned a mentor from the current staff to assist with their successful transition into their IRB position.

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

All IRB staff members are required to take and pass the Human Subjects module in PEERRS. Completion of additional modules in research administration, conflict of interest, or other relevant topics is recommended. In addition, staff members may also complete training modules offered by CITI.

b. Current Staff Continuing Education

As budget and availability permit, IRB staff members 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, or other local universities, societies, or organizations. Education is also provided via webinars such as those offered by AAHRPP, OHRP or PRIM&R.

Within the office, IRB-HSBS staff members participate in learning activities such as the IRB journal club, 'lunch and learn' presentations, and review of subscription journals. Time is devoted at each weekly staff meeting to discuss questions arising from review of applications. An additional meeting is held each week, as needed, to allow staff members to bring forward protocol issues for discussion. IRB staff members are also encouraged to monitor the dialogue of the IRB Forum and other human subjects research resources.

The IRB-HSBS encourages IRB staff members to obtain the Certified IRB Professional (CIP) credential.

c. Expedited Reviewer and Exempt Reviewer Education

IRB-HSBS staff appointed as expediting and/or exempt reviewers receive additional training on regulatory categories used to make these determinations as well as on the use of eResearch to conduct the reviews.

V. IRB Functions and Operations

A. Application Submissions in eResearch

Research applications (initial, scheduled continuing review, amendments and reports of adverse events and Other Reportable Information or Occurrences (ORIOs)) requiring IRB-HSBS review are submitted via the web-based [eResearch Regulatory Management System](#). 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-U-M IRB
- Establishment of a data or specimen repository

B. General Review and Approval Procedures

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.

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

Each IRB submission is assigned to a designated IRB-HSBS staff member. Prior to administrative review of an eResearch application, IRB-HSBS staff notifies the IRB chair and IRB director 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.

C. 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 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-HSBS 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 FDA regulation (e.g., IND and 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-HSBS jurisdiction must submit an initial application for review and approval of the study. No aspect of the study (including screening performed solely to determine eligibility for the study) may begin until IRB-HSBS 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-HSBS review, a preliminary assessment is made to determine if the proposed research qualifies for expedited review or must be scheduled for convened board review, in consultation with IRB chair(s) and IRB directors, as necessary (refer to SOP Part 3.V.H 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-HSBS

An initial application is eligible for approval only when the criteria found in [45 CFR 46.111](#) are met.

3. Scheduled Continuing Review

Continuing review is required for all research studies under IRB-HSBS oversight at intervals appropriate to the magnitude of risk of the project and other considerations. For research studies with federal sponsorship, the IRB conducts a continuing review at least once each year. As assessed by the convened board or expediting reviewer, some projects may require continuing review at an interval of less than one year (refer to SOP Part 3.V.D). 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 3.V.D and [Innovations and Demonstrations Initiative Website](#)). If a scheduled continuing review application is not submitted and approved by the expiration date, the eResearch system triggers an expiration notice for the project.

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

- Current study status
- Interim findings or citations to recent relevant literature, if applicable
- Investigator's current assessment of research risk
- Number of participants accrued
- Summary report of adverse events (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 held at the IRB office for IRB staff and member review. These materials provide the primary reviewer and IRB-HSBS 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 continuing review, the IRB-HSBS confirms that the current consent document is still accurate and complete. When appropriate, the IRB-HSBS will seek verification from an outside party that no material changes to the research have been made since the last IRB approval. The IRB-HSBS 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-HSBS policies will receive an exempt determination.

a. Study Closure (Termination Report)

The principal investigator is responsible for notifying the IRB-HSBS 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).

D. Frequency of Review

The IRB-HSBS 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
- Demonstrated need for additional oversight of the principal investigator (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 or research involving vulnerable populations such as prisoners
- Research locations in an international or other off-site location(s) where the IRB-HSBS 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-HSBS may approve an initial application or scheduled continuing review for a two-year interval if the project meets the following criteria as defined by U-M policy (refer to [HRPP Innovation and Demonstration Initiative Website](#)):

- No more than minimal risk to subjects
- No federal sponsorship
- 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 NIH-issued Certificate of Confidentiality

E. Monitoring and Verification

1. Data Monitoring

Detailed information about Data and Safety Monitoring Plans 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-HSBS may, at its discretion, perform monitoring or request monitoring (via UMOR) of a project in addition to that accomplished through initial review, amendment, and 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.

F. Reporting Changes to IRB-HSBS (Amendments)

A principal investigator may not implement any changes to an approved study under IRB oversight (e.g., changes to the protocol, informed consent document, advertisement, or subject incentive) 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 to the IRB promptly and are reviewed to determine whether each change was consistent with ensuring participants' 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, the 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-HSBS 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 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 (except administrative staff)
- Proposed changes in any other aspect of research

In its review, the IRB-HSBS 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 requires re-consent of previously enrolled subjects.

The IRB-HSBS may authorize its staff to administratively approve 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
- Changes in contact information for the investigator or IRB

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 minor changes that may be reviewed by the expedited procedure include:

- Addition or deletion of study team members
- Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study (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 un-validated survey or interview procedures
- Addition of or revision to recruitment materials or strategies
- Change to improve the readability of consent documents or to correct typographical errors, provided that such changes do not alter the intent of the previously approved document

The date of IRB-HSBS approval of an amendment does not extend the date by which a regularly scheduled continuing review must be completed.

G. Lapses in Approval

It is the responsibility of the principal investigator to submit a continuing review application before expiration of IRB approval and in ample time for IRB-HSBS 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-HSBS 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. No new subjects may be enrolled in the study during the lapse. A notice sent through the eResearch system informs investigators that sponsored project resources must not be expended for unapproved research activities. Following a lapse in approval, the investigator may also be asked to 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-HSBS 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).

In addition, projects in the state of Approved with Contingencies that do not receive full approval by the expiration date set at the time of contingent approval must be resubmitted to the IRB for full review.

H. Standard Review Procedures for Non-Exempt Research (Expedited and Convened IRB)

Each submission received by the IRB-HSBS (initial application, scheduled continuing review, amendment, or reports of adverse events or ORIOs) is reviewed either by a single reviewer or the convened board, as required. The IRB staff, in consultation with IRB chair(s) and IRB directors, as necessary, makes a preliminary assessment as to whether the submission qualifies for expedited (single member) review or must be scheduled for convened board review.

1. Expedited Review

a. 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.
- Research involving secondary analysis of prisoner data or interaction or intervention with prisoners (including obtaining informed consent) may be reviewed using the expedited procedure if a determination is made that the research poses no more than minimal risk to the prisoners being studied or included in the research meets the criteria for expedited review. The research must be reviewed by the prisoner representative, either as the expediting reviewer or as a consultant, but is not required. The reviewer must confirm that the requirements of [45 CFR 46 subpart C](#) or equivalent protections are met. Review of subsequent modifications and scheduled continuing reviews may be reviewed by the prisoner representative, but is not required.

- 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. Expedited Review Process

eResearch submissions qualifying for expedited review are accepted and reviewed by the IRB-HSBS on a continuing basis, during University business hours, except during seasonal holidays when University administrative offices are closed. The IRB-HSBS staff and reviewers strive 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 using the staff checklist. An application that is not complete is returned to the principal investigator (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 an expediting reviewer.

Expedited review is conducted by a single reviewer with relevant expertise. IRB-HSBS chair(s) or IRB members (including qualified IRB staff) appointed by the chair(s), may conduct expedited reviews under the regulations stated in [45 CFR 46.110](#) (refer to SOP Part 3.IV.A.2). 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 9 for conflict of interest procedures.

If relevant expertise to review an application does not exist among the expediting reviewers, then the IRB staff, in consultation with the chair and the IRB director, may request that an ad hoc consultant review the application and supporting materials. The outcome of this review is documented in the eResearch system for consideration by the expediting reviewer.

The application and supporting documents including informed consent documents, study protocols, survey instruments, grant applications and recruitment materials are accessed by the reviewer via eResearch. Materials that cannot be provided via eResearch must be submitted to the IRB office for review by IRB staff and reviewers. Materials provided for review via eResearch are identical for all research requiring IRB review, regardless of whether the review is conducted by the convened board or an expedited reviewer. A regulatory checklist is 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. To ensure timely review, the IRB staff uses eResearch to monitor reviewer workloads and application status.

d. Expedited Review Determinations

All expedited determinations, decisions, and contingencies issued by the IRB-HSBS are recorded in eResearch and are available for review by the members of the IRB, the IRB staff, the PI and study team. The PI and study team members receive written notice of the review outcome via eResearch, including extensive detail regarding any modifications required in order to achieve approval of the application.

i. 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 SOP Part 3.V.C.2 and Part 3.V.I). 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-HSBS 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 data safety monitoring plan, research conducted in an international setting, or a study team that has demonstrated the need for additional oversight. Projects which qualify under IRB-HSBS policies may be approved for a period of two years (729 days). Refer to [HRPP Innovation and Demonstration Initiative Website](#).

ii. 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. Contingent approval may not be granted where the requested changes are directly relevant to the regulatory determinations required for approval (refer to SOP Part 3.V.C.2 and Part 3.V.I). 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 designates whether the required changes may be reviewed and approved by the staff or whether the application must be returned to the reviewer for final approval.

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.

The IRB-HSBS 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 administratively withdrawn.

iii. Changes or Clarification Requested

For projects that require changes before the reviewer can make the regulatory determinations required for approval, 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 IRB-HSBS 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.

iv. Request Review by Convened Board or Other Review Path

If the reviewer finds that a study does not meet the criteria for expedited review, or the reviewer feels that the expertise of the full board would prove useful in the review, an expediting reviewer may return an application to the IRB-HSBS staff with a request to the chair that the study be placed on the agenda for the convened board. 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.

e. Reporting of Expedited Reviews to the Convened Board

Expedited approvals for the preceding month are reported and acknowledged by the board at each meeting of the convened IRB-HSBS 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.

2. Convened (Full) Board Review

a. Criteria for Convened Board Review

Projects requiring IRB-HSBS oversight that do not meet the criteria for 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
- Projects that do not fit within the research categories described 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)

In addition, research involving vulnerable populations, sensitive topics, or complex design elements that would benefit from review by the breadth of expertise represented on the board may be reviewed by the convened board.

b. Convened Board Review Process

IRB-HSBS meets twice per month (IRB Maize and IRB Blue), according to a published schedule to review assigned applications. The IRB full board administrator, 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 scholarly expertise or knowledge of the subject matter and is responsible for conducting an in-depth review of the protocol. 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.

Applications are typically assigned to the next available full board agenda based upon date of submission and whether the agenda for that meeting is considered full. However, if relevant expertise to review the application is not available for the next meeting date, then the IRB staff, in consultation with the IRB chair, may reassign the study to another meeting where the expertise of the attending membership is appropriate for the project.

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. 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 outcome of this review is presented in person at the board meeting when possible and/or documented in the eResearch system for review and consideration by the board in its deliberations.

Convened board reviews are assigned to primary and secondary reviewers via eResearch approximately one week before the assigned meeting date. The application and supporting documents including informed consent documents, study protocols, survey instruments, grant applications and recruitment materials are accessed via eResearch. Materials that cannot be provided via eResearch are set aside for review within the IRB office. Materials provided for review via eResearch are identical for all research requiring IRB review, regardless of whether the review is conducted by the convened board or an expedited reviewer. 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 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, and are expected to review the submission summary and consent documents for each study on the agenda.

The principal investigator or study team members may request to attend a board meeting or may be invited by the IRB-HSBS.

c. Convened IRB-HSBS Determinations

All convened board determinations, decisions, and contingencies issued by the IRB-HSBS are recorded in eResearch and are available for review by the members of the IRB, the IRB staff, the PI and study team. The PI and study team receive written notice of the review outcome via eResearch including extensive detail regarding any modifications required in order to achieve approval of the application.

i. Approve

The board 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 SOP Part 3.V.C.2 and Part 3 V.I).

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-HSBS policy. The expiration date represents the last day of the approval period.

The IRB-HSBS 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 data safety monitoring plan, research conducted in an international setting, or a study team that has demonstrated the need for additional oversight.

ii. Approve with Contingencies Pending

The IRB-HSBS 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 study 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 via an expedited procedure by the chair or primary reviewer, or must be 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-HSBS regardless of when the specified changes are submitted to the 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.

iii. Action Deferred

The IRB-HSBS may vote to defer action on an application when significant action(s) on the part of the investigator or the convened board is required before the IRB can consider approval or disapproval. If action is required on the part of 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.

iv. Disapproval

The IRB-HSBS 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-HSBS 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-HSBS 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.

v. Appeal of Disapproval by Principal Investigator (PI)

An investigator may submit an appeal to the IRB-HSBS 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.

vi. 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-HSBS for a full and considered discussion of the concern. Examples of these decisions include the transfer of an application to a different U-M 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).

d. Institutional Approval

Research approved by IRB-HSBS is still subject to disapproval by the Vice President for Research and, as applicable, other institutional officials. However, no institutional

official, including the Vice President, is empowered to approve research previously disapproved by an IRB.

I. 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-HSBS considers at least the following elements when evaluating and approving a research proposal:

1. Scientific Merit and Feasibility

In its review of research applications, 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 funding 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 U-M 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, IRB-HSBS verifies that the research plan, including research design, methodology, and allocation of resources will not expose participants to unnecessary risk. In order to make this determination, IRB-HSBS 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-HSBS will review the eResearch application to evaluate the risk/benefit ratio 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 ([45 CFR 46.102\(i\)](#)). Generally, studies with a low probability of harm are considered to pose minimal risk to subjects. Note: Prisoner research utilizes a different definition of minimal risk ([45 CFR 46.303 \(d\)](#)).

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

- The principal investigator'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

If the study does not meet the federal definition of minimal risk, then the IRB-HSBS 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-HSBS only considers the risks and benefits that may result from the research. Where the research involves a therapeutic intervention, this means that the risks of the research are 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-HSBS 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-HSBS, the protocol may be referred to a different IRB according to the policies outlined in the [OM Part 5.II](#).

4. Qualifications of the Principal Investigator

By University policy, the IRB-HSBS recognizes only one principal investigator (PI) for each application. This policy ensures that the principal investigator 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.I.A](#) 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-HSBS permits student trainees (undergraduate, graduate and post-graduate) to act as PIs, 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. 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 not permitted to conduct research involving more 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 information that allows an uncoerced, informed decision to enter a study. 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-HSBS may consider in making its determination are whether:

- The research is meritorious and the setting is appropriate
- The burdens of participating in the research fall on those most likely to benefit
- The solicitation 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
- The recruitment of vulnerable subjects is necessary or if it would be more appropriate to conduct the study with other, less vulnerable subjects
- The selection process, by design, will be protective of potential subjects who may be vulnerable, but will not deny appropriate opportunities to participate
- Vulnerable subjects will be adequately protected during recruitment

The IRB reviews all advertisements, materials, or methods intended to recruit prospective subjects. Recruitment materials are submitted as part of the eResearch application 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 materials, as well as the format of the material to ensure that the procedure for recruiting subjects does not pose an undue influence, does not include exculpatory language, does not promise free treatment when the intent is only to say that the subject will not be charged for taking part in the investigation, and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. Recruitment materials are submitted as part of the initial application or as part of an amendment. The IRB must approve the final content of any printed, audio, and video advertisements prior to implementation.

Generally, recruitment materials should be limited to the information the prospective subjects need to determine their eligibility and interest. The following may be included, though are not required:

- The name and address of the PI 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 additional information
- Information about payments to subjects. As a practice, when studies involve greater than minimal risk, recruitment materials should not emphasize the amount to be paid, by such means as large or bold type

6. Review of Payment Arrangements to Subjects

The IRB-HSBS 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 represent an 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 [U-M Standard Practice Guide 501.07](#)).

7. Data Safety Monitoring

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 (see SOP Part 3.V.E). Most studies reviewed by IRB-HSBS do not require special monitoring plans.

8. Protection of Subject Privacy and Data Confidentiality

The IRB-HSBS will ensure that the research plan contains adequate provisions to protect the privacy of subjects and maintain the confidentiality of data (see [OM Part 3, C.6.\(g\)](#)).

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 of Confidentiality issued by NIH should be obtained 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-HSBS seeks guidance from the U-M Information Technology Services regarding appropriate data security procedures for research under its oversight and includes an IT security consultant on its boards. See the [IRB-HSBS website](#) for guidance on data security.

9. Informed Consent Process

Throughout this section the term “consent” also refers to “parental permission.”

The IRB-HSBS reviews the proposed informed consent process, including consent documents, for each submitted application to assure that subjects or their legally authorized representatives provide legally effective, voluntary, informed consent. Informed consent materials (including oral scripts), requests for waivers or alterations of informed consent or waivers of documentation of informed consent, are submitted to the IRB-HSBS as part of the eResearch application. The IRB-HSBS assesses applications and issues waivers of documentation or waivers or alterations of some or all of the elements of informed consent, where appropriate under regulatory guidance.

Except as otherwise waived and approved by the IRB-HSBS, 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-HSBS 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, subjects (or their representatives) will be given sufficient opportunity, commensurate with the risk level of the research, to consider whether or not to participate, including time for questions and full discussion. Information about the study must be 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-HSBS 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.

In its review of informed consent documents, the IRB will ensure that all of the basic elements of informed consent, as well as any additional elements, as appropriate, 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 PI, sponsor or the University of Michigan is being released from liability for negligence. For projects involving more 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-HSBS website](#).

b. Waivers of Documentation of Informed Consent

Waiver of documentation is a regulatory term describing an informed consent process that eliminates the requirement to obtain a subject's signature on a written document. The IRB-HSBS may waive the requirement for the PI to obtain a signed consent form for some or all of the subjects if the requirements of 45 CFR 46.117(c) are satisfied.

Waivers of documentation of informed consent may be used in the research designs including, but not limited to:

- 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, the required elements of informed consent must be conveyed to the subject through an oral script or by electronic or printed text. Even though subjects do not sign a document, the IRB-HSBS may still require that subjects be provided with written information about the study. The text of any written or oral informed consent or any informational documents provided to subjects must be reviewed and approved by the IRB-HSBS before use.

c. Waivers of Informed Consent

The IRB-HSBS 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-HSBS 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-HSBS 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-HSBS 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 are not able to read the consent document (refer to [45 CFR 46.117\(2\)](#) and [OM Part 3.III.C.6 \(e\)](#)). This consent process is rarely used in projects overseen by IRB-HSBS.

10. 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, or otherwise require additional protections. In order to protect the rights and welfare of these subjects, the IRB-HSBS will consider additional safeguards to protect these individuals.

Subparts B, C, and D of the Common Rule 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-HSBS, this mainly applies to clinical research involving these populations.)
- Prisoners ([Subpart C](#))
- 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, 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-HSBS will 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 expert knowledge about the vulnerable population will review the application. If appropriate expertise is not represented by the IRB-HSBS membership, the IRB will seek information about the topic and may also engage a consultant to review the application and prepare a report.

For projects supported by the U.S. Department of Health and Human Services National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) that “purposefully requires” inclusion of children with disabilities or individuals with mental disabilities, the IRB must include at least one member who is primarily concerned with the welfare of these research subjects (refer to [34 CFR 350 and 34 CFR 356](#)).

The IRB-HSBS 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.D](#) for a detailed description of Michigan requirements and guidance for determining requirements for research outside of Michigan.

a. Research Involving Pregnant Women, Human Fetuses and Neonates

When reviewing research involving pregnant women, human fetuses, and neonates, the IRB-HSBS 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-HSBS may also choose to

refer these applications to IRBMED according to the policies outlined in the [OM Part 5.II](#).

In order to approve HHS-supported research involving pregnant women, fetuses, and neonates, the 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, policies or procedures. Refer to [OM Part 7.IV](#) for additional details.

b. Research Involving Prisoners

A prisoner means any individual involuntarily confined or detained in a penal institution such as 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](#) includes examples of individuals who are considered to be prisoners. By practice, most research involving direct interaction or intervention with prisoners is reviewed by the IRB-HSBS convened board but review of minimal risk research meeting the criteria for expedited review may also be reviewed via the expedited review process. The convened IRB will include, as a member of the voting quorum, a prisoner representative.

Federal regulations provide a slightly modified definition of “minimal risk” for prisoner research that IRBs and PIs must be mindful of in considering the assignment of subject risk:

Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

When reviewing research involving prisoners, the IRB-HSBS considers additional assessments in order to ascertain the voluntariness of the process and whether coercion or undue influence has been minimized.

- **Voluntariness of the informed consent process**
Due to the nature of institutionalization, inmates may not have sufficient autonomy to provide true, informed consent. The IRB will carefully examine the procedure for approaching and recruiting an inmate including any limitations placed on the process by the prison system.

- **Coercion during recruitment and consent**
The effect of the research on the living conditions and/or critical consequences for the inmates must be considered. The IRB will carefully examine whether participation in the research affects the inmates' living arrangements or provides early release options.
- **Undue influence during recruitment and consent**
For inmates living in a closed system with controlled wages, participation in a research project with a financial incentive may be considered an undue influence. In addition, by policy, some prison systems do not allow the payment of research incentives to prisoners during the period of their incarceration. The IRB-HSBS will consider such policies during its review.

In order to approve HHS-supported research involving prisoners, the IRB must apply the regulatory components of Subpart C. The IRB-HSBS will submit all required materials to OHRP, including those pertaining to the informed consent process, as provided for in [45 CFR 46.306](#). The IRB-HSBS follows [OHRP guidance on research with prisoners](#).

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-HSBS 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 research not supported by HHS, see the equivalent protections found in [OM Part 7.IV.B.5](#). The IRB considers the substantive elements of Subpart C in its deliberations, but may also utilize other comparable ethical guidelines, policies or procedures. For prisoner research not requiring review by OHRP, the IRB-HSBS will submit all required materials to UMOR for approval to conduct the research. For certain categories of research with prisoners detailed in [OM Part 7.IV.B.4](#), the study may only proceed after the Institutional Official or Deputy Institutional Official has consulted with appropriate experts including experts in penology, medicine, and ethics, and notice of the proposal is posted to the [HRPP website](#) for review and comment.

c. Research Involving Children

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-HSBS 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.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-HSBS 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, policies or procedures as defined in [OM Part 7.IV.C.4](#)

i. 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-HSBS 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-HSBS will make an assent determination for each protocol that includes children, including whether assent must be documented.

ii. 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-HSBS 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](#).

iii. 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 [45 CFR 46.406](#) or [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](#).

d. Research involving Adults with Cognitive Impairment or Other Impaired Decision-making Capacity

When research is likely to involve adults who may be cognitively or decisionally-impaired, the IRB-HSBS must be especially careful in its assessment of the risks of the research in relation to the benefits to the individual participant and whether the research question could be answered by enrolling adult subjects able to consent. 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 thereby impacting the subjects' capacity to provide full, effective informed consent.

i. Consent/Assent

In addition to the usual requirements, the IRB will assess the informed consent document and process as outlined by the PI to assure that:

- Adequate assurances are in place to assess the prospective subject's understanding of the research
- The consent document is written in a language and at a 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 PI should outline a plan to obtain assent from the subject and informed consent from a legally authorized representative (LAR)

ii. Legally Authorized Representatives

The IRB will review the study procedures to assure that the PI has a plan to inform the legally authorized representative (LAR) about the study, its implications for the subject, and the LAR'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, the subjects should be encouraged to appoint a legally authorized representative while they are capable. Once the LAR's appointment becomes legally effective, the LAR will re-consent to the subject's continued participation in the research or decide to end the subject's participation in the research. The subject remains free to decline participation at any time by withdrawing assent.

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](#) .

11. Other Special Review Considerations - Research in Schools and Universities

Most public and private K-12 schools as well as colleges and universities receive U.S. Department of Education (ED) funds and may be subject to additional research 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.

a. The Family Educational Rights and Privacy Act (FERPA) (34 CFR 99)

FERPA applies to research involving student education records for any institution receiving ED funding; therefore, 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 (including all students enrolled in college/university) unless certain exceptions apply. The IRB-HSBS provides guidance to researchers who use student records in their research, but the data steward for the organization holding the student data is responsible for compliance with FERPA. Questions regarding FERPA applicability and exceptions may be referred to the Office of General Counsel. Refer to [OM Part 11.B.3.](#)

b. The Protection of Pupil Rights Amendment (PPRA) (34 CFR 98)

The PPRA was created by the No Child Left Behind Act and applies to instructional or survey research conducted in elementary and secondary schools receiving funds under ED 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 ED conducted or supported research that is exempt from the Common Rule, particularly the requirement for documented parental permission. The IRB-HSBS provides guidance to researchers whose projects invoke the requirements of the PPRA, but the school providing access to its students for research purposes is responsible for compliance with the PPRA. Questions regarding PPRA applicability and exceptions may be referred to the Office of General Counsel. Refer to [OM Part 11.I.A.6.](#)

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

IRB-HSBS serves as the Privacy Board for research not subject to IRBMED oversight and involving Protected Health Information (PHI) for units that are part of the HIPAA covered entity but not part of the Medical School or UMHS, including University Health Services, provider clinics at the School of Dentistry, and centers and clinics within the Mary A. Rackham Institute (University Center for the Child and Family, University Center

for Language and Literacy, and the Adult Psychological Clinic). The IRB is authorized to review and approve following:

- Waiver of authorization for research not subject to the Common Rule, or exempt from IRB-HSBS 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-HSBS. The IRB-HSBS 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-HSBS may also be required 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.I.A.2](#) for more on HIPAA.

13. Studies Subject to Regulatory Requirements of Other Agencies

Some federal agencies adopting the Common Rule have created additional agency-specific regulations for the research they support.

Refer to [OM Part 11.II.A](#) and [HRPP Guidelines for Federally Sponsored Research](#) for information regarding additional regulatory requirements for research involving the U.S. Department of Defense (DoD), the U.S. Department of Education (ED), the U.S. Department of Justice (DOJ), the U.S. Department of Energy and the U.S. Environmental Protection Agency (EPA).

14. Studies Subject to ICH-GCP Standards

ICH-GCP standards apply to the conduct of clinical trials when required by the sponsor. Refer to [OM Part 11.1.C.2](#).

15. International Research

Generally, the IRB-HSBS reviews all international human subject research projects conducted by U-M investigators under its jurisdiction, rather than deferring review to a collaborating international institution. When an international site is engaged in the conduct of a U-M research project and the research is supported by a Common Rule agency, the regulatory requirements of [45 CFR 46](#) are applied and local IRB or ethics committee review is required. Supporting agencies may require a FWA. 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 U-M institutional policy. The IRB may require local IRB review, particularly for studies 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.

The IRB-HSBS 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 noncompliance to the IRB-HSBS. Research participants are provided with

the IRB-HSBS email address and international phone number as part of the consent process.

J. IRB Meetings

1. Standard Schedule

Convened IRB-HSBS meetings are scheduled twice each month throughout the year (IRB Maize and IRB Blue). The schedule, including the deadline date for submission of applications for each meeting, is published on the [IRB-HSBS webpage](#). Any scheduled meeting may be canceled if there are no agenda items for consideration.

IRB-HSBS 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 access to all applications referred to the full board for review.

2. Agendas

Agendas are prepared by IRB-HSBS 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. While there is no set limit on the number of agenda items, the agenda is designed to allow time for adequate discussion of each item. Agenda items may be moved to another meeting if the IRB staff or Chair determines that the agenda is too full.

The agenda also includes the list of studies approved via expedited and exempt review during the time since the last convened meeting.

3. Meeting Procedures

a. Meeting Chair

A single, appointed chair will preside over each meeting. This role may be filled by an IRB chair, vice chair, or experienced member appointed as acting chair when the chairs or vice chairs are unavailable.

b. Quorum

A quorum is defined as more than half the number of regular or alternate voting members of the IRB-HSBS and must include at least one non-scientist. At least one unaffiliated member who represents the general perspective of subjects should be

present at the majority of meetings in a given year (e.g., 10 out of 12 meetings per year). Before the start of each meeting the IRB chair and IRB full board administrator determine and document that quorum has been met. A quorum (including the non-scientist) must be present for each formal vote. If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored. 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. Attendance of all participating members is recorded in the meeting minutes.

c. Meeting Process

All IRB-HSBS members have access to laptop computers or tablets for use in the review of materials presented at the convened board. Reviews submitted by board members as well as notes of the board's discussions are projected during the meeting so that all members can review and make corrections to proposed contingencies. The projected notes also include the regulatory criteria necessary for the approval of each study (e.g., regulatory requirements for children, prisoners, waivers of consent, special DoD or other agency considerations). Regulatory criteria are posted as part of the electronic agenda and are included in the project notes.

d. 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. Minutes of meetings utilizing assistive technology must document that two additional conditions have been satisfied: 1) All application materials are available, via eResearch, to the remote member in advance of the meeting and throughout the meeting. 2) The chair of a meeting utilizing these alternative technologies facilitated the active and equal participation of the remote members.

e. Conflicts of Interest

Prior to each convened IRB-HSBS 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-HSBS to provide information relevant to the board's consideration of the application.

The IRB-HSBS 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.

Refer to SOP Part 9 for more on conflicts of interest.

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, responsible for conducting an in-depth review of the protocol, 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 an omission from the primary reviewer's materials or 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 the primary or secondary reviewer or the chair) for presentation.

g. Board Action

The convened IRB-HSBS may vote to take any of the actions described in IRB Determinations (SOP Part 3.V.H.2.c) with respect to an application for initial review, scheduled continuing review, an application for modification or AEs/ORIOs. All determinations, decisions, and contingencies issued by the IRB-HSBS are recorded in eResearch and are available for review by the members of the IRB-HSBS, the IRB staff, the PI and study team. PIs receive extensive detail regarding any changes required in order to achieve approval of the application.

h. Notification of Decisions

Following a convened IRB-HSBS 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-HSBS'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-HSBS determinations is available within eResearch for review by IRB-HSBS 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-HSBS will prepare and retain minutes of IRB meetings which shall be in sufficient detail to show:

- Attendance at the meeting including when an alternate member replaces a primary member and for each action including verification that quorum was met and maintained (majority and non-scientist present)
- The names of IRB-HSBS 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-HSBS 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-HSBS 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, typically at the next convened meeting. The ratified minutes are maintained by the IRB in accordance with applicable legal requirements and the data storage policies of the University and the IRB. The approved minutes (as a Word document) are uploaded into the meeting workspace in eResearch and are considered to be the official version of the minutes.

K. Records and Reports

The IRB-HSBS 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-HSBS members and their qualifications (degrees earned, area of expertise, etc.) sufficient to describe each member's anticipated contribution to IRB-HSBS 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-HSBS prior to the implementation of the eResearch system. These are filed in a secure manner at the IRB-HSBS 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-HSBS meetings, sufficiently detailed to show attendance at meetings, actions taken by the IRB-HSBS, 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-HSBS's SOPs for alternates) for any substitution
- Copies of official correspondence between IRB-HSBS 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 4 – ACTIVITIES SUBJECT TO THE HRPP

As part of the administrative review process described in SOP Part 3.V.C.1, the IRB staff, in consultation with senior research compliance specialists, IRB-HSBS directors or IRB-HSBS chairs, as necessary, assesses whether:

- The activity described in the application is research with human subjects as defined by the Common Rule.
- The research is exempt from IRB oversight.
- The University of Michigan is engaged in the research.

Only non-exempt, human subjects research where U-M is engaged requires IRB oversight. Refer to the [OM Part 3.III.C.4.a](#) for additional information.

I. Determining What is Research as Defined by the Common Rule

Research is defined under the Common Rule as “a systematic investigation, including research, development, testing and evaluation, designed to contribute to generalizable knowledge.” Refer to [45 CFR 46.102\(d\)](#). Not all activities involving people, their data or specimens, conducted by University researchers meet this definition. For example, activities such as journalism or program evaluation do not meet the definition of research under the Common Rule.

IRB staff members review all submitted eResearch applications to determine whether the proposed study meets the regulatory definition of research, using guidance found in [OM Part 4 Table 6](#), [OHRP Decision Charts](#), as well as in the eResearch application. IRB-HSBS chair(s) and directors may be consulted as necessary to determine if the study meets the regulatory definition of research.

II. Determining Whether Research Involves Human Subjects

The Common Rule defines a human subject as: “...a living individual about whom an investigator conducting research obtains (1) data through interaction or intervention with the individual or (2) identifiable private information...” (refer to [45 CFR 46 46.102\(f\)](#) for the complete definition).

The IRB-HSBS staff reviews all submitted eResearch applications that meet the regulatory definition of research to assess whether the proposed study involves human subjects [OHRP Decision Charts](#), guidance found in the [OM Part 4 Table 6](#), as well as the eResearch application. IRB-HSBS chairs, IRB-HSBS senior research compliance specialists, or IRB-HSBS administrators may be consulted as necessary to determine if the study involves human subjects.

eResearch applications that meet the definition of research with human subjects continue through IRB review process. Applications for projects that do not meet the definition of research

with human subjects are issued a “Not Regulated” determination through the eResearch system.

III. Determining Whether U-M is Engaged in Research

IRB-HSBS staff, in consultation with IRB chair(s), IRB directors, or the HRPP Director as necessary, determines 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, or obtain individually identifiable private information, for research 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. Refer to [OHRP Guidance on “Engagement of Institutions in Research”](#) and the [OM Part 4](#).

IRB-HSBS oversight is limited only to research in which U-M is engaged. IRB-HSBS also provides oversight for external individuals or institutions engaged in the research where the U-M has agreed to serve as IRB of Record via an IRB Authorization Agreement (IAA), an Individual Investigator Agreement (IIA), or Collaborating Institutional Agreement (CIA) and accepted additional responsibility for oversight of a research project or personnel. All such agreements are authorized by UMOR. See [OM Part 5.IV](#) and [OM Part 5.V](#).

IV. Determining When Research Begins and Ends

Research begins when a researcher *first* “obtains data through intervention or interaction,” or otherwise obtains “private information,” as described above.

Research is considered to continue and, therefore, to require continuing IRB approval and oversight, through data collection, long-term follow-up of subjects and completion of analysis of identifiable data. Refer to [OM Part 4.IV](#).

V. Authority to Make Regulated/Not-regulated Determinations

The IO has delegated the authority to make human research/not human research determinations to the IRB-HSBS and its staff in a manner consistent with approved SOPs. The IO also has the authority to make a regulated/not regulated human determination for any specific project or category of projects.

The University does not require PIs to seek a formal determination of “not regulated” from IRB-HSBS when the activity falls outside Common Rule definition of human subjects research (refer to [OM Part 4 Table 6](#)) or where U-M is not engaged in the research. PIs may consult informally with IRB staff or members to facilitate a self-determination. To obtain a formal, documented “not regulated” determination, rather than making an assumption that might later be determined to be incorrect, an eResearch “Activities Not Regulated as Human Subjects Research” application must be prepared. This application allows the PI to self-generate a determination

letter that may be used for funding or publication purposes or to request an IRB review to confirm the project is not regulated. 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 HIPAA or other regulations or institutional policies.

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

Refer to [OM Part 4.V](#) for additional information.

VI. Projects Meeting the Criteria for Exemption

Some categories of research that meet the Common Rule definition of research with human subjects fall within the criteria for exemption from regulatory oversight. To be considered exempt, the project must meet one of six exempt categories identified in [45 CFR 46.101\(b\)](#) (listed below) or the exemption categories defined by U-M policy (refer to [HRPP Innovation and Demonstration Initiative](#)). 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. Exempt research projects are not subject to continuing IRB oversight as long as modifications made to the project do not exceed the scope of the exemption.

A. Federal Exemption Categories

Federal exemption categories identified in [45 CFR 46.101 \(b\)](#):

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (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 if 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 which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

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

B. 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.*

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. IRB chair(s), expediting reviewers or designated IRB-HSBS staff, 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-HSBS in the review of exempt research. The application captures the information necessary for the IRB-HSBS 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-HSBS 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-HSBS 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 Determinations

The exempt determination is issued to the investigator via eResearch. Once an exemption has been granted, the project is not subject to continuing IRB-HSBS 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 regarding when the submission of an amendment is necessary.

Refer to [OM Part 4.VI.D](#) for additional information.

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, such as clinical interventions conducted by the Dental School or invasive procedures conducted by the School of Kinesiology, that would otherwise fall under the oversight of IRB-HSBS. IRB-Flint reviews research from the UM-Flint campus and 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.II](#) 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-HSBS staff members or reviewers determine that an outside entity or individual is engaged in research, they work with the IRB director or other designated staff member to determine the appropriate oversight mechanism such IRB approval, IRB Authorization Agreement (IAA), 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-HSBS 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-HSBS staff member will alert the IRB 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-HSBS 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

Refer to [OM Part 6.II](#).

III. Education

IRB-HSBS provides educational opportunities for researchers. Workshops, conferences, and consults are provided on regulations, institutional policies, and the eResearch application. Additional information is available on the [IRB-HSBS 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-HSBS 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-HSBS SOPs Part 3.V.E. and [OM Part 7.II](#) for additional information.

III. Payments to Research Subjects

The IRB-HSBS 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-HSBS evaluates plans for subject compensation.

Refer to IRB-HSBS SOPs Part 3.V.I.6 and [OM Part 7.III](#) for additional information.

IV. Vulnerable Subjects

Special rules apply to research involving vulnerable populations. The IRB-HSBS 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-HSBS, this mainly applies to clinical interventions involving these populations.)
- Prisoners ([Subpart C](#))
- 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-HSBS SOPs Part 3.V.I.10 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-HSBS 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-HSBS.

Refer to IRBMED SOPs and [OM Part 8](#).

PART 9 - CONFLICTS OF INTEREST

I. Conflict of Interest Policies

Refer to [OM Part 9](#) for 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-HSBS 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 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-HSBS member, including the chair(s), 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(s), 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.

No member, including the chair(s), shall participate in the discussion or review or unanticipated problems involving risks to participants or others if the member has a conflict as described above.

U-M legal counsel is available to IRB-HSBS to discuss a conflict of interest situation.

1. Convened Board Procedures

Prior to each convened IRB-HSBS 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 to provide information relevant to the board's consideration of the application.

The 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 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 assigning expedited reviews, the IRB staff will assess applications, to the best of their ability, for any conflicts with expedited reviewers. IRB staff will, to the best of their ability, not assign an application 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.

B. IRB Consultants

When a consultant is identified as a potential reviewer, they will be asked to verify that they have no conflict of interest in relation to members of the study team or with the research content of application.

Conflicts of interest involving consultants will be evaluated according to the same definition as IRB-HSBS members (refer to SOP Part 9.III.A above).

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-HSBS chair or director 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 or director 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-HSBS 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](#). IRB staff should notify the IRB

director to discuss the potential or actual conflict. 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, 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-HSBS 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 – QUALITY ASSURANCE AND RESEARCH COMPLIANCE

I. Quality Assessment, Improvement, and Assurance

In conjunction with UMOR and the HRPP, IRB-HSBS 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 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. All complaints and concerns related to the protection of human subjects or conduct of individual studies are reviewed by IRB-HSBS. Not all complaints or concerns reported to the IRB represent noncompliance.

Refer to [OM Part 12.II](#) for additional information.

A. Response to Complaints or Allegations of Noncompliance

If information brought to the attention of the IRB-HSBS, 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 will collect any additional information necessary to evaluate the credibility or accuracy of the information and determine whether additional 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-HSBS will promptly report the following to UMOR or other appropriate institutional officials:

- Any unanticipated problems involving risks to subjects or others (Refer to [OM Part 12.III](#) for detailed procedures on reporting unanticipated problems)
- Any serious or continuing noncompliance with federal regulations, institutional policy, or IRB requirements
- 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.C](#) for additional information.

D. Receipt and Initial Handling of Allegations of Noncompliance

When IRB-HSBS 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-HSBS 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-HSBS 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-HSBS 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.F](#) 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.

B. Roles and Responsibilities

The principal investigator of any research project is responsible for reporting to the IRB-HSBS, 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-HSBS 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

An unanticipated problem is an occurrence or information that has all of the following characteristics:

- It is “unexpected” in terms of the nature, severity or frequency given
 - Procedures described in the study documents
 - Characteristics of the subject population being studied
- It is “related” to the research, meaning there is a reasonable possibility that the event may have been caused by the procedures involved in the research
- It suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized

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

The principal investigator must also notify the IRB immediately if a study is suspended by an outside entity (e.g., OHRP, study sponsor) or if the principal investigator terminates the study for the safety of the human subjects. The ORIO application in eResearch is used for this purpose. Study suspensions must also be reported to UMOR for additional examination and possible external reporting.

IRB-HSBS office staff reviews the eResearch inbox numerous times each business day to monitor if any adverse events or ORIOs have been submitted. IRB staff conducts an initial review of the submission for completeness; assesses the submissions to determine if they represent an unanticipated problem, and routes serious unanticipated problems and serious, unexpected, and related adverse events for prompt review.

If the chair determines the report may represent an unanticipated problem involving risks to subjects or others, 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) is 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. 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 unanticipated problems occurring on studies under the direct oversight of IRB-HSBS, and external serious unanticipated problems. 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-HSBS members vote that a submitted report is an unanticipated problem, the following steps will be taken:

- The chair or chair's designee will notify UMOR
- The board will vote on additional actions. Possible actions to be considered include:
 - Suspension of the research
 - Termination of the research
 - Notification of current participants when such information may relate to participants' willingness to continue to take part in the research
 - Modification of the protocol
 - Modification of the information disclosed during the consent process
 - Providing additional information to past participants
 - Requiring current participants to re-consent to participation
 - Modification of the continuing review schedule
 - Monitoring of the research
 - Monitoring of the consent process
 - Referral to other organization entities
- The investigator will be notified
- The study records and IRB-HSBS minutes will document the findings and actions of the board

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 voluntary "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 the purposes of these procedures.

B. Suspension or Termination

The IRB-HSBS may suspend or terminate approval of research following appropriate review and deliberation for any of the following reasons:

- The research is not being conducted in accordance with IRB-HSBS requirements
- The research has been associated with unexpected harm to subjects
- The risks to subjects cannot be minimized or a favorable risk-benefit ratio cannot be maintained

Any suspension or termination of approval under this provision shall include a statement of the reasons for the action and inform the Principal Investigator of institutional notification and reporting requirements.

Key Definitions:

- **Suspension of Research Activity** – Suspension is the temporary withdrawal of IRB-HSBS approval for a human subjects research project or discontinuing a principal investigator's privilege to conduct human subject research. The suspension may be partial, in that certain activities may continue while others must 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 principal investigator's privilege of conducting the 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 participants 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 participants
- Consider whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., making arrangements for medical care outside of a research study, transfer to another researcher, or continuation in the research under independent monitoring)
- Consider informing current participants of the termination or suspension
- Have any adverse event or outcome reported to the IRB

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.

Refer to [OM Part 12.III.2](#) for reporting requirements to UMOR.

C. Institutional Reports

Upon receipt by UMOR of a report of IRB suspension or termination of research or a report of an unanticipated problem involving research subjects or others, UMOR will take additional action as appropriate. Reporting responsibilities of UMOR are detailed in [OM Part 12.III.3](#).

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.

PEERRS 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 required training. Individuals may not conduct research with human subjects until the training is complete.

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

III. Supplemental Education

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-HSBS educational offerings for the research community is found on the [IRB-HSBS website](#)

QUESTIONS / CONTACT INFORMATION

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Ann Arbor MI 48109-2800

734-936-0933

(fax) 734-936-1852

<http://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs>

Office for Human Research Compliance Review (OHRCR)

North Campus Research Complex

2800 Plymouth Rd.

Building 520, Suite 1172

Ann Arbor MI 48109-2800

734-647-0489

(fax) 734-936-1852

<http://research-compliance.umich.edu/office-human-research-compliance-review-ohrcr>

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