



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

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

Standard Operating Procedures

July 2020

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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 participants in biomedical and behavioral research conducted at the University of Michigan (U-M) 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), who serves as the Institutional Official (IO) for human research oversight, has established the HRPP as an integrated system consisting of research leadership, administration, and oversight functions. The oversight component includes education and training; quality assurance and compliance; and research review units including institutional review boards (IRBs) and other organizations charged with protecting human participants and promoting excellence in all aspects of human subjects research.

The HRPP Operations Manual (OM) is designed to (1) illuminate the system and its overarching governing rules, and (2) serve as a reference for investigators, IRBs, administrators, and others. The Standard Operating Procedures (SOPs) serve as the method by which the IRBs implement the policy outlined in the OM.

II. The Institutional Review Boards (IRBs)

The U-M IRBs review and oversee research conducted by the University to ensure that it meets ethical principles articulated in the Belmont Report and complies with federal regulations that pertain to human participant protection at [45 CFR 46](#) as well as 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 participants. Secondly, within that overarching 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 participants' 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 subjects research conducted by the University must be approved or determined to be exempt by a University IRB or an external IRB as specified in the IRB's SOPs. Research that has been reviewed and approved by a U-M 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, as described in OM Part 4.VI, a U-M IRB or an external IRB reviews and monitors all U-M research involving human participants, regardless of funding source. In addition, certain types of research involving human participants 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

The 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): (1) IRB-HSBS Maize and (2) IRB-HSBS Blue. These board primarily support researchers from U-M Ann Arbor, Dearborn and Flint campuses). Each IRB meets once per month, as necessary to review IRB submissions, and may meet more frequently to consider urgent matters.

UMOR provides administrative and compliance support for IRB-HSBS.

The IRB-HSBS Advisory Committee, an executive committee comprised of Associate Vice Presidents for Research (AVPs) (or designees), IRB-HSBS Chair(s) and Vice Chairs, the IRB director and IRB members, faculty-at-large, representatives with research experience, and others, meets 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, including educational and guidance materials, can be found on the [IRB-HSBS website](#).

II. Organizational Entities that Support IRB-HSBS

The following organizational entities contribute to the operation of the IRB-HSBS and the HRPP:

- U-M Office of Research (UMOR)
- Office of Research and Sponsored Projects (ORSP)
- Office of Research Compliance Review (ORCR)
- IRB Council
- eResearch
- Research Administrative Deans, representing the schools, colleges, and other academic units supporting the conduct of human participants research
- Other research review units with responsibility for monitoring specific categories of research, including the UMOR, U-M Medical School and Institutional Conflict of Interest Committees, and the Michigan Institute for Clinical and Health Research (MICHHR)

Additionally, key executive and administrative offices including the Provost, the Chancellors of the Flint and Dearborn Campuses, and the Office of General Counsel support the operation of the IRB-HSBS and the HRPP.

See the OM Part 2.II for a detailed description these entities.

PART 3 - IRB-HSBS POLICIES

I. Introduction

Rulemaking within the University of Michigan is divided three ways: (1) the Bylaws of the Board of Regents, (2) Regents Policies, and (3) rules adopted by subordinate University authorities under delegated legislative powers that become effective as provided by such subordinate authorities. HRPP policies fall within the third class of rulemaking.

II. The Operations Manual (OM)

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

At least once every five years, typically in conjunction with the Association for the Accreditation of Human Research Protection Programs (AAHRPP) re-accreditation cycle, UMOR initiates a comprehensive review of the OM. Revisions may be made at any time, however, as required by changes in law, ethical standards, institutional policy, quality assurance activities, or other considerations. Non-substantive revisions (e.g., to correct typographical errors, update links or incorporate summaries of new or revised laws or regulations governing the HRPP) may be made upon approval of the IRB Council and communicated to the IO or designee by the HRPP Director.

III. IRB-HSBS Standard Operating Procedures and Policies (SOPs)

A. General Provisions

IRB-HSBS, to which these SOPs refer, is designated by the University to review and monitor research under the University's Federalwide Assurance (FWA). The IRB follows Federal regulations, OHRP and other agency guidance, state and local law and University policy and operates under the oversight of the University's Vice President for Research. See OM Part 3 for detailed information.

Generally, IRB-HSBS has oversight for human participants research conducted by the schools, colleges, and units of the Ann Arbor, Dearborn, and Flint campuses that are not part of Michigan Medicine and the Medical School. Exceptions (i.e., circumstances under which applications submitted to IRB-HSBS must be reviewed by IRBMED) are allowed by agreement between IRB-HSBS and IRBMED under guidance from UMOR. For a more detailed description of IRB jurisdiction, see OM Part 5 and SOP Part 5.

The IRB-HSBS reviews research for compliance with state and local laws, regulations, and University policies that pertain to research involving human participants and consistent with

the ethical principles of the [Belmont Report](#). Additionally, IRB-HSBS reviews research for compliance with other federal and state regulations and statutes that apply to research under its jurisdiction, including the [Health Insurance Portability and Accountability Act \(HIPAA\) of 1996](#) and [Federal Educational Rights and Privacy Act \(FERPA\)](#).

The IRB-HSBS works 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 does not require additional review or approval by UMOR. Depending on their intended use, IRB-HSBS guidance materials may be developed with input from and review by stakeholders in 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 IRB-HSBS Chair(s) and Vice Chairs (*Note: These SOPs may reference the Chair role in either a singular or plural form*)

1. Chair(s)

IRB-HSBS has one or more Chair(s) appointed by the IO in consultation with the HRPP Director, and IRB directors. Each Chair serves at the will of the IO and has an appointment as a faculty member in one of the units under IRB-HSBS jurisdiction. Exceptions to these parameters must be approved by the IO. The Chair is qualified through experience and expertise, concerned about human rights and ethical issues, and familiar with regulations relevant to the use of human participants in research. A Chair may also serve as a board representative for their respective school, college, or unit. The appointment of a Chair will, as practical, rotate among the major units under IRB-HSBS jurisdiction. The Chair is appointed for a term of three years.

2. Vice Chairs(s)

One or more members of the IRB may be designated as Vice Chair(s) to serve in the event that the Chair is absent, not able to convene an IRB-HSBS meeting or perform other duties of the Chair. Vice Chairs are appointed for three year terms.

3. Acting Chair

An IRB member may be designated as an acting Chair in the event that the Chair or Vice Chairs are not available to convene an IRB-HSBS meeting. An IRB 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.

B. Qualifications and Appointment of IRB-HSBS Members

1. Regular Members

IRB-HSBS Maize and Blue have at least five voting members, including Chairs or Vice-Chairs. The board membership includes scientist members from the primary academic units under IRB-HSBS jurisdiction, including the Dearborn and Flint campuses, at least one member not affiliated with the University of Michigan, and one non-scientist are appointed to serve as full members for each board. The IRBs do not consist entirely of men or entirely of women.

Membership is sufficiently diverse (e.g. gender, race, cultural background, sensitivity to community attitudes or interests of special populations) to evaluate the types of research presented to the IRB-HSBS. IRB members have knowledge of the specific scientific disciplines relevant to the research they review. In addition to possessing the professional competence to review specific research activities, the primary consideration of the IRB membership is to ensure that the research complies with the federal regulations and ethical standards and principles for the protection of human participants in research. Members 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. IRB members must also possess knowledge of the local research context to fulfill their review responsibilities under federal regulations and the OM. The IRB membership is regularly supported by consultants from the Office of General Counsel for legal guidance and from Information Assurance regarding data protection issues. Additionally, if the appointed membership is not sufficiently knowledgeable about the scientific discipline or research context related to a specific project, consultants may be used to supplement IRB-HSBS review (see SOP Part 3. IV.G). If 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 or from the community.

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 retired members of the university faculty, staff or from the community.

Unaffiliated members may be scientists or non-scientists. To qualify as an unaffiliated member, neither the member nor any member of his/her immediate family may have a direct affiliation with U-M (e.g., full or part-time employee, contractor, current student in a degree program, or volunteer at the institution (other than IRB service)).

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 participants. Community members are often unaffiliated with the University.

The IRB-HSBS membership includes individuals who represent the interests of vulnerable populations, including prisoners and children.

A copy of the current membership roster is on file in the IRB-HSBS office and posted to the IRB website. The rosters are updated as necessary and provided to UMOR.

All members, including unaffiliated members, are expected to attend, actively participate in the discussion, and vote at the majority of IRB meetings during a calendar year. Members are also expected to complete review 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 on the Maize and Blue boards serve as alternate members on the other board (i.e., a full member on Blue serves as an alternate for a full 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 and are also appointed for unaffiliated 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. Experienced IRB-HSBS staff members are also 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. Leadership from the Dearborn and Flint campuses recommend members to represent their campuses. Individuals who are not affiliated with the University may also 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 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 issues 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 three years.

C. Terms of Appointment, Evaluation, and Reappointment

1. Chair(s) and Vice Chair(s)

IRB-HSBS Chair(s) and Vice Chairs serve three year terms and may be reappointed based on recommendations from UMOR, IRB-HSBS directors and staff, and mutual agreement of the nominee.

Prior to the end of the term, Chairs and Vice Chairs are evaluated by the HRPP Director and the IRB director(s). They are assessed based on continuing interest and availability for service, 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 a Chair or Vice Chair. Retiring Chair(s) who wish to continue their service at the end of their term may be reappointed as a full or alternate member of the IRB.

2. Members

Prior to the end of the member's term, the IRB Chair and IRB Directors evaluate members for reappointment as regular or alternate members, based upon their continued interest in and availability for service on the IRB. Members are also evaluated and provided with an annual participation report that provides information on meetings attended and reviews completed. This report is shared with the IRB Chair and the member's unit, if requested. This information is also considered as part of their reappointment process. Criteria for evaluation and reappointment include: attendance at meetings, level of participation at meetings, thoroughness of review, regulatory

knowledge, effective use of eResearch, working relationship with IRB staff and other IRB members, and interactions with principal investigators. Based upon this evaluation, some members may not be recommended for reappointment. Members may be evaluated more often if circumstances dictate. Members are informed of these expectations and the evaluation process at the time of appointment.

3. Termination of Appointment

IRB-HSBS Chair and Vice Chairs 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 HRPP Director, on the advice of the IRB Chair, will terminate the appointment.

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.

D. Compensation of Chairs and Members

The rate of any compensation for the roles of Chair and regular expediting reviewers is determined by UMOR in consultation with the academic units, if necessary. The rate of compensation for community members is determined by the HRPP Director in consultation with the IRB Director and the IRB Chair.

E. 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.

F. Periodic Review of Membership and Composition

The membership and composition of the IRB-HSBS Maize and Blue boards are 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.

G. 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 University faculty and staff or individuals from the community at large whose experience or expertise may assist 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 protocol.

2. Participation

Consultants may participate in the deliberations concerning any application, but are not counted for the purposes of establishing quorum and do not vote on the approval, disapproval, or other disposition of any application. Consultants may not participate in the review of any projects in which they have a conflicting interest (as defined in OM Part 9), except to provide information requested by the IRB. 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.

A consultant is required to sign a confidentiality agreement when participating in an IRB meeting.

H. IRB-HSBS Staff

1. Support and Supervision

The IRB-HSBS is supported by a professional staff who report to the HRPP Director. Day-to-day supervision is provided by the IRB Director and 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 work on 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 formally evaluated as part of UMOR's annual performance evaluation process and may be evaluated informally at the midyear. The performance evaluation is conducted by the staff member's direct supervisor and/or the IRB Director. The IRB Director is evaluated annually by the HRPP Director. The evaluation for each staff member includes both a written evaluation via the UMOR performance evaluation tool and a face-to-face meeting with the staff member's direct supervisor and the IRB Director. The evaluation is also provided to the HRPP Director and the UMOR HR group.

In addition, the IRB Directors monitor staff workloads and review metrics received from the eResearch system on a weekly basis or monthly. Regular quality assurance assessments of staff IRB application reviews are conducted and feedback is provided to the staff member. Identification of additional human subjects education for the individual staff member or for the IRB team may be identified as part of this process. Feedback is also sought from expediting reviewers regarding the quality of IRB staff review.

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

IRB-HSBS provides IRB staff and IRB members with sufficient training and opportunities for continuing education in order for them to effectively perform 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 perform their IRB membership responsibilities. 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, if possible
- Review of essential resource materials including historical background regarding human participants in research, federal regulations, the Belmont Report, OHRP information and guidance, and institutional policies and SOPs
- Completion of the human subjects module 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 for full committee or expedited review (see SOP Part 3.V.A.)
- Overview of full board operations and processes, meeting roles, and review presentation guidelines

b. Current Member Continuing Education

Educational presentations are offered convened meetings when the agenda permits. Topics include changes or updates to human participant or other regulations or U-M policies, changes to the eResearch application, and focused presentations on specific regulatory issues, including just-in-time refreshers. Invited speakers on special topics may be 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 resources, and are invited to participate in webinars such as those offered by AAHRPP, the 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 attendance at 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 participants research.

c. Chair and Vice Chair Education

Chairs and Vice Chairs meet with the IRB Directors and full board administrator to review roles, responsibilities, and working procedures required for their role, including relevant federal and state regulations, laws, guidance materials, and U-M policies.

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 sources of information 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 used to conduct reviews of electronically submitted applications.

All IRB staff members are required to complete the PEERRS human subjects module. Completion of additional PEERRS modules in research administration, conflict of interest, or other relevant topics is recommended. PEERRS human subjects certification must be renewed every three years. Staff members who review projects involving PHI also complete a HIPAA training module offered by the Michigan Medicine Compliance Office. Staff members may also complete training modules offered by CITI or MICHHR.

b. Current Staff Continuing Education

IRB-HSBS staff members regularly participate in learning activities including webinars (offered by AAHRPP, PRIM&R, and OHRP) and presentations (by the IRB education coordinator, IRB directors, or guest speakers) on regulations, policies, research approaches, and the use of eResearch. These activities often include the analysis and discussion of case studies. Time is devoted at weekly staff and protocol meetings to discuss questions arising from review of applications for the purpose of providing just-in-time education for the entire team. The IRB staff members maintain records of attendance at staff education sessions and include this information and documentation of active PEERRS certification as a part of the annual review process. Materials and presentations are made available to those who are absent. IRB staff members are also encouraged to monitor the dialogue of the IRB Forum, the PRIM&R Social and Behavioral Research Network, OHRP educational newsletters, and other human subjects research resources. Internal guidance is provided to staff on regulatory and office policies, procedures, and practices in reviewing human subjects research. Such guidance is updated or supplemented as needed.

As budget and availability permit, IRB staff members are provided with opportunities to attend (a) local and national conferences, (b) locally available educational presentations or courses such as those offered by IRBMED, (c) attend presentations offered by U-M researchers, or (d) presentations by other universities, societies, or organization.

IRB-HSBS staff members are encouraged to obtain the Certified IRB Professional (CIP) credential and where the budget permits, pays for the initial certification and recertification.

V. IRB Functions and Operations

A. Application Submissions in eResearch

IRB applications (initial, scheduled continuing review, amendments, and reports of adverse events and Other Reportable Information or Occurrences [ORIOs]) are submitted to IRB-HSBS 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:

- Human subjects research involving interaction or intervention (including projects qualifying for Exemption 1, 2, 3, 5 and 6)
- Secondary research uses of private information or biospecimens (including projects qualifying for Exemption 4 or not regulated determinations)

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- Activities not regulated as human subjects research
- Projects lacking immediate plans for the involvement of human subjects, their data, and/or their specimens
- Request for review by a non-U-M IRB
- Establishment of a data and/or biospecimen repository
- Multi-site studies

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 participants 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 Director if they have a potential or actual conflict of interest with any aspect of the application. If a conflict of interest is confirmed, the staff member will be excused from any IRB duties directly relating to the processing, review, or outcome determination of the application.

Using a staff checklist in eResearch, 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 or for the staff member to issue an exemption determination. 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 initial review, amendment, or continuing review application, 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 research is conducted as part of the investigator’s “university responsibilities”
- The research is exempt from IRB oversight
- The University of Michigan is engaged in the research

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. Research subject to FDA regulation (e.g., involving an IND or IDE), being conducted by Michigan Medicine faculty, staff or students, using Michigan Medicine patients as participants and certain other types of research applications are referred, after consultation, to IRBMED for review. See OM Part 5.

If the research is not regulated or is exempt, the staff member will issue the “Not Regulated” or exempt determination via the eResearch system.

2. Initial Review

Any investigator intending to initiate a research study involving human participants 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 an exemption determination for the study has been issued via eResearch.

Once the IRB staff member has determined that an initial application is subject to IRB-HSBS oversight, 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 (see SOP Part 3.V.I for the expedited and convened board review procedures). As applicable to the research, the following information is reviewed:

- The research protocol, including data management and security procedures
- 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

- External 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. For no more than minimal risk projects reviewed via expedited review, the IRB must also determine whether Scheduled Continuing Review is necessary for the project and document the reason for requiring it.

3. Scheduled Continuing Review

Under the revised Common Rule, continuing review is no longer required for projects that meet the criteria for expedited review [45 CFR 46.109 \(f\)](#), unless it is required by another law or regulation. The eResearch approval letter includes the date of the determination (effective date) and a notice that continuing review is not required.

The IRB can require continuing review these projects, but it must document its rationale. This determination is tracked in the eResearch system. Examples of criteria for requiring continuing review include:

- Past non-compliance issues with the investigator or related to the particular project
- Research conducted in an international setting
- Research involving an innovative, unusual, or complex study design
- Research involving an investigator with a financial conflict of interest
- Research collecting identifiable, sensitive data collected under an NIH Certificate of Confidentiality

For projects initially reviewed and approved prior to January 21, 2019, the IRB will make a determination whether a study will remain under the pre-2019 Common Rule and continue to require continuing review for projects qualifying for expediting review.

For projects for which continuing review has been eliminated, the eResearch system sends an annual touchpoint message to investigators to remind them of their continuing responsibilities to submit amendments and AE/ORIOs while the project is active and to terminate the application at study completion. ORCR also does random audits of these projects.

For research studies that require review by the convened IRB, continuing review is required until the research has progressed to the point that it involves either data analysis, including analysis of identifiable data and/or biospecimens, or accessing follow-up clinical data from procedures that participants would undergo as part of clinical care, [45 CFR 46.109 \(f\)](#). The eResearch approval letter includes the date of the determination (effective date) and a notice that continuing review is no longer required.

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
- Multi-center trial reports (these are rare for IRB-HSBS projects)

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. 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 and assesses the risks and benefits of the project. When appropriate, the IRB-HSBS will seek verification from an outside party, such as the Office of Research Compliance Review, 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.

The IRB will also assess whether continuing review is still necessary and appropriate for the project or if the research qualifies for exemption under [45 CFR 46.104](#).

If continuing review is required, the IRB will determine the interval appropriate to the magnitude of risk of the project and other considerations, but no less than once each year. Some projects may require continuing review at an interval of less than one year (see SOP Part 3.V.D).

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.

a. Study Closure (Termination Report)

The principal investigator is responsible for notifying the IRB-HSBS of the completion of a study, including analyses of identified data or biospecimens. Investigators are reminded of this responsibility at time of continuing review or in the annual touchpoint

message from project for which continuing review is not required. The Termination Report activity is also available for exempt studies.

D. Frequency of Review

For research requiring continuing 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 about whether the study can collect sufficient data to develop 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 takes place in an international setting or other off-site location(s) where the IRB-HSBS is serving as the IRB-of-record
- Principal investigator has a potential conflict of interest that warrants more frequent reporting and review
- Additional circumstances that the convened board would consider serious enough to warrant the additional oversight

The IRB may apply similar criteria in determining that continuing review is required for projects reviewed via expedited review under the new Common Rule.

E. Monitoring and Verification

With respect to any research project or class of research projects, the IRB-HSBS may impose additional monitoring requirements for 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 participants.

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 is unusually complex, to gauge the progress of recruitment for vulnerable participants or to follow the research progress on controversial subject matter.

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.

Examples of Special Monitoring Requirements include but are not limited to:

- Shortened approval periods and/or interim, scheduled reports from the investigator during the approval period
- Site visits to research locations
- Interviews with participants
- 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 participants. 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)

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 participants.

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 participants 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 participants, 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 surveys or interviews
- 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 amendment approval date does not extend the expiration date for a study (i.e., the date by which a regularly scheduled continuing review must be completed, if required). At the time of amendment, the IRB may determine that (a) continuing review is required based on changes made to the protocol, or (b) a project that was originally approved under the pre-2018 Common Rule no longer requires continuing review because it meets criteria for transition to the new rule.

G. Lapses in Approval

For projects requiring continuing review, 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 participants

currently participating in the study to continue the research interventions or interactions. No new participants 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.

Only the IRB can determine whether a project qualifies for elimination of continuing review under the 2018 Common Rule. Investigators must submit an SCR to the IRB for a formal determination. Projects that fail to do so will be considered to be in a lapsed state if the IRB approval for a 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 a Termination Report in eResearch to report the project closure.

In addition, new 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. Reports of Noncompliance and Other Reportable Information and Occurrences (ORIOs)

The IRB-HSBS requires prompt reporting of ORIOs for protocol deviations and other possible noncompliance, including events that may represent Unanticipated Problems involving Risks to Subjects or Others. OM Part 12 and SOP Part 12 describe the procedures associated with the reporting and review requirements associated with these events.

I. 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 46.110](#) 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:

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- The activity must present no more than minimal risk to participants. 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 participants and/or their responses would reasonably place them at risk of criminal or civil liability; would be damaging to the participants' 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 and the project falls into one or more criteria for expedited review. The research may 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. See SOP Part 3.III.V.f and OM Part.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, depending on the completeness of the application, the availability of reviewers, and the number of other submissions in process.

IRB staff conduct an administrative review of each application for completeness and adherence to regulatory requirements using the staff checklist. The staff member also assesses whether the project poses no more than minimal risk to participants and whether it fits within an expedited review category. 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 and includes their assessment of the appropriate expedited review category.

Expedited review is conducted by a single reviewer with relevant expertise. IRB-HSBS Chair or IRB members (including qualified IRB staff) appointed by the Chair conduct expedited reviews (see SOP Part 3.V.I.1.b). A secondary reviewer may be assigned by the IRB staff or requested by the expedited reviewer if the expertise of the secondary reviewer is needed for a particular study. The secondary reviewer submits their review via the reviewer checklist for consideration by the primary reviewer. The primary reviewer is responsible for issuing the determination for the application.

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.

Prior to assignment to an expedited reviewer or to a consultant, the IRB staff also makes an assessment to ensure that an application is not assigned to a conflicted expediting reviewer (e.g., the reviewer is a member of the study team or the spouse of a member of the study team). If a previously unreported conflict is identified in the course of reviewing an application, a new reviewer will be assigned to the application. See SOP Part 9 for more information about conflict of interest procedures.

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 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 that includes comments provided by the IRB staff. 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 ethical principles 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.

In order to approve a submission (initial applications, amendments, or scheduled continuing reviews) via expedited procedures, the expedited reviewer must determine that the research meets all of the criteria for IRB approval found at [45](#)

[CFR 46.111](#) and the criteria for expedited review described in OM Part 3.III.C.6 and SOPs Part 3.V.I.1.a. The expediting reviewer documents these criteria in the eResearch reviewer checklist as well as selecting the relevant category for expedited review.

c. Expedited Reviewers

Experienced full and alternate members of the IRB-HSBS may be appointed as an expediting reviewer by the Chair with the concurrence of the HRPP Director. 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 participants 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.

IRB-HSBS staff members who are sufficiently qualified through experience and expertise and are familiar with regulations relevant to the use of human participants in research may be appointed to the IRB as full or alternate members and as expediting reviewers. IRB staff members who are authorized to conduct expediting reviews must be qualified through academic or research experience, IRB employment or IRB experience, leading to familiarity with regulations and institutional policy relevant to the use of human participants in research. IRB directors and Chairs will jointly assess the readiness of staff to conduct autonomous expedited reviews and issue determinations based on previous education, experience, and performance in their current role.

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.

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. These communications are prepared by the IRB-HSBS staff and a written notice of the review outcome is

provided to the PI and study team members 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 in accordance with [45 CFR 46.111](#) and Subparts B, C, and D, as applicable and described in SOP Part 3.V.C.2 and Part 3.V.J. The reviewer must also identify the expedited review category used to approve the study.

Under the 2018 Common Rule, continuing review is not required for projects approved under expedited review. The expediting reviewer may determine that continuing review is required for a study as described in SOP 3.V.C.3 and must document the rationale in the eResearch reviewer checklist.

For amendments or continuing review applications reviewed and approved under the pre-2018 Common Rule, continuing review is required until the study reaches the point of analysis of deidentified data or is otherwise closed, unless transitioned to the provisions of the new rule.

For projects requiring continuing review, the approval period begins on the date of the submission of approval by the expedited reviewer. For federally-supported research or other projects requiring continuing review, the approval period shall not extend beyond one year (364 days). The expiration date represents the last day of the approval period.

ii. Approve with Contingencies

The expedited reviewer may make approval contingent on 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 under [45 CFR 46.111](#) and described in SOP Part 3.V.C.2 and Part 3.V.J. 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 be granted 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.

Under the 2018 Common Rule, continuing review is not required for projects approved under expedited review. The expediting reviewer may determine that continuing review is required for a study as described in SOP 3.V.C.3 and must document the rationale in the eResearch reviewer checklist.

For amendments or continuing review applications reviewed and approved under the pre-2018 Common Rule, continuing review is required until the study reaches the point of analysis of deidentified data or is otherwise closed, unless transitioned to the provisions of the new rule.

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. Via eResearch, the investigator will be provided with detailed instructions regarding the changes required to the application or study materials or additional information 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 expedited reviewer finds that a study poses more than minimal risk or otherwise does not meet the criteria for expedited review, finds that research appearing on the expedited review list to be greater than minimal risk, or recommends that the expertise of the full board would prove useful in the review, the application is returned to the IRB-HSBS staff with a request that the Chair place the study on the agenda for the convened board. The expediting reviewer must document that rationale for this determination and the rationale for requesting review by the convened IRB in the reviewer checklist.

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 issued by the IRB-HSBS during the period since the last IRB meeting are reported and acknowledged by the board at each meeting of the convened IRB-HSBS through an eResearch report listing the applications reviewed. The board is given an opportunity to discuss any of the applications. Any board member can access these applications links in the Expedited report and 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 participants
- 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)
- Projects referred to the convened board by the IRB Chairs or at the request of an expediting reviewer
- Projects involving interactions or interventions with prisoners
- Projects receiving support from a federal agency or other sponsor that choose to limit the use of expedited procedures
- Projects or categories of projects for which the IO has determined convened IRB review is required

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

The IRB-HSBS meets two times per month (IRB Maize and IRB Blue), according to a published schedule to review assigned applications. Meetings may be cancelled if there are no applications ready for review. The IRB full board administrator, in consultation with the IRB Chair or Vice Chair, assigns a primary and secondary reviewer from the IRB membership for each initial application. This includes assignment of reviews to the members that represent special populations, such as the prisoner representative or child advocate. 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, may serve as the representative for a vulnerable population, or may be chosen from the membership at-large, including the non-scientist and unaffiliated members.

Applications that are complete and ready for board review 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 participant 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 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, all 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. Consultant reviewers may be provided with access for all of the materials in the eResearch application or only with those materials necessary for their specific review.

To facilitate the board's review, the principal investigator or study team members may request to attend a board meeting or may be invited by the IRB-HSBS to answer questions or provide clarification about the research study. However, neither the PI nor the study team will be permitted to be present for the discussion or vote of the submission.

c. Convened IRB-HSBS Determinations

An initial, amendment, or SCR submission may be approved or disapproved only upon a majority vote by the voting members present, assuming the required quorum is met. The IRB staff records the number of members voting for and against a motion, and the name of any abstaining member.

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 (see 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. 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

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 and the reason for the required changes before the IRB can issue 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 [45 CFR 46.111](#). The IRB, in its vote, must indicate whether the response to contingencies can be reviewed and approved via expedited procedures by the primary or other expedited 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 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 participants research when it determines that the study design does not provide, and is unlikely to be modified to provide, adequate protection to participants. 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 participants.

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.

J. Criteria for IRB Approval

All applications for non-exempt research with human participants and submitted for initial review, continuing review or amendment is reviewed by a single expediting reviewer or by the convened board and approved in accordance with the requirements of [45 CFR 46.111](#) and [Subparts B, C, and D](#) as applicable. 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 participants 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. For many projects reviewed by the IRB-HSBS, the primary risk is breach of confidentiality. The term “benefit” is used in the research context to see something of positive value related to health or welfare. In many cases, the research reviewed by IRB-HSBS does not provide a direct benefit to participants.

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 participants
- Medical or psychosocial resources that participants 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. The IRB-HSBS will only approve research if risks to participants are reasonable in relation to the anticipated benefits to the participants or the importance of the knowledge to be gained from the research.

Benefits of the research include those that may accrue to the individual participant 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 reviewers 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 participants. 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 participants, the IRB considers the following:

- The principal investigator's assessment of the risk level as presented in the eResearch application
- Whether study procedures are consistent with sound research design
- The probability (likelihood) and magnitude (potential severity) of possible harms
- Whether the participants are vulnerable in some way
- The steps taken or planned by the investigator to alleviate the potential harms including the quality of the data safety monitoring plan (DSMP), as applicable
- The investigator's history of compliance with research protocols and IRB procedures

In assessing the potential risks and benefits of a given study, the IRB-HSBS only considers risks and benefits that may result from the research itself. This means that the risks of the research are distinguished from risks and benefits of therapies (for studies that involve a therapeutic intervention) that participants would receive even if they were not participating in the research. Similarly, the IRB should not consider possible long-range effects of applying knowledge gained from a particular study as a potential research risk (for example, the possible effects on public policy).

The IRB-HSBS will rely on 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 IRBMED 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 participants.

5. Recruitment, Screening Selection and Enrollment of Participants (Equitable Selection of Participants)

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 participants, paying particular attention to the participant inclusion and exclusion criteria and recruitment procedures.

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 participants 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 procedures for identifying those groups are adequate
- The benefits and burdens are fairly distributed
- The recruitment of vulnerable participants is necessary or if it would be more appropriate to conduct the study with less vulnerable participants
- The selection process, by design, will be protective of potential participants who may be vulnerable, but will not deny appropriate opportunities to participate
- Vulnerable participants will be adequately protected during recruitment

The IRB reviews all advertisements, materials, or methods intended to recruit prospective participants. Recruitment materials are either submitted as part of the eResearch application or provided in hard copy if the materials are in a format that cannot be uploaded into the application. The IRB reviews the information contained in

the recruitment materials, as well as the format of the material to ensure that the procedure for recruiting participants does not pose an undue influence, does not include exculpatory language, does not promise free treatment when the intent is only to indicate that the participant 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 participants 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 purpose of the research, including the condition of the study, if any
- 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 participants
- The location of the research and the person or office to contact for additional information
- Information about payments to participants. 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 Participants

The IRB-HSBS will review the arrangement for payments or other participation incentives offered to participants. All information concerning payment, including the amount and schedule of payments is described in the consent document and in the eResearch application 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 participant population
- The plan for prorating payments in the event that a participant withdraws from a study prior to its conclusion. Where appropriate, credit for payment accrues as the study progresses and may not be contingent upon the participant completing the entire study.
- Whether the payment is considered sufficient to take into account other costs to the participant for participating in research (e.g. travel and 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) (see [U-M Standard Practice Guide 501.07](#))

7. Data and Safety Monitoring

For projects posing more than minimal risk to participants or for NIH-funded clinical trials, the IRB will review the study plan for monitoring data collected to ensure participant safety. Because IRB-HSBS reviews only a small number of such projects, most projects do not require formal monitoring plans, but all investigators are required to report potential unanticipated problems that might suggest safety issues associated with the project. See SOP Part 12.II for more on incident reporting. See OM Part 7.II for more on data and safety monitoring.

8. Protection of Participant Privacy and Data Confidentiality

The IRB-HSBS will ensure that the research plan contains adequate provisions to protect the privacy of participants and maintain the confidentiality of data (see OM Part 3.C.6.g. and [HRPP Guidance on Privacy and Confidentiality](#)).

a. Privacy

The protection of participant 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 participants have a reasonable expectation of privacy and whether reasonable people might 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 participant will be told during a debriefing process, if any

b. Confidentiality

Confidentiality relates to the protection of participant data that have been shared with the researcher in a relationship of trust with the expectation that information will be protected or disclosed as agreed upon in the consent process. The IRB's evaluation of the data confidentiality plan presented in the eResearch application includes:

- 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 for the study

- Whether the information obtained about participants might be of interest to 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 (CoC) issued by NIH should be obtained to protect the research data and the identity of the participants from subpoena or other legal processes. NIH-funded research that collects identifiable, sensitive information is covered by a CoC as part of the terms and conditions of the grant. See the [HRPP CoC](#) website for more information. See also the [NIH CoC Kiosk](#).
- Disclosures to participants about confidentiality plans and whether documentation of consent should be waived to protect confidentiality
- Sufficiency of the plan for data security

When needed, the IRB-HSBS seeks guidance from U-M Information Assurance consultants regarding appropriate data security procedures for research under its oversight and includes IT security consultants on its boards. See the [IRB-HSBS website](#) for guidance on data security.

9. Resources

Depending upon the complexity and risks associated with a research study, the IRB-HSBS considers whether the study team has adequate resources to conduct research and protect participants by evaluating the qualifications of research staff, facilities available for the research, time allotted to the research, likelihood of recruiting participants, and availability of counseling or other support resources that might be necessary for research participants.

10. 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 ensure that participants or their legally authorized representatives provide legally effective, voluntary, informed consent. Informed consent materials (including oral scripts and online consent information), requests for waivers or alterations of informed consent, and 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 participant in non-exempt research unless the investigator has obtained

the legally effective informed consent of the participant or the participant'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 participant 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, participants (or their representatives) are 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 using language that is readily understandable to the participant. The discussion may be supplemented with additional information (e.g., video, 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 is documented by the use of a written consent form approved by the IRB-HSBS and signed by the participant or the participant's legally authorized representative. A copy is given to the person signing the form. A consent document is valid only after it is approved 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](#), including a concise and focused summary of the key information that a participant would want to have before deciding to participate. For many projects reviewed by IRB-HSBS, the informed consent document is not lengthy and this summary is not necessary. The consent document must not contain any exculpatory statements suggesting that any of the participant'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 participant. See OM Part 7.VI for more information.

A detailed explanation of the elements of informed consent, including templates and suggested wording is posted on 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 participant'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 participants if the requirements of [45 CFR 46.117\(c\)](#) described in OM Part 3.III.C.6.e. are satisfied. Many of the minimal risk projects reviewed by IRB-HSBS qualify for a waiver of documentation.

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

- Telephone, web-based, or self-administered mail surveys
- Research involving deviant or illegal behavior or involving socially sensitive issues such as HIV status where the consent document might represent the only record of the participant's involvement.
- Projects involving participants who are members of distinct cultural group or community in which signing forms is not the norm

When the IRB waives the requirement for documentation of informed consent, the required elements of informed consent must be conveyed to the participant through an oral script or by electronic or printed text. Even though participants do not sign a document, the IRB-HSBS may still require that participants be provided with written information about the study. The text of any written or oral informed consent or any informational documents provided to participants 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 \(d\)](#).

For projects sponsored by the Department of Defense, there are limitations on waiving informed consent. See [HRPP Guidance on Additional Requirements for Department of Defense \(DoD\) Sponsored Research](#).

d. Short Form, Comprehensive Oral Script, and Witness

For populations that are unable to read a consent document and where documented consent is required, the IRB-HSBS may approve a short form consent process that documents that the elements of informed consent required by HHS to be presented orally to the participant or the participant's legally authorized representative, and signed by a witness. See [45 CFR 46.117\(2\)](#) and OM Part 3.III.C.6 (e).

11. Special Review Considerations for Projects Involving Special and Vulnerable Populations

Research may, by design or by random recruitment, involve participant populations that may be vulnerable to coercion or undue influence or otherwise require additional protections. The IRB-HSBS will consider additional safeguards to protect the rights and welfare of these individuals.

Subparts B, C, and D of the Common Rule include additional IRB review requirements that apply to research supported by DHHS and other federal agencies adopting these standards:

- Pregnant women, human fetuses, and neonates ([Subpart B](#))
- Prisoners ([Subpart C](#))
- Children ([Subpart D](#)) (In Michigan, the legal age to consent to treatments or procedures involved in research is 18 years.)

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.II provide equivalent protections for vulnerable populations as research participants.

When individuals from these populations (as well as other potentially 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 setting) participate in research, the IRB-HSBS will require investigators to specify what additional protections, if necessary, 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.

The IRB-HSBS applies additional scrutiny in reviewing the informed consent process for studies that involve vulnerable participant populations. Special attention is given to assessing the autonomy, cognitive capacity, and/or potential coercion of the potential participants during the informed consent process. The informed consent process is particularly salient for certain populations including children, 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 when protections are proportional to risks. It is the responsibility of the person obtaining the participant's consent to determine that the person has sufficient capacity to give it. Unless the requirement is waived by the IRB, each prospective participant or a legally authorized representative must provide a legally effective informed consent to participate in the project.

Laws governing who may consent on behalf of cognitively-impaired or incapacitated adults vary from state to state. See OM Part 11.II.A 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 the additional protections required by [Subpart B](#).

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. 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. See OM Part 7.II.A 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 that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. The OM Part 7.II.B and [OHRP Prisoner FAQs](#) include 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 prisoner 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 consider in the assignment of participant 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 makes additional assessments in order to ascertain the voluntariness of the recruitment and informed consent 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 inmates 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 participant 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 participants. This requirement does not apply to

exempt research projects aimed at a broader participant population that only incidentally includes prisoners (e.g., a survey of the general population).

For research not supported by HHS, the IRB considers the substantive elements of Subpart C in its deliberations, but may also utilize other comparable ethical guidelines, policies or procedures. The IO or DIO assumes the role of the HHS Secretary for studies requiring certification or approval as described in [45 CFR 46.306\(a\)\(2\)](#).

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.1.a

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 participants 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) (see [34 CFR 98](#), [20 USC 1232g](#), [34 CFR 99](#), OM Part 11.I.B.5 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 participant.

In order to approve HHS-supported research involving children as participants, 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.II.C.

i. Evaluation of Assent

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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 consistency 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 waive the requirement for child assent and determines whether written assent is required. 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\(c\)](#) includes provisions for waiving parental permission in research that is designed for conditions or a participant population where parental or guardian permission is not a reasonable requirement to protect participants (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 and 407](#). Wards may participate in such research only if it meets the provisions of [45 CFR 46.409\(a\)](#). In such cases, the IRB will require an advocate to be appointed for each child. For additional guidance, see [IRBMED Guidance on Research Involving Children who are Wards](#).

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 participants who are not cognitively or decisionally-impaired and thus 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 participants' 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 participant's understanding of the research
- The consent document is written in a language and at a readability level appropriate to the participant
- If the participant 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 participant's cognitive capacity
- If the participant is unable to provide legally effective informed consent, the PI should outline a plan to obtain assent from the participant and informed consent from a legally authorized representative (LAR)

ii. Legally Authorized Representatives

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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 participant, and the LAR's role in providing initial and ongoing consent.

If participants 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 participants 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 participant's continued participation in the research or decide to end the participant's participation in the research. The participant 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.

12. 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 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 for researchers may impose additional requirements such as particular consent processes or district approval processes that would not be required by the IRB. These include the Family Education Rights and Privacy Act (FERPA) (34 CFR 99) and the Protection of Pupil Rights Amendment (PPRA) (34 CFR 98. See [34 CFR 98](#), [20 USC 1232g](#), [34 CFR 99](#), OM Part 11.I.B.5, and [HRPP Guidance: Additional Requirement for Research Supported by the Department of Education](#).

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

IRB-HSBS reviews projects involving Protected Health Information (PHI) for units that are part of the U-M HIPAA hybrid covered entity but not part of Michigan Medicine, which may include the 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) or for external entities that are providing access to PHI for U-M researchers for their projects. 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

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 participants 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

See OM Part 11. OM Part 11.I.A.4 for more on HIPAA.

14. 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.

See OM Part 11.II.B 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).

15. Studies Subject to ICH-GCP Standards

ICH-GCP standards apply to the conduct of clinical trials involving drugs, medical devices or biologics when required by the sponsor. These standards rarely apply to research reviewed by IRB-HSBS. See OM Part 11.III.B.

16. International Research

Generally, the IRB-HSBS reviews all international human participant 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 IRB-IRBS will require local IRB or ethics committee review and the regulatory requirements of [45 CFR 46](#) apply. An FWA may be required for international partners who receive federal support. 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 an international research site is not engaged in the conduct of the research, the IRB may instead 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.

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 participant, 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 participant complaints, unanticipated problems involving risk to participants 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.

K. IRB Administrative Functions

1. IRB Meetings

a. Standard Schedule

IRB-HSBS full board meetings are scheduled once a month for each panel (Blue and Maize). 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, with the agenda and access to all applications referred to the full board for review. This information is supplemented by an email with a copy of the agenda.

b. 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 a subsequent meeting if the IRB staff or Chair determines that the agenda is too full.

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

c. Meeting Procedures

i. 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. The meeting Chair serves as a voting member of the IRB and counts toward the meeting quorum.

ii. 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 scientist and one non-scientist. At least one unaffiliated or community member who represents the general perspective of participants should be present at the majority of meetings in a given 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. When the IRB reviews a study involving prisoners, the prisoner representative must be present. Similarly, if the IRB reviews a study involving a population vulnerable to coercion or undue influence, members who have experience with such a population are present. 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, including the non-scientist and unaffiliated members, is recorded in the meeting minutes.

iii. 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, and special DoD or other agency considerations). Regulatory criteria are posted as part of the electronic agenda and are included in the project notes. These materials are used to create the minutes for the meeting.

iv. Alternate Meeting Format (Teleconference or Videoconference)

In the event that an IRB meeting cannot be convened in person or where some members cannot be present for a scheduled meeting, the meeting may be held or some members may attend via teleconference, videoconference or similar means. Remote attendees have access to all of the application materials via eResearch in advance of and throughout the meeting. The meeting Chair is responsible for ensuring that remote members have the opportunity to have equal and active participation in the meeting. Minutes for such meetings must document that these two conditions are met.

v. Conflicts of Interest

Prior to each convened IRB-HSBS meeting, the full board administrator will determine if any members have conflicts of interest with any of the applications that are to be reviewed and will note the conflict on the agenda. No IRB member, including the Chair(s), is permitted to be present for, nor participate in, the deliberations or vote on the disposition of an application in which the member has a conflict. 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, at each meeting the IRB Chair asks whether any member has a conflict of interest for which they should be excused from discussion and vote.

See SOP Part 9 for more on conflicts of interest.

vi. Presentation of Reviews

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

Primary reviewers are responsible for conducting an in-depth review of the protocol, provide a summary overview of the project and discuss specific concerns related to the conduct of the study or the human participants involved.

Secondary reviewers may review other elements of the application not discussed in the primary reviewers presentation or offer other concerns about an application.

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.

vii. Board Action

The convened IRB-HSBS may vote to take any of the actions described in IRB Determinations (SOP Part 3.V.1.2.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.

viii. Notification of Decisions

Following a convened IRB-HSBS meeting, the staff prepares a written notification transmitted via the eResearch system to inform the PI of the outcome of IRB review. The notification includes at least the following information:

- The IRB-HSBS's decision and the date it was reached
- For an approved project, the approval date, the expiration date, if applicable, and notification of any interim reporting requirements
- For a project approved with contingencies, 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, the IO, and other authorized persons. For projects that receive an IRB suspension or termination, a written notice is provided to the HRPP Director who transmits the information to UMOR for additional disposition and notification, as necessary, to other interested parties, such as government authorities with jurisdiction (e.g., OHRP) and, in the case of a sponsored project, the Office of Research and Sponsored Projects (ORSP).

ix. 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
- Confirmation of any waivers of informed consent or documentation of consent ([45 CFR 46.116\(c\), \(d\)](#)) as described for the specific protocol in the eResearch application or for the inclusion of vulnerable participants 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 prepares minutes including this information. The minutes are distributed for review by IRB members, who 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.

L. 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
- Resumes of all members
- Past IRB rosters
- Written SOPs
- Documentation for each research study is retained in the eResearch system, including study protocols, informed consent documents, recruitment materials, and data collection instruments, and correspondence with the study team. The eResearch study record also includes continuing reviews, amendments, adverse events and ORIOs, including unanticipated problems, and data and safety monitoring reports (if any) reported on each study.
- For studies approved via the expedited procedure, the eResearch record includes the applicable expedited criteria used to approve the submission. The record also includes, if applicable, the rationale for requiring continuing review (see SOP Part 3.V.C.3).
- For studies referred to the convened board that fall within the criteria for expedited review, the minutes will document the reason for the referral, including when a reviewer has determined that a procedure described in the expedited review categories poses more than minimal risk to participants.
- 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. 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, retained in the eResearch
- 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.

See OM Part 3.III.D.4. and Part 11.II.F 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 IRB-HSBS directors or Chairs, as necessary, assesses whether:

- The activity described in the application is research with human participants 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 participants research where U-M is engaged requires IRB oversight. See the OM Part 3.III.C.4.a for additional information and OM Part 4.I-IV.

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.” See [45 CFR 46.104](#). 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.

II. Determining Whether Research Involves Human Participants

The fact that an activity is research does not mean that it is "human subjects" research under the Common Rule.

The Common Rule defines a human subject as a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

See [45 CFR 46.102\(e\)](#) for the definitions of intervention, interaction, private information, identifiable private information and biospecimens.

Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information being collected) in order for obtaining or using the information to constitute research involving human subjects.

Research using specimens derived from living individuals may be considered human subjects research under the Common Rule. Guidance on whether or not a project involving human specimens may be considered regulated research is available on the following federal websites:

- Office for Human Research Protections Decision Charts
- NIH Office for Extramural Research Human Subjects Research Homepage

The National Institutes of Health (NIH) has developed additional guidance in its grant application instructions to help determine when research involves human participants.

The IRB-HSBS staff reviews all submitted eResearch applications that meet the regulatory definition of research to assess whether the proposed study involves human participants using [OHRP Decision Charts](#), guidance found in the OM Part 4, Table 6 as well as the eResearch application.

eResearch applications describing projects that meet the definition of research with human participants continue through IRB process. An eResearch "Not Regulated" determination is issued for projects that do not meet the definition of research with human participants

III. Determining Whether the University is Responsible for the IRB Oversight of Human Subjects Research

For each application, the IRB-HSBS staff in consultation with the IRB directors, Chair or the HRPP director, if necessary, will determine whether University of Michigan engaged in the conduct of human participants research. The University is responsible for IRB oversight of human participants research when its *employees or agents* are engaged in the conduct of human participants research. [An] institution is considered to be *engaged* in a particular non-exempt human participants research project when its employees or agents for the purposes of the research project obtain:

- Data about the participants of the research, including identifiable biospecimens, through intervention or interaction with them;
- Identifiable private information about the participants of the research; or
- The informed consent of the human participants for the research.

An institution's employees or agents are individuals who:

- Act on behalf of the institution;
- Exercise institutional authority or responsibility; or
- Perform institutionally designed activities.

Employees and agents can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

The activities and obligations of U-M employees, students, and agents are considered to be “University responsibilities.” For example, a faculty member who provides professional services at an outside institution under a contract between the University and the outside institution, and who is paid for his/her work by the University, is performing “University responsibilities.” Conversely, a faculty member who performs outside activities for unrelated institutions and not as part of his/her U-M appointment is not involved in “University responsibilities” in that context.

If the institution is the direct recipient of an HHS grant for non-exempt human subjects research, it is also considered to be engaged even where all of the human subjects research activities are carried out by another institution. See [OHRP Guidance on “Engagement of Institutions in Research”](#) and the OM Part 4.

IRB-HSBS oversight is limited to research in which U-M is engaged. When the University collaborates on a research project involving another institution or an outside individual, the IRB-HSBS accept oversight for the project and serve as the IRB-of-Record. In addition, U-M may decide to cede oversight to a commercial IRB or another institution's IRB. See OM Part 5.III and IV.

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. Screening activities and pilot testing are part of the research process and must be reviewed and approved (or an exemption issued) before those activities can begin.

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. See OM Part 4.IV.

For projects requiring continuing review, if IRB approval lapses (i.e. expires), no interventions or interactions may occur and no identifiable data may be collected or analyzed, until the project is re-approved by the IRB. See SOP Part 3.III.V.G and OM .III.C.4.f of this regarding lapse in IRB approval. If the IRB application is terminated, no interaction or intervention with participants or work with their identified data can be conducted.

Once all personal identifiers and links to identifiers are destroyed, the research is no longer regulated under federal regulations or the University’s HRPP.

Secondary analysis of data collected as part of a previous study that retains identifiers must be submitted to the IRB for approval or exemption. The language of the original consent is a factor in the IRB’s determination of whether secondary data analysis may be conducted.

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. 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 "Not Regulated" determination from IRB-HSBS when the activity falls outside Common Rule definition of human subjects research (see OM Part 4 Table 6 or where U-M is not engaged in the research. Some types of projects that are not regulated under the Common Rule may require review only for the purpose of assessing compliance with HIPAA or other regulations or institutional policies. Investigators may consult informally with IRB staff or members, however to obtain formal documentation of a "Not Regulated" determination, an "Activities not regulated as human subjects research" IRB application must be submitted in eResearch. This application type allows the PI to generate a "Not Regulated" determination letter for some research activities or to request an IRB review to confirm the status of the project that may then be used for funding or publication purposes. The U-M Office of Sponsored Programs may require investigators to submit an application to obtain a formal "Not Regulated" determination in order for funding to be released.

Once a "Not Regulated" determination has been issued, the IRB is no longer involved in the oversight or monitoring of the project.

See OM Part 4.V for additional information, including examples of research that does not require IRB oversight.

VI. Policy on Exempt Research

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 or more exemption categories identified in [45 CFR 46.104](#) (listed below) or exemption categories defined by U-M policy (see [HRPP Innovation and Demonstration Initiative](#)). By institutional policy, only research that poses no more than minimal risk to participants is qualified for exemption.

A. Federal Exemption Categories

Federal exemption categories identified in [45 CFR 46.104](#):

1. *Research, conducted in established or commonly accepted educational settings* that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
 - (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB

Application of this exemption category to research with children is limited to the use of educational tests or to observation of public behavior where the investigator does not participate in the activities being observed. It cannot be applied to projects involving surveys or interviews with children.

3. 3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
 - (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
- (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant

adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

NOTE: This category may not be applied to research with children.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
 - (i) The identifiable private information or identifiable biospecimens are publicly available;
 - (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
 - (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

See U-M Exemption 5 below for non-federally supported research and demonstration projects conducted by or subject to the approval of state department or agency heads, and that otherwise meet the above requirements.

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.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8). (Not implemented by U-M).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
 - (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
 - (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
 - (iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results. (Not implemented by U-M)

B. Applicability of Subparts B, C and D to Exempt Research

Each of the federal exemption categories may be applied to research subject to 45 CFR 46, Subpart B (*Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research*) if the conditions of the exemption are met. [45 CFR 46.104\(b\)\(1\)](#)

Exempt status is not granted for research subject to [45 CFR 46, Subpart C](#) (*Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects*), except where the research is intended for a broader participant population and only incidentally involves prisoners. ([45 CFR 46.104\(b\)\(2\)](#))

Exemptions 1, 4, 5, 6, 7, and 8 may be applied to research subject to [45 CFR 46, Subpart D](#) (*Additional Protections for Children Involved in Research*). [45 CFR 46.104\(b\)\(3\)](#) indicates special limitations in the application of exempt status to research with children for exemption 2(i) and 2(ii). Exemptions 2(iii) and 3 cannot be applied to research with children. Those exemption categories with limitations for research involving children are also noted below.

Note: U-M has not implemented Broad Consent and therefore exemption categories 7 and 8 are not applicable to U-M research.

C. U-M Exemption Categories

The following exemption is defined by U-M policy (see [HRPP Flexibility Initiatives](#)):

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

The following are U-M legacy exemption categories that were retired as of June 11, 2018.

- U-M Exemption 2a: *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 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. Research that is federally funded, FDA-regulated or was issued a Certificate of Confidentiality is not eligible for this category.
- 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. Research that is federally funded, FDA-regulated or was issued a Certificate of Confidentiality is not eligible for this category.

D. Authority to Grant Exemptions

Under U-M policy OM Part 4.VI.C, the authority to grant exemptions is delegated to the IRB by the IO. Investigators must submit an application for exemption via the eResearch application for all projects. Exempt determinations may not be made by investigators without an eResearch application because of their inherent conflict of interest with their own research. The IRB-HSBS staff, members and directors have the authority to grant exempt determinations, with exception of federal Exemption 5 and U-M Exemption 5a which must be issued by the HRPP director.

Exemption determinations for projects that qualify for exemption with limited IRB review ([45 CFR 46.104\(2\)\(iii\) and \(3\)\(i\)\(C\)](#)) must be reviewed by an expediting reviewer to confirm that the study has adequate plans for the protection of subject privacy and confidentiality of data ([45 CFR 46.111\(7\)](#)). The expediting reviewer will issue the exemption determination.

In addition, investigators are permitted to generate an exemption determination letter for some projects qualifying for exemption categories 1, 2, and 3, based upon their responses to key qualifying questions in the eResearch system, subject to the following limitations:

- Does not involve data subject to HIPAA or FERPA
- Does not include studies requiring "limited IRB review" (Exemptions 2 and 3)
- Cannot involve undisclosed deception or concealment (Exemption 3)
- Student investigators must include a faculty advisor as a member of the study team
- No financial conflicts of interest are disclosed by study team members

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- Key study team members have completed PEERRS human subjects training

System-generated exemption determinations are subject to audit by the IRB to validate the outcome. If determination errors are identified, the IRB requires amendments to correct those errors.

1. Exempt Reviewers

Most exempt reviews are conducted by experienced IRB staff members. Expediting reviewers and qualified members of the IRB-HSBS staff may conduct exempt reviews and issue determinations. See OM Part 4.VI.C.

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 participants 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.

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

2. Review of Applications for Exemption

The eResearch application provides an exempt application pathway from the Interaction/Intervention or Secondary Use application types 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 in most cases 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. A sample of consent document 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.

System-generated exemption determinations are audited the by the IRB to validate the outcome. If determination errors are identified, the IRB requires and reviews amendments to correct those errors.

For projects that qualify for exemption 2 or 3 with limited IRB review, investigators must submit additional details in the eResearch application regarding the protection of sensitive, identifiable information collected as part of the research, including procedures for protecting participant privacy and data security and management procedure implemented to protect the confidentiality of data, and informed consent and recruitment materials. An IRB expedited reviewer, via the limited IRB review process, must determine that there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data as required by [45 CFR 46.111 \(a\)\(7\)](#) before issuing the exemption determination. Continuing review is not required for projects that are determined to be exempt with limited IRB review.

3. Exemption Determinations

The exempt determination notification letter is issued to the investigator via eResearch, generated either by the IRB staff member or by the investigator if this option is made available based upon responses to qualifying questions. The notification letter includes the exemption category assigned to the study as well as instructions regarding when the submission of an amendment is necessary. 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.

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

PART 5 – IRB JURISDICTION, COOPERATIVE RESEARCH, AND RELIANCE AGREEMENTS

I. Introduction

The U-M has registered nine IRBs under its Federalwide Assurance with the U.S. Department of HHS. The IRB-Health Sciences and Behavioral Sciences is made up of two IRBs operated by UMOR. IRB-HSBS reviews health, behavioral, educational, and social science research outside of Michigan Medicine (formerly known as the University of Michigan Health System, or UMHS), including research from the U-M Dearborn and Flint campuses. IRBMED consists of 6 IRBs that review research proposed by Michigan Medicine

II. University of Michigan IRB Jurisdiction

OM Part 5.II outlines the default jurisdiction of IRBMED and IRB-HSBS, exceptions, and procedures for transferring jurisdiction from one IRB to the other.

A. IRBMED

1. Primary Jurisdiction

- All research proposed by faculty, staff, students or trainees affiliated with Michigan Medicine, including the Medical School
- All research using the patients, medical records, or facilities of the University of Michigan Health System
- All FDA regulated research
- All clinical investigations conducted by School of Dentistry
- Research using the Functional MRI (fMRI) Laboratory, except for researchers under IRB-HSBS jurisdiction that conduct social/behavioral projects using the IRBMED-approved fMRI Master Protocol

2. Exceptions

By agreement of the IRBs, IRB-HSBS may review some categories of exempt research submitted by Medical School researchers, and recruitment activities involving Michigan Medicine patients but do not involve the conduct of the research within a Michigan Health System facility or access to medical records.

B. IRB-HSBS

1. Primary Jurisdiction

All research conducted by the faculty, staff, students or other trainees with a primary appointment in U-M Ann Arbor schools, colleges, units or programs, or with U-M Dearborn or Flint and not subject to IRBMED jurisdiction. These include but are not limited to:

- U-M Institutional Research
- U-M Ann Arbor campus units:
 - College of Architecture and Urban Planning
 - College of Engineering
 - College of Literature, Science, and the Arts
 - College of Pharmacy
 - Institute for Social Research (ISR)
 - Ford School of Public Policy
 - Law School
 - Mary A. Rackham Institute
 - Rackham Graduate School
 - Ross School of Business
 - School of Dentistry
 - School of Education
 - School of Environment and Sustainability
 - School of Information
 - School of Music, Theatre, and Dance
 - School of Kinesiology
 - School of Nursing
 - School of Public Health
 - School of Social Work
 - Stamps School of Art and Design
 - University Health Services
- U-M Dearborn campus units:
 - College of Arts, Sciences, & Letters
 - College of Business
 - College of Education, Health, & Human Services
 - College of Engineering & Computer Science
- U-M Flint campus units:
 - College of Arts and Sciences
 - College of Health Sciences
 - School of Education and Human Services
 - School of Management
 - School of Nursing

C. General Exceptions

1. In any case where the IRB with primary jurisdiction determines that it does not have the appropriate expertise or is not appropriately constituted to review a research proposal, the project may be transferred to the IRB with appropriate expertise for review and approval.
2. In those instances, in which COIs preclude a quorum for review, the project may be transferred to an alternate IRB with appropriate expertise for review and approval.

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The selection of an alternative IRB will be made by the chair of the referring IRB in consultation with the receiving IRB, if the chair does not have a disqualifying conflict. If the chair has a disqualifying conflict of interest, the IO or designee will make the selection.

3. In those instances, in which another IRB or a faculty member, staff member, student, or other trainee requests review by an alternate U-M IRB, the IRB Directors or Assistant Directors will review the reasons for such a request; and decide which IRB shall conduct the review. The IO may overrule a Director's refusal to refer an application to another U-M IRB.
4. In rare instances, in which the rules outlined in this section do not clearly define which IRB to use and the IRB Directors cannot agree on jurisdiction, the matter may be referred to the IO for a recommendation.

The IRB is also authorized, at its discretion, to invite individuals with special expertise to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals will disclose any conflicts of interest to the IRB and they may not vote with the IRB.

III. 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 (see OM Part 4.III and [OHRP Guidance on Engagement of Institutions](#)).

The OM Part 5.III describes the overall roles and responsibilities of the institution, the IRBs, and PIs when interacting with outside collaborators or performance sites determined to be engaged or not engaged in the conduct of the 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-HSBS Single IRB Coordinator or IRB Director to determine the appropriate oversight mechanism such as IRB approval from the collaborator's IRB, an IRB Authorization Agreement (IAA), an Individual Investigator Agreement (IIA), or Collaborating Institution Agreement (CIA) for the outside entities.

IV. Reliance Agreements

See OM Part 5.IV

See IRB-HSBS [Research with Collaborators](#) webpage.

NIH policy, the Common Rule, and certain sponsors require that multi-site and collaborative research use a sIRB model. When one IRB acts as the reviewing IRB (IRB-of-Record) for other institutions, referred to as Relying IRBs, a written reliance agreement (also called an IRB Authorization Agreement) between the involved institutions is required. The IRB-HSBS must approve the arrangement either for individual studies or for a category of projects. The University does not enter into Reliance Agreements with external entities for projects that have been determined to be exempt.

U-M is a signatory to the SMART IRB agreement as well as Master Agreements with several commercial (independent) IRBs.

IRB-HSBS staff meets weekly with representatives from the HRPP, including the HRPP Director, and from IRBMED to review requests to cede or accept IRB oversight to facilitate discussion and ensure consistent decision-making across the institution. The HRPP Director has the authority to determine whether the institution is willing to accept or to cede IRB oversight for a particular study.

eResearch includes application types to manage ceding IRB oversight to another institution or providing oversight to external organizations via the Multi Site application. The ceding application, "Review by a Non-UM IRB" application is used to collect information about the local conduct of the research, including registering U-M study team members and documenting required human subjects training, and routes the application to the UMOR Conflict of Interest Committee for individuals who may have a COI disclosure. The Multi-Site Coordinating Center application includes a 'participating site' module to collect information from and route information to sites that will rely on IRB-HSBS as the IRB-of-Record. Where IRB-HSBS serves as the IRB-of-Record for external collaborators who are engaged in research but not involved in the interaction or intervention with human participants at their site, the standard Interaction/Intervention application may be used to manage these relationships.

V. IRB-HSBS Resources

The IRB-HSBS has a dedicated Single IRB Coordinator who is responsible for managing the reliance agreement process for IRB-HSBS. IRB-HSBS has developed guidance materials that describes the process for accepting or ceding IRB oversight for research projects and that outlines the roles and responsibilities of the each parties to a reliance agreements found on the IRB-HSBS [Collaborative Research](#) website.

VI. Reviewing IRB Responsibilities

See the IRB-HSBS [Collaborative Research](#) webpage and OM Part 5.IV.

IRB-HSBS may elect to serve as IRB-of- Record for one or more collaborating (relying) institutions. The SMART or other Reliance Agreement documents the relationships and reporting obligations between the parties.

IRB-HSBS collects and tracks information from/about individual relying sites including, but not limited to FWA and AAHRPP status, study team members and qualifications, study team training, conflict of interest management plans, relevant state laws or institutional procedures, and any required language required in the informed consent document (if appropriate to the rely site's role in the research.) The information is used to determine whether to extend IRB-HSBS oversight to the relying site.

As part of the expedited or full committee review of a study, the IRB-HSBS agrees to serve as the IRB-of-Record for a relying site. Additional relying sites may be reviewed and approved via amendment using the expedited review process.

Where informed consent will be obtained from participants at the relying site, IRB-HSBS provides templates for the creating of site-specific informed consent documents.

For projects using the Multi-Site application, IRB-HSBS transmits approved materials and regulatory determinations to the relying sites via the Participating Sites function in the eResearch application. This function is also used by relying sites to report required information (e.g., reportable events including UaPs, protocol deviations, and potential noncompliance as well as site-specific requests for amendments) directly to IRB-HSBS. For projects involving only one or two relying sites and not using the Multi-site application, relying sites will communicate directly with sIRB coordinator.

Any relying site may communicate directly with the IRB-HSBS to discuss questions, concerns, or obtain interpretation of determinations by contacting the IRB-HSBS Director, Chair or Single IRB Coordinator.

VII. Relying IRB Responsibilities

See the IRB-HSBS [Collaborative Research](#) webpage and OM Part 5.IV.

IRB-HSBS may be required to rely upon (cede) external IRBs as required by regulation, grant or contract issued by a funding source, or other non-financial study sponsor, as a condition of participating in the research (e.g., a commercial (independent) IRB as delineated by a sponsor or federally sponsored research in compliance with the Common Rule). IRB-HSBS may also voluntarily choose to cede IRB oversight at the request of the institution, sponsor, PI, or other external party associated with the research. As described earlier, Reliance Agreements will govern the relationships and reporting obligations between the parties.

IRB-HSBS the eResearch "Review by Non-UM IRB" application to collect and maintain U-M required information for the compliant local conduct of the research by U-M throughout the lifespan of the study.

VIII. Unaffiliated Investigators

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See HRPP OM Part 5.

See [Collaborative Research](#) webpage and OM Part 5.V.

IX. Community Based-Participatory Research (CBPR)

See OM Part 5.VI.

PART 6 – ROLES AND RESPONSIBILITIES OF INVESTIGATORS AND RESEARCH STAFF

I. Eligibility to Perform Research at the University of Michigan

Eligibility requirements for conducting research involving human participants vary depending on the role of the researcher. Engaged study team members must be appropriately qualified by training and/or experience to perform their research responsibilities, and must be listed on the IRB application. See OM Part 4 and [OHRP Guidance on Engagement in Human Subjects Research](#) for about “engagement” in research.

A. Principal Investigator

The Principal Investigator (PI) bears ultimate responsibility for all activities associated with the conduct of a research project, including compliance with federal, state and local laws, institutional policies, and ethical principles. The PI remains ultimately responsible even when some aspects of the research are delegated to other members of the study team.

Students/trainees (i.e., undergraduate students, graduate students, postdoctoral fellows, and other individuals in programs designed to provide non-independent research experiences) are permitted to serve in the role of PI, but must have a faculty advisor (FA) who shares in the student's/trainee's responsibility for the conduct of the research. Undergraduate students may be permitted to serve in the role of PI on minimal risk studies only.

See OM Part 6.I.A.

B. Co-Investigator

Co-Investigators (Co-Is) are a subset of the study team who have special responsibilities on research projects. Co-Is are obligated to ensure that the project is designed and conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of research involving human participants. A Co-I must be qualified by training and experience to conduct his or her responsibilities on the research project.

Each Co-I must explicitly acknowledge to the Institutional Review Board (IRB) their participation as a Co-Investigator on the study and will be asked to acknowledge their addition to any existing IRB-approved study. Co-Is will be notified of, but will not be required to acknowledge, submissions from the PI to the IRB, such as amendments, adverse event reports, scheduled continuation reviews, and terminations, and any related communications regarding such submissions.

See OM Part 6.I.B.

C. Faculty Advisor

All research conducted by students/trainees, including postdoctoral fellows, must include a Faculty Advisor (FA) as a member of the study team. In addition to the expectation that the FA provide active mentorship to the trainee during the conduct of the research, the FA

shares responsibility with the student/trainee researcher for the ethical and regulatory compliance conduct of the research and is institutionally accountable for the study.

See OM Part 6.I.D.

D. Other Study Team Members

Other study team members include individuals who contribute to the scientific development or execution of a study in a substantive, measurable way, and include:

- Study Coordinator: The Study Coordinator is a research professional that works under the direction of the PI to support, facilitate, and coordinate the daily study activities and plays a critical role in the conduct of the study.
- Research Staff: Individuals who are involved in the design, conduct, or reporting of research. These individuals must accept their role and answer conflict of interest questions prior to IRB submission of the application.
- Biostatistician: Statisticians are study staff that analyze data collected during the study.
- Consultant: A consultant is a specialist in a specific area of the study, usually from outside the normal study staff.
- Other: This category is used for study team members who do not fit into any of the defined roles. By practice, external study team members are labeled with this role
- Administrative Staff: Individuals who are not involved in the design, conduct, or reporting of research (e.g. unit administrators). These individuals are not required to accept their role or complete conflict of interest questions.

See OM Part 6.I.E.

E. Students/Trainees

U-M students/trainees serve as PIs, however supervision by faculty members is required for any research performed by students/trainees in any role, to ensure the proper conduct of research and protection of participant rights and welfare.

OM Table 8 provides information about permissible roles for U-M faculty, students/trainees, and staff on IRB applications. Exceptions to these requirements are at the discretion of the Institutional Official (IO) or designee.

See OM Part 6.I.F.

II. Key Responsibilities of Investigators and Research Staff for the Protection of Human Participants

See OM Part 6.II.

PART 7 – PARTICIPANT PROTECTION

I. HRPP Protection Extends to All Participants

The HRPP protects the rights and welfare of all individuals who participate in University research as human participants, regardless of whether they are intended “primary” participants of the research or their participation is ancillary to the main study intervention. For example, a survey might ask primary participants for private information about their friends or family members. If that information is identifiable those friends and family members are considered human participants in addition to the primary participant. See OM Part 4.II and SOP Part 4.II for a definition of human participants.

The classification of certain individuals or groups of individuals as human participants or not human participants is important because it triggers a number of requirements under federal regulations and the HRPP.

See OM Part 7.1 for additional information.

II. Vulnerable Participants

Additional protections are required when participants may be vulnerable to coercion or undue influence. Federal regulations identify special protections for children, and prisoners as vulnerable participants ([45 CFR 46 Subparts C and D](#)). IRBs and researchers must consider if some or all participants in a protocol are likely to be vulnerable beyond regulatory definitions, and ensure that additional safeguards are in place to protect the rights and welfare of these participants. Vulnerable populations include, but are not limited to:

- Children (individuals who have not attained the legal age to consent for procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted);
- Prisoners (individuals involuntarily confined or detained in a penal institution, including individuals 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);
- Individuals who are cognitively impaired or lack decision-making capacity; and
- Individuals who otherwise may be subject to coercion or undue influence (e.g., economically or educationally disadvantaged persons; employees or students of investigators conducting the study; patients of physician-investigators).

When members of any of these groups participate in research, the IRB-HSBS requires investigators to specify what additional protections, if any, will be provided to these persons to protect their rights and welfare (e.g., minimize risks unique to these groups and the possibility of coercion or undue influence). In reviewing these research projects, the IRBs ascertain that inclusion of a vulnerable population is adequately justified and that safeguards are implemented to minimize risks unique to that population.

The federal regulations also include special requirements for research involving pregnant women, fetuses and neonates under Subpart B.

Laws governing research involving vulnerable populations, including laws on who may consent on behalf of children or cognitively impaired or incapacitated adults, vary from state to state. Guidance on Michigan law, additional requirements of federal funding agencies, and international research is described in OM Part 11.

The IRB-HSBS applies the following standards when reviewing research involving vulnerable populations:

- For federally supported research, the IRBs comply with all of the requirements of [45 CFR 46](#), to the extent the sponsoring agency has adopted the standards reflected in Subparts B-D.
- For research not subject to the above regulations, U-M has developed standards that are intended to provide protections equivalent to those described in federal regulations. In some cases, the Institutional Official (IO) substitutes to provide judgment normally assigned to the U.S. Department of Health and Human Services (HHS) Secretary in certain situations described below.

See SOPs Part 3.V.J.11 and OM Part 7.II for additional information.

III. Data and Safety Monitoring Plans and Boards (DSMPs)

Data and safety monitoring is a process designed to protect the safety of individual participants in research studies and to ensure the validity of research results and scientific integrity of a study. The portions of a protocol that describe the steps the research team will take to identify, address and report any physical, social, or psychological events that may result from participation in a study constitute a data and safety monitoring plan (DSMP).

Formal DSMPs are required for NIH-funded clinical trials and research that poses more than minimal risk to participants. They are generally not required for minimal risk research, but may be required by the IRB-HSBS depending upon the complexity and size of the study design.

See SOPs Part 3.V.J.7 and OM Part 7.III for additional information.

IV. Advertising and Recruitment Materials

The IRB-HSBS reviews all advertising materials intended to recruit prospective participants for IRB-regulated research. Recruitment materials are submitted as part of the eResearch application and are reviewed as part of the initial review or submitted as part of an amendment and must be approved prior to use.

Refer SOP Part 3.V.J.5 and OM Part 7.IV for additional information.

V. Payments to Research Participants

The University recognizes the importance of encouraging individuals to participate in research as human participants and the value of the time, effort, and risk participants contribute to University research efforts. The University permits payments or other consideration to compensate participants for these contributions, as long as the following criteria are met:

- Payment arrangements are specifically approved in advance by the relevant IRB;
- Payments or other consideration provided to participants in return for their participation are not so significant as to be coercive or unduly influential (e.g., inducing participants to accept unreasonable risks);
- Payments are prorated when appropriate, and should not be contingent upon the participant completing the study, to avoid inducing participants to continue in a study when they otherwise would withdraw;
- Arrangements are made by the PI to assure proper accounting of payments made to participants, and required reporting to tax authorities, as required by University policy, with due consideration of privacy concerns.

Note: See [U-M Standard Practice Guide 501.07](#), Research Subjects Incentives, and SOP Part 3.V.J.5.

VI. Compensation for Injuries

University policy and IRB procedures, as directed under, [45 CFR 46.116\(b\)\(6\)](#) require that for research involving more than minimal risk, the informed consent process provide an explanation as to whether any compensation or treatment will be provided to an injured participant (injury in this context refers both to physical injuries and to less tangible injuries, such as injury to reputation or legal rights). If so, the compensation and treatment is described, or the participant is told where to find additional information. Exculpatory language (e.g., language that provides that a participant "assumes the risk" for participation in a study) is prohibited in informed consent documents as described in [OHRP Guidance on Exculpatory Guidance in Informed Consent Documents'](#)

See OM Part 7.VI and OM Part 10 for additional information.

PART 8 – USE OF TEST ARTICLES

IRB-HSBS defers the oversight of any FDA-regulated clinical investigations including those involving investigational new drugs (INDs) or investigational device exemptions (IDEs) to IRBMED.

See OM Part 5.II and Part 8.

PART 9 - CONFLICTS OF INTEREST

I. Applicable Conflicts of Interest Policies

See OM Part 9.1 for detailed information regarding the institutional, state, and federal bylaws, policies, procedures, and practices concerning employees' outstanding financial or management interests that could form the basis of a conflict.

II. Conflicts of Interest of Investigators and Research Staff

See OM Part 9.II for detailed information on identification disclosure and review of outside interests related to human subjects research.

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

Real or perceived conflicts of interest on the part of any individual conducting research with human participants or responsible for the protection of human participants 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.

An IRB Member, Consultant or IRB staff member will not be assigned the review if he/she (and/or their spouse, domestic partner, or dependents):

- Is the principal investigator or other member of the study team
- Has a significant financial interest in the research, as described in OM Part 9.II
- Has other conflicts that the member/consultant, IRB, the COI Committee or UMOR believes might hamper that individual's ability to perform an impartial review.

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 and also discussed in SOP Part 3.V.B, Part 3.V.G.1.b, and Part 3.V.K.1.

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), are 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.

See also SOP Part 3.V.K.1.

2. Expedited 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.

See also SOP Part 3.V.G.1.b.

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 (See 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.

See also SOP Part 3.V.B.

IV. Institutional Conflicts of Interest

In support of the public interest, the University, acting as an organization, may form relationships with, enter into affiliations or agreements with, or invest in outside companies or organizations for mutual benefit. These relationships may place the University in situations of Institutional Conflict of Interest (ICOI). See OM Part 9.IV for more information.

PART 10 – SPONSORED RESEARCH

See OM Part 10 for additional information.

PART 11 – Laws, Regulations, and Standards

See OM Part 11

PART 12 – QUALITY ASSURANCE AND RESEARCH COMPLIANCE

I. Quality Assessment, Improvement, and Assurance

In conjunction with UMOR, HRPP, and the Office of Research Compliance Review (ORCR), IRB-HSBS monitors the quality of the regulatory process and strives to improve its operations. For procedures related to the QA/QI process, see to OM Part 12.

II. Reportable Events: Adverse Events, Unanticipated Problems, Noncompliance, Suspensions, and Terminations of IRB Approval

A. Background

It is a condition of the U-M Federalwide Assurance of Protection for Human Subjects (FWA) that the institution have written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, head (or designee) of any federal department or agency conducting or supporting the research, and any applicable regulatory bodies including the U.S. Department of Health and Human Services OHRP:

- Unanticipated problems involving risks to subjects or others
- Serious and/or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB(s)
- Suspension or termination of IRB approval

B. Definitions

1. Adverse Events (AEs)

OHRP defines an AE as "any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participant's participation in research, whether or not considered related to the participant's participation in the research." Further, "adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research." (OHRP, *Unanticipated Problems Involving Risks & Adverse Events Guidance*, 2007)

In the context of multi-site studies, OHRP further defines internal and external AEs from the perspective of a particular engaged institution, where internal AEs are those AEs experienced by participants enrolled by the investigator(s) at that institution, and external AEs are those AEs experienced by participants enrolled by investigator(s) at other institutions engaged in the study.

2. Unanticipated Problems

In general, OHRP defines unanticipated problems as any incident, experience, or outcome that meets **all** of the following criteria:

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- It is “unexpected” in terms of its nature, severity, or frequency given 1) the research procedures described in the protocol-related documents such as IRB-approved research protocol and informed consent documentation, and 2) the characteristics of the participant population being studied;
- It is “related” or “possibly related” to the participation in the research, meaning there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and
- 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. (OHRP, *Unanticipated Problems Involving Risks & Adverse Events Guidance*, 2007)

Although all unanticipated problems are either AEs or ORIOs, not all AEs and ORIOs are unanticipated problems.

3. Suspension

Suspension of an IRB approved protocol is when an approved protocol is partially or completely stopped by the IRB pending future action by the IRB or other regulatory entity in order to protect research participants. If the IRB is undertaking further inquiry, a voluntary “hold” during this fact-finding period does not constitute a suspension of IRB approval for purposes of the HRPP reporting to external agencies or sponsors.

4. Termination

Termination of an IRB approval is defined as a permanent halt in IRB approval of all research related activities as a result of direct action by the IRB. A request from a principal investigator (PI) to terminate IRB-approval at the end of a study's defined approval period, or at any other earlier point during the approval period, does not constitute a termination of IRB approval for the purposes of the HRPP reporting to external agencies or sponsors.

5. Noncompliance

The failure of a person or organization to act in accordance with the requirements of a law, regulation, policy, or the requirements and/or determination of an IRB.

6. Serious Noncompliance

Noncompliance that materially increases risks or causes substantive harm to research participants or materially compromises the rights or welfare of participants, including consideration of the following:

- Harm to participants
- Exposure of participants to a significant risk of substantive harm
- Compromised privacy and confidentiality of participants
- Willful or knowing research misconduct on the part of the investigator

- A violation of ethical principles for human research
- Damage caused to the scientific integrity of the data collected

7. Continuing Noncompliance

Noncompliance that recurs after an investigator has been notified of a similar or related noncompliance concern pertaining to one or more protocols.

8. Allegation of Noncompliance

An unconfirmed report of noncompliance.

C. Roles and Responsibilities for Required Reporting of Reportable Event

This section outlines general roles and responsibilities related to reportable events. An additional description of reporting procedures related to noncompliance is included in section III of this part.

1. Researchers

The PI of any research project is responsible for tracking, documenting, and reporting adverse events (AEs) and other reportable information or occurrences (ORIOs), including self-identified noncompliance to the IRB overseeing that project, and must understand the nature and significance of unanticipated problems. PIs must follow IRB reporting guidelines. Information that must be reported to the IRB, along with the timelines for reporting, is posted on the [IRB-HSBS](#) website. All reportable information is submitted by researchers through the eResearch Regulatory Management (eRRM) system for review by the IRB, and must include a detailed description of the events, the investigators assessment, any actions taken, and supporting documents.

In addition, PIs must forward to the IRB any inspection, audit, or investigation reports issued by internal or external sponsors or oversight authorities as required by IRB policies or by a study-specific reporting plan approved by the IRB. Key responsibilities of researchers are described in more detail in OM Part 6.

2. The IRB-HSBS

IRB-HSBS staff members conduct the initial review of a report to ensure completeness and to make a preliminary assessment of whether the report meets the OHRP definition of an unanticipated problem (including those reports not characterized by the investigator or sponsor as an unanticipated problem) or a serious, unexpected, and related adverse event. Reports of concern are first discussed with the IRB directors and then forwarded to the IRB Chair or an IRB member with expertise for review, either of whom may act on behalf of the IRB.

The IRB Chair is authorized to take immediate action to protect the health and safety of research participants. Such action may take the form of (a) asking the investigator to voluntarily impose a hold on the recruitment and/or research intervention to facilitate

further inquiry by the IRB and/or institutional officials; (b) suspending recruitment or enrollment, (c) altering or suspending current interventions, or (d) terminating the IRB's approval of the project.

Any such action of the IRB Chair will be documented in the IRB research record immediately. If the IRB Chair imposes a partial or complete suspension, the IRB Chair will report the suspension to the HRPP Director within three business days. The IRB Chair, via the IRB Director, shall report any such action taken to the convened IRB at its next regularly scheduled meeting.

While the IRB is undertaking further inquiry, any voluntary "hold" during the fact-finding period does not constitute a suspension of IRB approval for purposes of the HRPP reporting to external agencies or sponsors.

The convened IRB will review reportable events occurring on studies under its direct oversight including potential UaPs (internal and external), serious adverse events, and serious and/or continuing noncompliance from studies that are otherwise reviewed via the expedited procedure. The IRB may endorse an interim action by the Chair, if any, or take a different action or additional actions. If immediate action is not required to protect the health and safety of research participants, any of the above actions must be approved in advance by a vote of the IRB.

3. Institution

If the IRB-HSBS determines that a submitted report is an unanticipated problem, the IRB will notify the HRPP Director within three business days. The HRPP Director will then report the unanticipated problem to appropriate federal agencies and sponsors within one month, absent special circumstances, such as the need for extensive data gathering or analysis.

If the IRB makes a determination of suspension or termination, it will inform the HRPP Director within three business days or less. The HRPP Director will notify federal agencies and sponsors (if required by regulations or agreements), as well as the Institutional Official (IO), IRB, Associate Vice President for Research, principal investigator (PI), and other institutional and external entities as needed, within one month (absent special circumstances such as the need for extensive data gathering or analysis). The following information will be included when making required reports to federal agencies:

- Title of the research project and/or grant proposal in which the problem occurred
- Name of the principal investigator (PI) on the protocol
- Number of the research project assigned by the IRB and the number of any applicable federal awards (e.g., grants, contracts, or cooperative agreements)
- A detailed description of the problem
- Actions the University is taking or plans to take to address the problem (e.g., revise the protocol, suspend participant enrollment, terminate the research, revise the

informed consent document, inform enrolled participants, increase monitoring of participants, etc.)

Reports are shared with other sites involved in research as appropriate.

See OM Part 12.II or additional information.

III. Compliance Oversight

A. Noncompliance Review Procedures

1. Process Summary

Generally, reports of potential noncompliance related to specific research projects are first reviewed by the IRB-HSBS. The IRB may take interim actions, such as those described in SOP Part 12.II.C2, to protect human participants while a concern is under review. Any suspension or termination of research is reported to the HRPP Director so that UMOR (UMOR) may make the required external reports. If, after initial review, the IRB-HSBS decides that the report may represent serious and/or continuing noncompliance, it reports the case to the HRPP Director. The HRPP Director may conduct additional fact-finding using the resources of the Office of Research Compliance Review (ORCR) and additional faculty input as needed. When the IRB makes a final determination of serious and/or continuing noncompliance, it reports the determination to the HRPP Director, so that the HRPP Director may make the required external reports.

The review procedures described in this section are followed for all complaints or allegations of noncompliance including reports of attempts to exercise undue influence over IRB staff or member or HRPP administrator, described in OM Part 1.V.

Complaints that are not related to a specific research project, may be directed to the IRB Chair, the HRPP Director, or the nearest organizational entity. All inquiries are taken seriously and are directed to the appropriate personnel, while following procedures to that promote a fair and objective outcome.

2. Policy against Retaliation for Reporting

Consistent with the requirements and spirit of the Michigan Whistleblowers Protection Act, a University employee may not be discharged, threatened, or otherwise discriminated against (with respect to compensation, terms, conditions, location, or privileges of employment) because the employee made a report (or is preparing to make a report) of a violation or suspected violation of applicable human research laws or regulations, University policy, or IRB requirements, unless the employee knew the report was false or materially misleading. Any violation of this policy must be reported to the University. The University's Compliance Hotline is option that permits confidentiality to be maintained.

B. How Compliance Concerns are Brought Forward

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

C. 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.III.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. The IRB Director determines whether the complaint or allegation of noncompliance is reportable immediately to the IRB Chair(s) for a determination of potential serious and/or continuing noncompliance. If the IRB Director concludes that the concern clearly is without merit or that the conduct in question (i) clearly does not constitute serious and/or continuing noncompliance; and/or (ii) can be addressed through minor corrective action agreed to by the principal investigator (PI) or other involved parties, the matter may be appropriately addressed and closed.

D. Chair and Board Considerations and Determinations

Potential noncompliance, particularly if the conduct in question might constitute serious and/or continuing noncompliance, is referred to the IRB Chair(s) for additional review. The IRB Chair(s) must perform or make arrangements for any additional fact finding necessary to make an initial determination. In reviewing the alleged noncompliance, the Chair(s) may request a meeting with the PI and others to discuss the allegations and provide an opportunity for the study team to answer any questions.

While the investigation is taking place, the Chair(s) may request ask an investigator to voluntarily "hold" new participant accrual or research-related interventions, unless doing so would place participants at risk of immediate harm. Such a voluntary hold does not constitute a suspension of IRB approval for purposes of the HRPP reporting to external agencies or sponsors. The Chair, IRB members, IRB staff members or consultants with an actual or apparent conflict of interest associated with the research, or the individuals who are the subject of the allegation must not be involved in the investigation of the allegation.

After reviewing relevant information gathered about the alleged noncompliance, the Chair(s) must make a preliminary assessment as to whether or not it has caused injury to a subject, represents an unanticipated problem involving risks to participants or others, or constitutes potentially serious and/or continuing noncompliance with IRB determinations, applicable regulations, or HRPP policies. If the Chair(s) determines that the conduct does not represent serious or continuing noncompliance, the Chair(s) may direct the relevant parties to develop an appropriate corrective action plan.

If the Chair(s) determines that the conduct represents potentially serious and/or continuing noncompliance, the matter (together with sufficient background to facilitate an informed discussion and decision) must be referred to the convened IRB for review and discussion of

the findings and recommendations for corrective actions (examples described below). The convened IRB may vote to approve the recommended actions or request additional information for consideration before proceeding to a vote. The results of the convened IRB meeting will be provided to UMOR within one month, absent extenuating circumstances.

See OM Part 12.III.E.

E. Actions of the HRPP Director as Delegated by the Institutional Official (IO)

See OM Part 12.III.F.

F. Response to Determinations of Noncompliance

The IRB-HSBS, as well as the IO and other institutional authorities, has the authority at any time to suspend or terminate approval of human research following appropriate review and deliberation for any of the follow reasons: that (a) is not being conducted in accordance with applicable laws and regulations, institutional policy, or IRB requirements, (b) has been associated with unexpected serious harm to participants or others, and/or (c) is believed to impose unreasonable risks to participants or others for any other reason.

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

Other sanctions may be imposed in response to findings of noncompliance depending on the severity and nature of the noncompliance. Examples include the following:

- Development and implementation of case-specific corrective action and mitigation plans
- Protocol modification or termination
- Modification of the continuing review schedule
- Monitoring of the consent process
- Notifications to or re-consenting of participants
- Recommended or mandatory education or mentoring requirements
- One-on-one mentoring
- Regular or remedial IRB courses
- Additional on-line training modules
- Additional professional certification
- Attendance at regional/national meetings/seminars
- Increased monitoring or oversight
- Random or targeted audits

The IO may institute any or all of the following additional sanctions:

- Embargo or destruction of research data
- Refunding improperly billed/incurred costs

- Notification to publishers with present or past submissions of circumstances of noncompliance and status of data
- Faculty or staff suspension from engagement in University research
- Other disciplinary sanctions up to and including dismissal (in consultation, where required by University policy, with other appropriate institutional authorities and subject to any additional University due process requirements)

See OM Part I2.II.G

G. Institutional Notification and Reporting Requirements

In the event the IRB-HSBS votes that the alleged noncompliance constitutes serious and/or continuing noncompliance, the IO must ensure the prompt reporting of this information to government authorities with jurisdiction, if applicable, and to sponsors to the extent required by any relevant regulations, grants, or contracts. In addition, reports are made to other entities including accrediting bodies as required. The HRPP Director will provide notification of external reporting to the IO, the IRB, the Associate Vice President for Research, the principal investigator (PI), and other institutional entities as indicated.

Where the IRB votes determines that the alleged noncompliance is not serious and/or not continuing, the IO may accept the IRB determination, reject the determination and report externally as required, or conduct an additional investigation of the allegation.

See OM Part 12.III.B.H

PART 13 – EDUCATION AND TRAINING

I. Education in General

The University of Michigan 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. (See OM Part 13).

A. Required Education

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. This courses are modeled on the Collaborative Institutional Training Initiative (CITI) human subjects protection modules and provide training required per university, state, and federal regulations. Certification in the PEERRS course is granted for three years from the last date the user passes a certification test. Completion of this course is a requirement for IRB approval and is monitored through the IRB application.

Good Clinical Practice (GCP) training is required for all researchers and research staff involved in the conduct, oversight, or management of NIH-funded clinical trials or specific studies conducted under GCP requirements. GCP training must be completed every three years or sooner if required for the conduct of a specific study.

More information about these programs can be found on the [HRPP](#) website

II. IRB Chairs, Members, and Staff Education

IRB Chairs, members, and staff are trained through a detailed orientation procedure to provide them with the knowledge and skills to effectively discharge their duties and uphold the federal and local laws, University policies, and ethical standards on research with human participants. Continuing education for IRB staff and members is also required and is provided in the form of workshops, presentations, webinars, printed and electronic resources that are shared on an on-going basis.

IRB-HSBS initial training and orientation and continuing education is described in SOP Part 3.IV.I. IRB members and staff also required complete the PEERRS human subjects training module and to renew this training every three years. The IRB office tracks the status of this

training and follows up with members to ensure completion. Staff training is considered as part of their annual review process.

III. Researchers and Research Staff Education

The IRB-HSBS offers a number of educational sessions on the Ann Arbor, Dearborn, and Flint campuses designed to improve the understanding of regulatory requirements, IRB application completion, and special topics related to research with human participants. These include the IRB-HSBS formal education series offered in the fall and winter terms and ad hoc presentations by the IRB-HSBS Educational Coordinator to classes and groups upon request. The IRB staff offers IRB-on-the-Road office hours in schools and colleges served by the IRB-HSBS to permit investigators to discuss their individual research questions. Members of the research community can also attend educational sessions offered by IRBMED and MICHHR and online resources offered by CITI. Information about IRB-HSBS educational opportunities is posted on the [IRB-HSBS](#) website.

The IRB-HSBS, IRBMED, and HRPP websites provide researchers with an extensive number of resources including guidance materials and access to resources from OHRP, NIH, DoD, and other regulatory agencies.

QUESTIONS / CONTACT INFORMATION

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734-936-0933
(fax) 734-936-1852

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

Office of Research Compliance Review (ORCR)

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Ann Arbor MI 48109-2800
734-647-0489
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<http://research-compliance.umich.edu/office-human-research-compliance-review-orcr>

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