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1. PURPOSE

1.1. This policy establishes the role, authority, function, and jurisdiction of the Institutional Review Board.

2. REVISIONS FROM PREVIOUS VERSION

2.1. Addition of 3.1.4


3. POLICY

3.1. The Role of the Institutional Review Board

3.1.1. 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 (IRB00000545) designated in its Human Research Protection Program and under its Federalwide Assurance (FWA#00005844). Under this FWA, MU will comply with the Federal Policy for the Protection of Human Subjects, known as the Common Rule, for all federally-supported human subject research. 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.

3.1.2. 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 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, waivers, or partial waivers of patient HIPAA authorization.

3.1.3. 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

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

3.1.4. In the event of an emergency or disaster (e.g., public health or weather-related), the procedures in these SOPs may be modified as appropriate for the situation. Such modifications may include alternative meeting procedures, alternative procedures for the submission and review of modifications, alternative procedures for prompt reporting, and any other changes necessary to ensure appropriate ongoing oversight and conduct of research. Because procedural modifications may vary based on the nature of the event, these cannot be anticipated and described in these SOPs. Instead, such procedural modifications will be recorded in an addendum to the SOPs, note-to-file, or other appropriate means of documentation and communicated to the research community. This documentation will be maintained in accordance with applicable record retention requirements.

3.2. IRB Authority


3.2.1. 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.

3.3. IRB Functions

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

- Conduct the initial and continuing review of research protocols;

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- Report determinations and decisions, in writing, to investigators and the institution via the ORC Staff;
- Determine which research protocols require review more frequently than once per year;
- 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;
- Require that proposed changes in research are promptly reported;
- 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;
- 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;
- 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.
- 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
- 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.
- The IRB provides annual reports to the Marquette University IO via the RCO. The IRB is supported by the ORC.

3.4. IRB Jurisdiction:

3.4.1. The IRB has jurisdiction only over MU personnel engaged in research that involves the use of human subjects, private identifiable data/specimens:

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