Marquette University
Human Research Protections Program
Office of Research Compliance

Institutional Review Board (IRB) Standard Operating Procedures and Policies

Adopted by MU IRB Oct 2010, Revised January 2014
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1. **List of Acronyms used in this Document**

CFR – Code of Federal Regulation  
DHHS – Department of Health and Human Services  
FDA – Food and Drug Administration  
HRPP – Human Research Protection Program  
IO – Institutional Official  
IRB – Institutional Review Board  
MU – Marquette University  
OHRP – Office for Human Research Protections  
ORC – Office of Research Compliance  
PI – Principle Investigator  
RCO – Research Compliance Officer for Human Subjects

2. **The Role of the Institutional Review Board**

The role of the Marquette University (MU) Institutional Review Board (IRB) is to protect the rights and welfare of human subjects by reviewing each study involving research with human subjects according to the criteria found in the Common Rule (45 CFR 46) or FDA (21 CFR 50 and 21 CFR 56) regulations. MU has at least one local IRB designated in its Human Research Protection Program and under its Federalwide Assurance (FWA). Under this FWA, MU will comply with the Federal Policy for the Protection of Human Subjects, known as the Common Rule. All federally-supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All human subjects research conducted or supported by the Department of Health and Human Services (DHHS) will comply with all Subparts of DHHS regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46 and its Subparts A, B, C, and D). These protections ensure that human subjects participate in research only after providing legally effective, fully informed consent when consent is required by law for the ethical and legal conduct of the research. The IRB’s decisions when reviewing all studies, regardless of funding, are based on the ethical principles in the Belmont Report, the “Declaration of Helsinki,” Wisconsin state laws, and MU policies.

The Health Insurance Portability and Accountability Act (HIPAA) provides standards to protect the privacy of individually identifiable health information created or received in a health care setting. Marquette University is a "hybrid entity" with seven health care components. Each Health Care Provider Unit is responsible for compliance with the regulation and with maintaining appropriate records, including disclosures. In lieu of establishing a Privacy Board, Marquette University has empowered its IRB to grant approval or waiver of patient HIPAA authorization.

The IRB exercises autonomy in decision-making. The Office of Research Compliance (ORC) is the administrative home of the IRB and supports the IRB’s independence from external influences. The IRB Chair fosters an environment that encourages the free and full participation of all IRB members in its deliberations. As an integral component of the ORC, the IRB maintains an open line of communication with the Research Compliance Officer (RCO), IRB Manager and the ORC staff, who are the primary contact between the IRB and campus researchers, staff, and any others who require assistance or desire interaction with the IRB. The IRB also has a direct

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relationship with the Vice Provost for Research, who serves as the Institutional Official (IO). The IO is the University official who is ultimately accountable for the IRB and the ORC.

1.0 IRB Authority

The IRB has the following authority:

- to approve research, require modifications to research protocols in order to approve research, or disapprove research;
- to require progress reports or other information from investigators in order to effectively oversee the conduct of the research and the informed consent process; and
- to place restrictions on, suspend, or terminate the approval of research that is not being conducted in accordance with IRB requirements, involves unanticipated problems involving risks to subjects or others, or conducted without prior IRB review and approval.

The IRB is constituted by the IO and is registered with the Department of Health and Human Services, Office for Human Research Protections (OHRP) under MU’s Federal Wide Assurance (FWA #00005844).

2.0 IRB Functions

The IRB ensures the adequacy of human subject protections by taking the following actions:

(1) Conduct the initial and continuing review of research protocols;
(2) Report determinations and decisions, in writing, to investigators and the institution via the ORC Staff;
(3) Determine which research protocols require review more frequently than once per year;
(4) Determine which research protocols require verification from other sources, other than the investigator, that no material changes have occurred since the most recent IRB review and approval;
(5) Require that proposed changes in research are promptly reported;
(6) Require that changes in approved research are not initiated without prior IRB review and approval, except, when necessary to eliminate apparent immediate hazards to subjects;
(7) Require that any unanticipated problems involving risks to subjects or others be promptly reported to the IRB Chair by the ORC and, when appropriate, by the IO to pertinent federal agencies;
(8) Require that any deviation/noncompliance from any IRB approved protocol procedures, forms, and other attachments and/or any failure to follow any applicable human research protection regulations and policies
(including but not limited to HHS, FDA, Marquette IRB) be promptly reported to the ORC and IRB.

(9) Require that any serious or continuing noncompliance with MU Human Research Protection Policies and/or federal regulations, or the requirements or determinations of the IRB, be promptly reported to the IRB, the ORC, the IO, and, when appropriate, via the IO, or via the RCO on behalf of the IO, to pertinent appropriate federal agencies; and

(10) Require that any suspension or termination of IRB approval be promptly reported to the IO, the ORC, and, when appropriate, via the IO, or via the RCO on behalf of the IO, to pertinent appropriate federal agencies.

(11) The IRB provides annual reports to the Marquette University IO via the RCO. The IRB is supported by the ORC.

3.0 IRB Jurisdiction

The IRB has jurisdiction only over research that involves the use of human subjects, identifiable data, or tissues derived from human subjects:

(1) Research by MU faculty (any percent time appointment, including adjunct and emeritus), staff, administrators, or students, conducted under MU auspices.

(2) Research to satisfy a requirement imposed by MU for the award of a degree or the completion of a course of study, including requirements for a thesis or dissertation, or professional/capstone project.

4.0 IRB Membership

The IRB is composed mostly of members representing the University and includes members who are scientists, members who are non-scientists, and members who are not affiliated with MU. The IRB has a balance of men and women, drawn from a diverse cross-section of the Milwaukee community racial and ethnic groups. (45 C.F.R. § 46.107 and 45 C.F.R. § 46.304).

The members bring sufficient experience, expertise, diversity of membership, (including race, gender, and cultural backgrounds) and sensitivity to issues such as community attitudes, to promote respect for the IRB’s advice and counsel in safeguarding the rights and welfare of human subjects. The collective experience and the professional preparation of IRB members includes: expertise in a range of health and behavioral sciences; familiarity with relevant standards of professional conduct and practice; and knowledge of vulnerable or special populations, including children, prisoners, pregnant women, handicapped children, mentally disturbed persons and others (i.e., disabled persons). The members of the IRB possess the professional competence necessary to review the various kinds of human subject research that are conducted at MU. The IRB composition meets the requirements of the 45 C.F.R. 45.107.

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This diverse membership ensures that the IRB has the competence to judge the acceptability of the research in terms of institutional commitments and regulations, applicable laws, and standards of professional conduct and practice.

IRB involves *ad hoc* consultants as needed. The IRB has access to ORC staff for assistance in interpretation of federal regulations regarding human subjects research and to MU’s Office of General Counsel for interpretation of applicable federal, state, and local laws.

### 4.1 Membership Appointment

The IRB conducts its business with the participation of the following persons: Chair, Vice-Chair, IRB voting members, alternate IRB voting members, and occasionally non-voting *ad hoc* consultants. All IRB appointments are made as follows: Individuals volunteer to be considered for IRB appointment. The IO consults with the RCO regarding the candidates for IRB membership. The IO issues the appointment letter.

### 4.2 IRB Chair

The Chair of the IRB is a respected, active MU faculty or staff member who is concerned about human subjects protection and ethical issues, and is well informed about federal and state regulations relevant to human subject research. The Chair is knowledgeable about the application of ethical principles and regulatory requirements when reviewing human subjects research, and sets an example for IRB members. The Chair also leads the IRB meetings and facilitates communication between investigators and the ORC. As a representative of the institution and the IRB, the Chair exhibits high standards of moral integrity and ethical conduct.

The Chair meets on a weekly basis, or as needed, with ORC staff to review research actions that do not require review by the full board, including reviewing expedited continuing reviews and amendments. The Chair is available for consultation with ORC staff members as needed regarding any human subjects research concerns.

The Chair serves a term of three-years, but may serve two consecutive three-year terms. The IRB proposes a nominee for Chair to the IO. If acceptable, the IO issues the appointment letter. Acceptance of the IO’s Letter of Appointment carries with it the acknowledgement of the primacy of ensuring human subject protections.

Whenever the Chair is not available, the Vice-Chair assumes the responsibilities of the Chair during the period of absence or other unavailability.

The IO may remove an IRB Chair at any time.

### 4.3 IRB Vice-Chair

The IRB proposes a nominee for Vice-Chair to the IO. If acceptable, the IO issues the appointment letter for a three-year term. A Vice-Chair may serve two consecutive three-year terms at the discretion of the IO. Acceptance of the IO’s Letter of Appointment carries with it the acknowledgement of the primacy of ensuring human subject protections.

The position of Vice-Chair is a learning position with the intent of being Chair-in-Training. The potential candidate for this position should consider these responsibilities when accepting the
Vice-Chair position. As a representative of the institution, and the IRB, the Vice-Chair must exhibit high standards of moral integrity and ethical conduct.

The IO may remove an IRB Vice-Chair at any time.

4.4 Voting Members

As mandated by 45 C.F.R. 46.107, the IRB has more than five regular, voting members. The membership roster must include at least one IRB member who is a scientist, at least one member who is a non-scientist and at least one member who is not otherwise affiliated directly or through any immediate family members with MU.

Many IRB members are recruited from among both active and retired members of the faculty and academic staff of MU. Ideally, the scientist IRB members have experience in research involving human subjects.

The unaffiliated members may be scientists or non-scientists. They or their families do not have any affiliation with MU, and they are recruited from the community of Milwaukee and its vicinity. These persons are included in the IRB in order to provide a perspective on the research that is from outside of the university community (as required by law).

The ORC solicits member nominations through direct contact from interested individuals within and outside the University for affiliated and non-affiliated members. These nominations are solicited as needed and typically when board members resign, take a leave of absence, or their terms end. One or more qualified nominees are presented to the IO for approval. The appointment procedures are described above in the Membership section of this document. Acceptance of the IO’s Letter of Appointment carries with it the acknowledgement of the primacy of human subject protections. As a representative of the institution, and the IRB, each member must exhibit high standards of moral integrity and ethical conduct.

All IRB members (voting and non-voting) are instructed that activities related to research protocol review or other IRB-related activities performed during the time of an IRB member’s appointment will be conducted in strict confidence and not discussed outside of the context of these duties.

IRB members are requested to serve a minimum three-year term, which is renewable at the IO’s determination.

IRB members are expected to participate in an initial education program, conduct reviews of research protocols in a timely manner, attend and contribute to the IRB review and discussion of protocols during full board meetings, and attend any required continuing education for IRB members.

The IO may remove an IRB member at any time.

4.5 Alternate Voting Members

The IRB may recruit alternate members to substitute for any of the primary voting members of the IRB. Alternate members have voting rights, except that they may not vote at meetings attended by their respective primary members. Alternate members are included in determining or
establishing quorum at IRB meetings, when the respective primary members are absent. Alternate members are approved by the IO.

The procedures for appointment, the expectations for membership, and the procedure for removal of an alternate member are the same as that of a primary voting member. Alternate voting members are appointed to three-year, renewable terms.

4.6 Ad Hoc Consultant Reviewers

The IRB may invite scientists or non-scientists who have special expertise to assist the IRB in its review of research protocols. These ad hoc reviewers may be from within MU or outside the MU community. Ad hoc reviewers have access to all documents submitted to the IRB relevant to the specific research protocol under review, may participate in the IRB meeting during discussion, and make recommendations on the research protocol, but they may not vote with the IRB. Ad hoc reviewers may also be asked to provide written comments in addition to, or in place of, attending the IRB meeting. The ad hoc reviewer’s identity and any documents they create may be kept confidential at their request.

4.7 Member Liability Protection

Marquette University maintains an “Educational Organization Errors and Omissions Policy,” under which “Individual Insureds” include “members of an Institutional Review Board (as recognized by the U.S. Food and Drug Administration and U.S. Department of Health and Human Services.” The policy provides defense and indemnity with respect to claims for damages arising from a “Wrongful Act,” which is “any actual or alleged error, omission, act, misstatement, neglect or breach of duty in the discharge of duties” by an Individual Insured. This includes both affiliated and unaffiliated IRB members.

4.8 Resignation from the IRB

IRB members are expected to serve a minimum of three years on the IRB. Members who wish to resign from the IRB are requested to do so in writing to the RCO or IO. A member will be expected to attend all meetings and conduct all protocol reviews assigned up until the date their resignation takes effect.

4.9 IRB Member Education

IRB members participate in both initial and continuing education. These programs focus on the ethical principles and regulatory requirements underpinning human subject protections and how to apply those principles and requirements to the initial and continuing review of research protocols.

4.9.1 Initial Education Program

The initial education program consists of in-person training provided by the ORC and on-line training found at: http://phrp.nihtraining.com/users/login.php. All IRB Chairs and Vice-Chairs, members, and alternates must participate in the training (or its equivalent) before actively participating in the IRB. The initial education program includes information about the following areas:
(1) Ethical Principles and *The Belmont Report*
(2) Regulatory Requirements
(3) MU Federal Wide Assurance (FWA)
(4) MU Institutional Policies and Procedures
(5) IRB’s Role and Responsibilities
(6) Research Protocol Review Criteria and Review Process
(7) Informed Consent Process and Document
(8) Vulnerable Populations: Pregnant Women, Fetuses, Prisoners, Children and Others
(9) Investigator Responsibilities
(10) HIPAA Policies and Procedures

New primary voting IRB members are loaned a copy of Bankert and Amdur’s *Institutional Review Board Management and Function*, Second Edition. IRB members are expected to return their copies to the ORC upon resignation from the IRB.

### 4.9.2 Continuing Education Program

Continuing education programs may include scheduled short current topics (case studies and current events) and Just-in-Time (JIT) training that flows from issues raised in the course of the review of research protocols. IRB members are encouraged to attend local, regional, and national educational conferences as appropriate. Continuing education modules are included in the agenda for every convened meeting.

### 5.0 IRB Operations

The ORC supports the IRB by setting up the IRB meeting schedule, attending IRB meetings to provide assistance and record the IRB’s discussion and decisions, managing the IRB records for the institution, and communicating the IRB’s decisions, in writing, to investigators. The ORC staff are not voting members of the IRB. Additionally, the ORC triages exempt and expedited protocols, conducts pre-reviews, conducts consultations with researchers, presents training programs to students, staff, and faculty, drafts and reviews policies and procedures, and provides overall support to the IRB management and function.

### 5.1 Record Retention and Security

The PI and IRB are expected to maintain and retain the appropriate records for each research study, consistent with federal regulations and MU’s records retention policies.

#### 5.1.1 Principal Investigator Record Retention

Each PI must retain records of all correspondence relating to the use of human subjects in research as required by MU procedures and federal regulations. Copies of such items include, but are not limited to: the initial application, letters of approval (initial, continuing review, and amendments), and informed consent forms. Research study records including signed consent
forms and other data that must be stored in accordance with the approved protocol. All records of human subject research are subject to inspection by federal authorities and internal IRB audits.

The IRB (through the ORC) maintains records of all protocols and correspondence submitted to the IRB and minutes from all full board meetings. The IRB retains such records for a minimum of three years after the completion of the study. Relevant records will be accessible for inspection and copying by authorized representatives of OHRP, DHHS, FDA and Sponsors, at reasonable times and in a reasonable manner.

5.2 Meetings

IRB members convene regularly to fulfill their mandate to oversee research involving human subjects at MU. The IRB generally meets once per month, but may add additional meetings if the IRB determines they are necessary. Alternatively, a monthly meeting may be cancelled. The IRB meeting schedule is available on the ORC web site and is subject to change.

The IRB has an agenda for the meetings. The agenda includes all research protocols awaiting action by the IRB and informs the members about research that has been approved by experienced reviewers through exempt or expedited review procedures. A meeting packet is provided to IRB members approximately one week before the meeting to allow sufficient time to review the research protocols. The meeting packet contains a copy of the IRB agenda, each protocol up for review, with any supporting documents including research tools, informed consent documents, assent documents, and recruiting materials.

5.3 Quorum

A quorum is defined as greater than 50% of the voting membership including attendance of at least one non-scientist.

The approval of a research protocol requires the vote of a simple majority (greater than 50%) of the voting members present at the meeting.

Voting members may attend full board meetings of the IRB by teleconference or videoconference, if they have been provided a copy of all of the items for review in advance of the meeting, and the equipment permits meaningful participation in discussion and voting. There are no provisions for any other kind of proxy or written vote, since IRB members must be in attendance to vote. However, IRB members may submit written comments or questions in relation to the protocols or other issues under review, including in advance of a convened full-board review.

5.4 Conflict of Interest

IRB members must disclose any known potential conflicts of interest to the Chair at the start of the IRB meeting. IRB members may not participate in the voting on research protocols in which they may have conflicting interests. Whenever research in which a member of the IRB has an apparent conflict of interest is being reviewed, that member may be asked to recuse him or herself from the meeting (leave the room) for the duration of the discussion and review of that research protocol if the member’s presence could create a bias.
For more information about financial conflict of interest, visit OHRP’s guidance document, *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection*.

### 5.5 IRB Meeting Minutes

The ORC prepares minutes of each meeting of the IRB, documenting the Committee’s review of research protocols, policy discussions, and continuing education. The minutes are recorded in sufficient detail and include the following:

1. **IRB Member attendance and the presence of any invited investigators or guests.**
2. **IRB committee acknowledgement of administrative actions by the IRB Chair or designated representative taken for Expedited and Exempt protocols.**
3. **Summary of the discussion, in particular discussion of required modifications for each research protocol reviewed.**
4. **Decisions reached on each research protocol reviewed.**
5. **Votes on the decisions, including a tally of votes for, against, abstaining and total present for the vote. Recusal of members due to conflicting interests is also documented.**
6. **Reasons for requiring modifications to secure approval of a research protocol, for disapproving a research protocol, or suspending or terminating a research protocol.**
7. **If a waiver or alteration of informed consent or a waiver of documentation of informed consent is requested, the specific findings supporting the IRB’s determination.**
8. **The level of risk involved in the research as indicated by the level of review the research receives.**
9. **The review frequency for the next continuing review. If no shorter review frequency is noted, the protocol will undergo review annually.**

A copy of the minutes is provided to the IRB members for review in the meeting packet, to give members an opportunity to request clarifications or suggest changes to the minutes. Suggested modifications to the minutes are discussed at a full board meeting and agreed to by consensus.

The IRB may request the attendance of investigators at an IRB meeting so that IRB members may ask questions and clarify information. Researchers' team members may, and often do, also attend IRB meetings. For more on researcher attendance at IRB meetings, see *HRPPolicy 98.101 - Researcher Attendance at Convened IRB Meetings*. 

### 5.6 Communication of IRB Findings and Actions to the Investigator and the Institution

The ORC staff is charged with attending full board IRB meetings, and working with IRB members who conduct expedited reviews and reviews of claims of exemption in order to
facilitate the communication of the IRB’s findings and actions to the PI and the Institution. Communication of IRB requests for revisions and modifications are submitted to the PI by e-mail. Communication of IRB approval is done officially in writing. Customarily a copy of the correspondence is sent to the PI by e-mail, with a signed original sent via campus mail. For student PIs, the approval letter is sent to the PI’s advisor on campus. When projects are indicated as externally funded, the ORC will send an electronic copy of the approval letter to the Office of Research and Sponsored Programs (ORSP).

While the ORC will communicate with PIs as necessary, it is ultimately up to the PI to ensure that all requirements have been met in a timely fashion and that human subject research is only conducted after the MU IRB has reviewed and approved the protocol. Additionally, the PI is responsible for ensuring that the only human subject research conducted is that described in the approved Protocol Summary Form.

### 6.0 IRB Research Protocol Approval Criteria

Before approving a new research protocol involving human subjects, the IRB must determine whether all of the criteria from 45 C.F.R. § 46.111 (and 21 C.F.R. § 56.111 when appropriate) are satisfactorily met in the research proposal. PIs are responsible for ensuring that any other required reviews have been completed and must provide the IRB with documentation of the results of those reviews. PIs may not start their research (e.g., advertisement, recruitment, screening, etc.) until all the appropriate reviews have been completed and they have received written notification of IRB approval.

All human subjects researchers must complete education about human subject protections as a requirement of MU’s Federalwide Assurance for the Protections of Human Subjects filed with the Department of Health and Human Services (DHHS). The IRB training course "Protecting Human Research Participants," sponsored by the NIH Office of Extramural Research, is required for all human subjects investigators, regardless of whether a protocol is exempt, expedited, or full review. Approval of human subjects research protocols will not be granted until all Marquette human subjects researchers listed in that protocol complete NIH training, and certificates of completion have been filed with the Office of Research Compliance. This applies to new submittals at time of initial approval, and existing protocols at their continuing review, three-year review, or review of a modification. The IRB may accept equivalent training, including CITI training performed through another institution. The IRB does not require proof of training of non-Marquette research staff. The PI is responsible for ensuring that the non-Marquette personnel are trained appropriately.

The approval of research protocols may only be given when all of the following conditions exist (per 45 C.F.R. § 46.111):

1. Risks to subjects are minimized (a) by using procedures which are consistent with sound research design and do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to individual subjects, or from the importance of the knowledge that may reasonably be expected to result from the research.
(3) Selection of subjects is equitable (the risks and benefits from the research are evenly distributed).

(4) Appropriate, legally effective informed consent is sought from prospective subjects (or their legally authorized representative).

(5) Informed consent/assent will be appropriately documented as required by the IRB, unless IRB waives documentation requirement.

(6) When appropriate, the research protocol has adequate provisions for monitoring data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(8) When subjects are likely to be vulnerable to coercion or undue influence, such as pregnant women, fetuses, prisoner, children, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards are included.

Additional requirements that must be satisfied, not listed under 45 C.F.R. 46.111, include the following; HIPAA requirements, FERPA requirements, Marquette policy, Local and state law.

### 6.1 Informed Consent Process and Documentation

Respect for persons requires that potential subjects, to the degree that they are capable, be given the opportunity to choose what shall happen to them. The informed consent process is the primary mechanism by which respect for persons is ensured. The IRB reviews the informed consent documents that PIs will use to ensure that the Informed Consent Document shall include the following, per 45 C.F.R. 46.116:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

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An explanation of who to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject; and

A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

The MU consent template must be used, unless the IRB grants an exception.

The IRB has the authority to observe or have a third party observe the consent process and any other research procedures at any time.

6.2 Waiver to Obtain Informed Consent, Alterations of Informed Consent, Waiver of Documentation of Informed Consent

Under certain circumstances, the requirement to obtain or document informed consent from subjects may be waived by the IRB. Alternatively, the IRB may alter the requirement to obtain informed consent.

6.2.1 Waiver to Obtain Informed Consent and Alterations of Informed Consent

The IRB may waive or alter the requirement to obtain informed consent, if the IRB finds (and documents with specificity) that one of the two sets of criteria below (either all of part A or all of part B criteria) are met.

A1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

A2. The research could not practicably be carried out without the waiver or alteration. (45 C.F.R. § 46.116(c)).

or

B1. The research involves no more than minimal risk to the subjects;

B2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

B3. The research could not practicably be carried out without the waiver or alteration; and

B4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. (45 C.F.R. § 46.116(d)).

For a flowchart of the decision-making process, visit OHRP’s decision chart, http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c10.

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6.2.2 Waiver of Documentation of Informed Consent

An IRB may waive the requirement for the PI to obtain a signed consent form for some or all subjects, if one or more of the following conditions exist:

(1) The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. (45 C.F.R. § 46.117(c)(1)).

(2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. (45 C.F.R. § 46.117(c)(2)).

In cases in which the signed consent requirement is waived, the IRB may still require the PI to provide subjects with a written statement regarding the research. For more information, see Guidance Document Waiver of Documentation of Consent Guidance. For a flowchart of the decision-making process, visit OHRP’s decision chart, http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c11.

7.0 Recruitment and Other Study Related Materials

Printed materials developed for the sole purpose of recruiting human participants for research activities must be reviewed and approved by the IRB and must be stamped with the IRB approval date. Noncompliant materials may not be posted or otherwise disseminated.

Electronic versions of printed recruitment materials or advertisements developed for printing in newspapers or other periodicals must be submitted in hard copy format for review and approval by the IRB.

Copies of all approved and date stamped recruitment materials will be sent to the PI for his/her records. Alterations to the approved, stamped recruitment materials must be submitted to the IRB as a protocol amendment and be approved by the IRB before use.

8.0 Review Process for New Research Protocols

PIs who intend to conduct research involving human subjects are responsible for submitting a research protocol and any other supporting documentation to the IRB for review and approval, or securing an authorization agreement where the Marquette IRB relies on another IRB. No research with human subjects may begin (no data may be collected or subjects recruited) until the IRB provides written approval.

8.1 Authorization agreements

For research involving multiple institutions, the regulations that govern human subjects research allow for one institution to rely on the IRB of another institution by use of an authorization agreement. While the ORC can answer questions and assist with the process, ultimate decision-making authority at MU resides with the IO, however an Authorization Agreement requires
agreement between both/all institutions. For more information, view Guidance on Authorization/Reliance Agreement Procedures.

8.2 Exempt Human Subjects Research

Under 45 C.F.R. § 46.101 (b), certain types of minimal risk research qualify for exemption from further IRB review if the research meets the requirements of one or more of the following categories:

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

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

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

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

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

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

Research investigations potentially qualifying under one or more of the categories for Exempt status must submit a completed “Protocol Summary Form” to the IRB. If the IRB or its designees determine the research study does not meet the requirements for Exempt status, the PI may be asked to resubmit for Expedited or Full Review. If the IRB or its designees has determined the research study qualifies for Exempt status, a written letter will be issued to the PI acknowledging the study is Exempt from further review and under which of the six categories cited in 45 C.F.R. § 46.101(b).

Studies acknowledged by the IRB as Exempt do not need to seek Continuing Review approval unless otherwise requested by the IRB office. Any changes to the study protocol might require prior approval from the IRB as it may disqualify the study from Exempt status. For more information about when an amendment is required for an exempt protocol, see *IRB Guidance on Amending Your Human Subjects Protocol*, available on the IRB Policies & Procedures portion of the ORC’s website.

The IRB is informed of all exempt research protocols through inclusion of this information on the next available meeting agenda, and documentation in the meeting minutes in accordance with 45 C.F.R. § 46.110(c) and 21 C.F.R. § 56.110(c). An acknowledgement of research by exempt procedures is complete by itself and does not require any ratification by the convened IRB. However, the IRB may raise questions about any research that was previously acknowledged under exempt procedures.

The IRB will determine which individuals are allowed to perform exempt review determinations. This list may include members of the IRB and members of the ORC staff, as designated by the IRB.

### 8.2.1 Exempt Review Process

The IRB and/or the assigned Reviewer (may include ORC members designated by the IRB) reviews the claim of exemption and determines whether the research meets criteria for exemption. Exemptions may be submitted using the Marquette Protocol Summary Form, or at the discretion of the reviewer, a facilitated review using IRB paperwork from another institution may be conducted. The reviewers may:

1. Grant the Exemption,
2. Request further information before a determination can be made,
3. Determine that the proposed activity does not meet the definition of research and/or does not involve human subjects.
4. Determine that the research does not meet exemption criteria and must be reviewed by the IRB under expedited or full board review processes.

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The assigned reviewer ensures that all criteria for exemption are considered, met, and documented. The results of the review are subsequently communicated, in writing, to the PI by the ORC. Researchers should allow two weeks (10 business days) for initial review of exempt protocols.

NOTE: When the PI or a member of the research team has an existing relationship with the potential participants as current instructor-student or employer-employee, those projects should not be exempted due to the IRB’s recognition of increased risk (possible feelings of coercion or undue influence). An exception is when the participants are from the MU Psychology Pool, as any possibility of coercion and undue influence is already minimized.

8.3 Expedited Human Subjects Research Review

Certain types of research protocols may be eligible for review under expedited review procedures. The research must involve no more than minimal risk and fit one or more of the categories for expedited review procedures as specified in the regulations (45 C.F.R. § 46.110 and 21 C.F.R. § 56.110).

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 C.F.R. § 46.102(i))

There are nine categories of research eligible for expedited review procedures. These categories include the following:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   
   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   
   (b) Research on medical devices for which:
   
   (i) an investigational device exemption application (21 CFR Part 812) is not required; or
   
   (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   
   (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   
   (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of

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blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight week period and collection may not occur more frequently than two times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

   (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   (b) where no subjects have been enrolled and no additional risks have been identified; or
   (c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The PI may submit a new “Protocol Summary Form” for review by specifying the relevant criteria/criterion that makes it eligible for expedited review. The IRB members review a research protocol under expedited procedures if it meets the criteria, even if not submitted as expedited. Any IRB member may choose to have any protocol reviewed at a convened meeting.

8.3.1 Expedited Review Process

At least one member of the IRB is assigned as a primary reviewer. The IRB Chair designates which experienced members from the IRB are eligible to conduct these reviews. The ORC performs an initial review of all expedited protocol submissions for completeness and to determine an appropriate IRB reviewer based on expertise.

All assigned IRB members review the research applications to determine if the research meets the definition of minimal risk and the criteria of one or more of the eligible categories. IRB members assigned to review expedited research protocols may request clarification, require modification, or request that one or more additional IRB members also review the protocol. IRB members may request that a protocol be reviewed by the full board, but may not disapprove a research protocol under expedited procedures (45 C.F.R. 46 110(b)).
Under expedited review procedures, the determination options are:

(1) **Approved:** Approve as is, no additional changes necessary.

(2) **Approved with minor changes,** the revisions may be reviewed by the Office of Research Compliance.

(3) Not approved at this time, a revised version must be submitted for review. If PI does not wish to submit a revised version, the protocol will be reviewed at a full board meeting of the IRB. (4)

(4) Request additional IRB member or members to review.

(5) **Refer to the IRB Chair or Full Board:** for review at a full board meeting of the IRB.

The IRB members assigned to review the proposal may not disapprove a research protocol under expedited review procedures.

The ORC communicates the determinations of the IRB via email or in writing to the PI, and in the case of student investigators, also to the student’s faculty advisor. If instructed by the assigned IRB member, the ORC may review protocol revisions. Review time for expedited protocols varies based on ORC staffing, IRB member availability, and transportation time between the ORC and IRB members. Current processing time is approximately four weeks; timing is subject to change. The IRB is informed of all research protocols reviewed and approved under expedited review procedures through inclusion of this information on the next available convened meeting agenda, which is documented in the meeting minutes in accordance with 45 C.F.R. § 46.110(c) and 21 C.F.R. § 56.110(c). An approval of research by expedited procedures is complete by itself and does not require any ratification by the convened IRB. However, the IRB does have the opportunity and the authority to raise questions about any research that was previously approved under expedited procedures.

### 8.4 Full Board Review of Research

For each convened IRB meeting, all IRB members will receive a copy of all new protocols scheduled for review, along with any supporting documents (including, but not limited to, research tools, informed consent documents, and recruitment materials). All IRB members receive a complete agenda packet, regardless as to whether or not the member plans to attend the meeting. If any alternate members are scheduled to attend the meeting, the alternate will receive the complete agenda packet. Alternate members only receive agenda packets for convened meetings for which they are scheduled to attend.

For new protocols reviewed at convened meetings, at least one voting member of the IRB is assigned to be the primary reviewer. The ORC assigns IRB members as primary reviewers based on the nature of the research itself and the expertise and experience of the IRB member, when possible.

All PIs who submit a new protocol for review are invited to attend the convened IRB meeting in which their full-review protocol is scheduled for review. Faculty members are encouraged, but not required, to attend. Student PIs are required to attend the meeting with his or her faculty
advisor or another faculty member who is familiar with the research for new human subjects research protocol. For more on researcher attendance at meetings, see HRPPolicy 98.101 - Researcher Attendance at Convened IRB Meetings.

The investigator, if in attendance at the convened meeting, is asked to provide a brief description of the research project, focusing on the involvement of human subjects. The IRB then has the opportunity to ask questions and seek clarification from the investigator. The investigator is excused prior to the IRB’s discussion and vote. If the investigator is not present, the primary reviewer is expected to provide a description of the research.

After sufficient discussion, the members make a determination on each research protocol. If the IRB needs additional information, the protocol is incomplete, additional time is needed for discussion, or the IRB needs to delay voting for any other reason, the protocol may be tabled. An IRB member, typically the primary reviewer, must initiate a motion prior to a vote. The motion must be seconded by a second voting IRB member prior to the vote. When a motion is not seconded, it does not go forward to a vote. Any motion that is seconded must go forward for a vote unless the person who made the motion withdraws it. If a motion does not pass, another motion may be made for consideration.

If the IRB proceeds with a vote, the following determinations may be made:

1. **Approved:** Approve as submitted.

2. **Approved with Conditions:** The protocol is approved pending fulfillment of contingencies. Contingencies are reviewed and approved by the primary reviewer(s) and do not require review by the convened IRB. Investigators have 6 months from the date of initial review to meet contingencies. If contingencies are not met within that timeframe, the protocol will be administratively withdrawn by the ORC. Investigators may request an extension if extenuating circumstances exist.

3. **Disapproved:** The research protocol cannot be approved as proposed.

The decisions will be based on the votes of the majority (more than 50%) of the voting members present at a full board IRB meeting.

Researchers should contact the ORC as soon as possible if they plan to submit a protocol that requires review by the full board. Protocols are not accepted less than two weeks before a scheduled meeting unless there are extenuating circumstances. IRB meetings may be canceled if there are no items for review on the agenda.

Any IRB member may make a motion on a topic not listed on the agenda. The IRB may choose to vote on items not previously listed on the agenda.

### 9.0 Vulnerable Populations

Vulnerable populations may include women, human fetuses, neonates, prisoners, children, persons with physical handicaps or mental disabilities, and persons who are disadvantaged.
9.1 **IRB Review of Research Involving Fetuses, Pregnant Women, or Human In Vitro Fertilization**

When the proposed research involves fetuses, pregnant women, or human in vitro fertilization, the IRB considers the additional protections outlined in Subpart B, of 45 C.F.R. § 46. In addition, the IRB will only review research involving fetuses, pregnant women, and human in vitro fertilization when there is at least one member present who is uniquely qualified by their experience and training to review and approve the research. The IRB’s discussions, findings, and determinations are documented in the IRB meeting minutes for each specific research protocol.

9.2 **IRB Review of Research Involving Prisoners**

When the proposed research involves prisoners, the IRB considers the additional protections outlined in Subpart C of 45 C.F.R. § 46. In addition, the IRB will only review research involving prisoners when there are members present who are uniquely qualified by their experience and training to represent the interests of prisoners in the review and approval of this research. The MU IRB has a member who has the appropriate background and experience to serve as a Prisoner Representative. This member only counts toward quorum when he or she is present and reviewing studies covered by subpart C. The IRB’s discussion, findings and decisions in regard to the requirements of 45 C.F.R. § 46.305 and 45 C.F.R. § 46.306 are documented in the IRB meeting minutes.

9.3 **IRB Review of Research Involving Children**

When the proposed research involves children, the IRB considers the additional protections and the parental permission and assent procedures outlined in Subpart D of 45 C.F.R. § 46. The IRB discussion, findings and determinations in regard to the requirements of 45 C.F.R. § 46.404 through 45 C.F.R. § 46.408 are documented in the IRB meeting minutes. The ORC provides IRB reviewers with a checklist titled, “IRB Review of Protocols Involving Children.” For any protocol involving children, the IRB must determine which of the categories of research apply to that study, if any, and provide the rationale.

9.3.1 **Assent for Minors**

In the State of Wisconsin, only individuals 18 years or older may legally consent to participate in research. Individuals who do not have this authority to consent must still provide assent. “Assent” is an active affirmation to participate in a research study. If the individual giving assent is able to read and write, then assent should be documented using the IRB Assent template; otherwise, assent should be obtained through dialogue with the subject. The assent discussion and form should be in language understandable to the subject and contain the same elements as those stated under “Informed Consent Process and Documentation.” For further information regarding Assent for Minors including a Parental Permission Template and Assent Template, see http://www.marquette.edu/researchcompliance/human/index.shtml.
9.4 IRB Review of Research Involving Informed Consent by a Legally Authorized Representative

When the proposed research involves individuals who may not be able to provide informed consent for themselves, the IRB reviews the research to ensure the rights, welfare, and autonomy of those individuals are respected. Wisconsin state law allows, under certain specific situations, designated persons to provide substituted judgments for others who may not be completely able to provide informed consent for themselves, specifically parents of minor children and legally appointed guardians. When reviewing research with vulnerable populations, including adults with diminished cognitive capacity and the potential need for other persons to provide consent for subjects, the IRB may seek legal counsel opinion or expert consultation from neuropsychologists or other professionals.

10.0 Continuing Review of Human Subjects Research

The initial approval of research is based on both the PI’s presentation of information and IRB’s assessment of the risks, benefits, and anticipated results of the research as set forth in the protocol application. At the time of initial review the IRB determines a period of approval and the frequency of any continuing review based on the kind and degree of anticipated risk for subjects and/or others. Depending on the degree of risk, the IRB may conduct continuing review at a fully convened meeting or under expedited review procedures.

The IRB may approve the research for a period less than one year when there are concerns regarding the PI’s level of experience or competency to conduct the research, a history of non-compliance with IRB-approved protocols or institutional policies and procedures, or for other reasons, including concerns over the level of risk. If the IRB believes or finds that an investigator has not conducted the research according to the IRB-approved protocol, the IRB may require verification from sources other than the investigator that no material changes in the conduct of the research have occurred since previous IRB review and approval (e.g., auditing or monitoring of consent documentation). This verification should be in writing and submitted for IRB review along with the Continuing Review Form. Any requirement of verification will be communicated to the PI by the IRB in writing with an approval notification for the research.

The IRB conducts continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. This means that continuing review will occur on or before the one-year anniversary date of the previous IRB review, even though the research activity may not begin or support for the research may not be received until after the IRB approval date. When the IRB has approved the research for a period less than one year, continuing review will occur before the end of the approval period.

10.1 Content of Continuing Review

The IRB reviews the Continuing Review Form and the research protocol. Amendments to the research protocol, informed consent documents, or other supporting documents, may be submitted and reviewed concurrently with the continuing review. The PIs must submit all of the following for the Continuing Review:
(1) The Continuing Review Form that includes:

(a) A summary of the progress of the research at MU and other sites if appropriate.

(b) A summary of any preliminary results or findings from this research at MU and other sites.

(c) A summary of any recent literature, findings, or other relevant information that might affect the risks associated with the research, the risk-benefit analysis, or a subject’s willingness to continue participation.

(d) The total number of subjects accrued since the initial approval and the total number of subjects enrolled to date.

(e) A summary of research subject demographic information.

(f) A summary of recruitment and informed consent process information and mention of any problems.

(g) A summary of any Adverse Events that have occurred since the initial review or the most recent continuing review, including whether they were of unanticipated frequency and/or severity, related to the research intervention itself, procedure, drug, device or biologic, whether they modify the risk-benefit analysis, result in modifications to the research protocol to further minimize risk, and/or to the informed consent document.

(h) A description of any amendments to the research protocol or informed consent documents that have been reviewed and approved by the IRB since the most recent initial or continuing review approval.

(i) Any proposed amendments to the research protocol or informed consent documents, submitted on a separate Amendment form.

(j) It is the responsibility of the PI to ensure that the protocol is submitted in a timely fashion and that any required modifications are completed to secure the continuing review.

10.2 Required Continuing Review Determinations

The IRB makes the following determinations in order to approve research for continuation:

(1) That the research continues to satisfy the criteria set forth in 45 C.F.R. § 46.111 regarding minimizing risks, the anticipated risks remain reasonable in light of the potential for benefit, and there is a plan for an equitable selection of subjects, an adequate informed consent process and documents, provisions for monitoring the data for safety, and provisions to ensure the privacy of subjects and confidentiality of data collected.

(2) Where applicable, the additional protections for vulnerable subjects such as pregnant women, fetuses, prisoners, and children as specified by regulations and the IRB, are in place and remain adequate.

(3) That the informed consent documents are accurate and complete, and any significant new findings that may affect a subject’s willingness to continue participation have been incorporated into the documents and communicated to research subjects in active treatment, if the IRB determines such information might affect their willingness to continue in the research.

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(4) Whether the research requires verification from sources other than the PI (e.g., other institutional review boards, the FDA, Sponsors, or institutional sources or committees) that no material changes in the research have occurred since the previous review. The IRB may request an audit of study files to ensure adequate protections if there are concerns that there may have been material changes without prospective IRB review and approval.

10.3 IRB Continuing Review Processes

10.3.1 Continuing Review under Expedited Review Procedures

For research protocols the IRB initially approved under expedited procedures, the IRB conducts continuing review under expedited procedures unless new risks or information have been identified that warrant full board review. Research protocols previously approved by the full IRB may be eligible for review under expedited review procedures in accordance with 45 C.F.R. § 46.110, under either Category 8 or 9:

**Category 8:** Continuing review of research previously approved by the full board IRB as follows:

(1) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(2) Where no subjects have been enrolled and no additional risks have been identified; or

(3) Where the remaining research activities are limited to data analysis.

**Category 9:** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where Categories 2 through 8 do not apply but the IRB has determined and documented at a full board meeting that the research involves no greater than minimal risk and no additional risks have been identified.

10.3.2 Continuing Review by the Full Board

For research that was initially approved by the full board IRB, continuing review will also be conducted by the full board IRB using the same procedures used during initial review.

The IRB makes the following decisions:

(1) **Approved:** Approved for continuation.

(2) **Approved with contingencies:** Conditional fulfillment is required to secure approval for continuation. Contingencies may be reviewed and approved by a primary reviewer. If contingencies are not approved prior to expiration, then the protocol will expire and a new protocol must be submitted.

(3) **Tabled:** Table the discussion for further review at a subsequent full board meeting.

Adopted by MU IRB Oct 2010, Revised January 2014
Disapproved: The continuing review cannot be approved as proposed.

The decisions will be based on the votes of a simple majority (more than 50%) of the voting members present at a full board IRB meeting.

The ORC will communicate the IRB’s decision, in writing, to the PI.

10.4 Study Completions and Closeouts

In order for the IRB to maintain accurate records of active studies, whenever a research study is identified by the PI as being “completed” or “closed,” the PI must complete and submit a Final Report Form to the IRB. Once a Final Report Form has been submitted and reviewed, the ORC will code the protocol records as complete in the ORC database. ORC staff will remove the protocol file from the active files and archive. If neither a Continuing Review Form, nor a Final Report Form is received by the ORC by the expiration date, the protocol will be closed and a closure notice will be sent to the PI. Protocols may not be re-opened once closed.

11.0 Proposed Modifications to Previously Approved Projects (Amendments)

The PI must conduct the research in accordance to the specific methods that were set forth in the application approved by the IRB. MU policy and the federal regulations require that the PI report proposed changes in a previously approved research project promptly to the IRB. No changes in approved research may be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to research subjects.

11.1 Minor Modifications to Previously Approved Research

The IRB may review minor changes in previously approved research during the period for which approval has been given, under expedited review procedures (45 C.F.R. § 46.110 and 21 C.F.R. § 56.110). A ‘minor change’ is a change in approved research that can be approved through expedited review procedures that neither materially increase risk, nor materially decrease benefit, nor materially decrease scientific merit. If the change is not considered ‘minor,’ it must be reviewed by the full board IRB at a convened meeting.

Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB. The IRB Chair or experienced IRB members review the amendment, after a pre-review by ORC, to ensure all criteria for review are considered, met, and documented.

If the reviewer determines that the amendment involves significant changes or new risks that warrant review by the full board IRB, the amendment will be referred to a full board meeting. The IRB Member(s) conducting the review of the amendment make one of the following determinations:

   (1) **Approved** as submitted.
   
   (2) **Modifications** are required to secure approval to implement.
   
   (3) **Refer** for review by full board IRB.

Adopted by MU IRB Oct 2010, Revised January 2014
The IRB members may not disapprove an amendment to a research protocol under expedited review procedures.

The IRB is informed of all amendments to previously approved research protocols reviewed and approved under expedited review procedures on the next available meeting agenda and this is documented in the IRB meeting minutes in accordance with 45 C.F.R. § 46.110(c) and 21 C.F.R. § 56.110(c).

The date of approval of an amendment does not change the original approval period or the expiration date by which the regularly scheduled continuing review of the research project should be done.

11.2 Greater Than Minor Modifications to Previously Approved Research

Proposed amendments which including greater than minor modifications to an approved project are reviewed by the full board IRB at one of its regularly scheduled meetings. The IRB makes one of the following determinations:

(1) **Approved as written.**
(2) **Approved with Contingencies,** modifications are required to secure approval.
(3) **Table** for further review at a subsequent full board IRB meeting.
(4) **Disapprove:** Modification cannot be implemented.

The decisions are based on the votes of the majority (more than 50%) of the voting members present at a full board IRB meeting. IRB members are requested to ensure all criteria for continuing review are considered, met, and documented. This also includes the information about the results of the review that the ORC will communicate, in writing, to the PI.

The date of approval of an amendment does not change the original approval period or the expiration date by which the regularly scheduled continuing review of the research project should be done unless the amendment increases the risk to benefit ratio, thus warranting the study to be reviewed more frequently.

12.0 Reporting of Unanticipated Problems Involving Risks to Subjects or Others (Adverse Event Reports)

The IRB is responsible for ongoing monitoring of the safety and welfare of human subjects. Part of this monitoring is ongoing review and assessment of Adverse Events related to participation in the research.

**Adverse Events** are any occurrences during the conduct of a research study that ultimately harm a subject. Adverse Events may either be related or unrelated to the research study.

For example, adverse Events may be the result of the following:

(1) The interventions and interactions used in the research.
(2) The collection of identifiable private information in the research.
(3) An underlying disease, disorder, or condition of the subject.
(4) Other circumstances unrelated to the research or any underlying disease, disorder, or condition of the subject.

Examples (1) and (2) are events which are related to the study, while (3) and (4) are not.

The Federal regulations at 45 C.F.R. § 46.103(b)(5) and 21 C.F.R. § 56.108(b)(1) require Institutional Review Boards to establish a procedure for “ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head, of any unanticipated problems involving risks to subjects or others…. Adverse Events must be reported to the IRB using an Adverse Events Report Form which can be found on the ORC website.

For more about Adverse Events, see HRPPolicy 98.104 – Reporting of Non-Compliance and Unanticipated Problems Involving Risks to Subjects or Others.

The PI is responsible for knowing and adhering to the guidelines of the IRB, proper reporting, and maintaining copies of Adverse Events in the study file. PIs are also responsible for the accurate documentation, investigation, and follow-up of all possible study-related Adverse Events.

12.1 Adverse Events Review Process

The adverse events review process is outlined in HRPPolicy 98.104, Reporting of Non-Compliance and Unanticipated Problems Involving Risks to Subjects or Others.

13.0 IRB Role in Continuous Quality Improvement (CQI)

The IRB has a role in CQI from both the policy perspective and review process perspective to ensure that there is general consistency among the IRB members in applying human subject protections. The IO will meet with the IRB Chair and/or ORC as needed to identify common issues and concerns of the IRB, and to work towards improvements.

14.0 IRB Audits and Protocol Monitoring

The MU IRB is responsible for ongoing oversight of approved protocols to ensure the continuing protection of human subjects and compliance with IRB policies and federal regulations. The IRB, the RCO, or an IRB-designee has the authority to audit or review IRB-approved research. For more information about audits and protocol monitoring, see HRPPolicy 98.103 – IRB Audits and Protocol Monitoring.

In addition, the RCO shall, on a periodic basis, review grant-funded research projects. The RCO shall perform these reviews regularly. Human subjects research protocols to be reviewed will be selected on a random basis from the list of grants funded within the previous 12-month period. The RCO may contact the PI for clarification when performing these audits. If deficiencies, problems, or concerns arise, the PI may be asked to respond in writing to address the concerns and state any corrective actions. If deficiencies, problems, or concerns continue, the RCO will notify both the IO and the IRB. The IRB may perform its own audit or protocol monitoring under HRPPolicy 98.103.
15.0 IRB Role In Handling Allegations of Non-Compliance

Human subjects research that deviates from the approved protocol, policies, procedures, stipulations, decisions, state, or federal law is non-compliant and subject to further inquiry by the IRB and the ORC. All reports and complaints of non-compliance should be directed to the ORC (via email, phone, mail, or in person). The ORC will investigate all allegations of non-compliance in collaboration with the Chair and the IO. If necessary the ORC may, under the direction of the IRB, send the investigator/s in question a notice requesting the immediate suspension of all specified research activities while the issue of non-compliance is reviewed, consistent with Federal Mandate 45 C.R.F. § 46.113. This initial notice will also include a statement detailing the rationale for the IRB’s action. The IO will be copied on any notice, as well as, on occasion, Deans and Department Chairs.

The IRB functions solely in the role of deciding whether non-compliance of human subject research has occurred and may require: amendments to the research protocol and/or consent process; auditing the protocol; submission of a DSMP; submission of periodic status reports; contacting past or current participants with additional information (for current participants whenever that information might affect their willingness to continue to take part in the research); re-consenting participants; destruction of data; modifying the approval period; suspension; or termination of research projects involving the use of human subjects. Any disciplinary actions will be governed by the Deans, Chairs, or the Provost. For noncompliance that occurred with a student PI, the Graduate School would determine whether/how the noncompliance affects the student and his or her graduate work.

All cases of non-compliance where the IRB determines to be serious or continuing noncompliance will be promptly reported to the IO. All cases of serious or continuing non-compliance may be reported to appropriate groups within the university (e.g., Office of General Counsel, Board of Trustees, etc.). Additionally, when research is HHS conducted, supported, or research that is FDA regulated, all cases of serious or continuing non-compliance will be reported to appropriate federal agencies (e.g., OHRP, FDA, etc.). The Research Compliance Officer may report to appropriate federal agencies and university groups on behalf of the IO.

For more information about protocol deviations and noncompliance, see HRPPolicy 98.104, Reporting of Non-Compliance and Unanticipated Problems Involving Risks to Subjects or Others.

16.0 Study Related Complaints

Complaints related to studies will be referred to the ORC Staff for investigation. ORC Staff will consult with the IRB Chair for further action.

17.0 Appeals Process

If a PI disagrees with the determination of the IRB at the exempt or expedited review levels, the PI may request consideration by the full-board.

If a PI disagrees with the determination of the convened IRB, such as a requirement for changes to secure approval, a decision to disapprove, an unfavorable determination, or other reasons, the
PI may appeal by submitting a written request to appeal the decision, including in the appeal the reasoning for the request and supporting information.

If a PI disagrees with a determination of serious or continuing noncompliance by the IRB, the PI may appeal.

The burden of proof is on the PI. The IRB retains final authority on an appeal. No issue can be appealed more than twice.

18.0 Student Investigators

A student who submits an application for new protocol review by an IRB must list a faculty member or academic staff as the student’s supervisor. The supervisor must sign the protocol summary form either via hard copy or electronically. The supervisor, by signing, is indicating that he or she read and reviewed the research plan and approved the scientific and ethical aspects of the research. The faculty supervisor will supervise all compliance with human subjects’ guidelines.

19.0 Participation of Students and Employees in Research

The IRB has a policy about students and employees as participants in research projects. See HRPPolicy 98.102 – Participation of Students and Employees in Research for more information.
ADVERSE EFFECT An undesirable and unintended, although not necessarily unexpected, result of research or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy).

ASSENT Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

ASSURANCE A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved [Federal Policy § ___.103].

AUTHORIZED INSTITUTIONAL OFFICIAL An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

CONFIDENTIALITY The treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

EXPEDITED REVIEW Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [Federal Policy § ___.110] The research must involve no more than minimal risk and fit one or more of the categories for expedited review procedures as specified in the regulations [45 C.F.R. § 46.110 and 21 C.F.R. § 56.110].

FULL BOARD REVIEW Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting [Federal Policy § ___.108].

HUMAN SUBJECT: Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for
obtaining the information to constitute research involving human subjects. (45 C.F.R. § 46.102(f))

**INFORMED CONSENT** A person’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution, or agents thereof from liability for negligence [Federal Policy § 116; 21 C.F.R. §§ 50.20 and 50.25].

**INSTITUTIONAL REVIEW BOARD** A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research [Federal Policy §§ ___.102(g), ___.108, ___.109].

**MINIMAL RISK** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 C.F.R. § 46.102(i))

**OFFICE FOR PROTECTION FROM RESEARCH RISKS (OPRR)** The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (45 C.F.R. Part 46) governing research involving human subjects.

**PRINCIPAL INVESTIGATOR (PI)** The scientist or scholar with primary responsibility for the design and conduct of a research project.

**PROTOCOL** The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

**RESEARCH** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (45 C.F.R. § 46.102(d))

**RISK** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only “minimal risk.”

**VOLUNTARY** Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject’s decision to participate (or to continue to participate) in a research activity.
Appendix B: Current Forms for Researchers

http://www.marquette.edu/orc/irb/forms-templates.shtml
22.0  Appendix C: Current Documents for ORC and IRB Internal Use

Protocol Deviation Findings – S:\Human\Deviations

IRB Review of Protocols Involving Children (Pink Sheet)
23.0 Appendix D: Current IRB-Approved Policies

Human Research Protection Policy 98.101 – Researcher Attendance at Convened IRB Meetings

Human Research Protection Policy 98.102 – Participation of Students and Employees in Research

Human Research Protection Policy 98.103 – IRB Audits and Protocol Monitoring

Human Research Protection Policy 98.104 – Reporting of Non-Compliance and Unanticipated Problems Involving Risks to Subjects or Others

University HIPAA Policy
Appendix E: ORC Guidance Documents and Templates

Consent/Assent/Parent Permission Form Instructions and Template
http://www.marquette.edu/orc/irb/forms-templates.shtml

Amending Your Human Subjects Research Protocol
http://www.marquette.edu/orc/irb/policies.shtml

Data and Safety Monitoring: Does My Protocol Need a Data and Safety Monitoring Plan
http://www.marquette.edu/orc/irb/policies.shtml

Deviation/Noncompliance Reporting Guidance
http://www.marquette.edu/orc/irb/policies.shtml

Guidance on Waiver of Documentation of Consent
http://www.marquette.edu/orc/irb/forms-templates.shtml

Guidance on Authorization/Reliance Agreements and Requests
http://www.marquette.edu/orc/irb/forms-templates.shtml

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25.0  Appendix F: Human Subjects Regulations Decision Charts

1. Perform analysis – Is MU Engaged?
   a. Guidance document from OHRP –
      http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html
   b. Is an MU employee or student the Principal Investigator? If so, then Yes.
   c. Is an MU employee or student part of the research staff? If so, then Yes.
      i. A person is part of the research staff if he or she:
         1. Obtains information about living individuals by intervening or
            interacting with them for research purposes
         2. Obtains identifiable private information about living individuals
            for research purposes
         3. Obtains the voluntary informed consent of individuals to be
            subjects in research, or
         4. Studies, interprets, or analyzes identifiable private information or
            data for research purposes
   d. Is MU the direct recipient of federal funds to perform the research? If so, then
      Yes.

2. Perform analysis – “Is an activity research involving human subjects?”
   a. OHRP Decision Chart -
      http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c1

3. Perform analyses – Is the human subjects research eligible for exemption?
   a. OHRP Decision Chart -
      http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c2
   b. NOTE: When the PI or a member of the research team has an existing relationship
      with the potential participants as current instructor-student, or employer-
      employee, careful consideration should be made before exemption due to the
      IRB’s recognition of increased risk (possible feelings of coercion or undue
      influence).
      i. An exception is research performed with the Psych Pool as participants, as
         any possibility of coercion and undue influence is already minimized with
         the way the pool is set up.

4. Perform analysis – Does an exemption apply?
   a. ORHP Decision Charts –
      i. Exempt Category 1 -
         http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c4
      ii. Exempt Category 2 or 3 -
         http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c4
      iii. Exempt Category 4 -
         http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c5
      iv. Exempt Category 5 -
         http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c6
      v. Exempt Category 6 -
         http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c7

5. Perform analysis – May the IRB review be done by expedited procedures?
   a. OHRP Decision Chart -
      http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c8

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