1. PURPOSE
   1.1. This policy establishes the criteria for IRB approval.

2. REVISIONS FROM PREVIOUS VERSION
   2.1. None

3. POLICY
   3.1. 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. No research with human subjects may begin (no data may be collected or subjects recruited) until the IRB provides written approval.

   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.

   3.2. Certification of human subjects research training: Certification is required for all MU PI, student PI, and faculty advisors. Additionally, anyone serving as a member of the research team engaged in any of the following activities should complete training as well:
   - obtaining information about living individuals by intervening or interacting with them for research purposes;
   - obtaining identifiable private information about living individuals for research purposes;
   - obtaining the voluntary informed consent of individuals to be subjects in research; and
   - studying, interpreting, or analyzing identifiable private information or data for research purposes.

   MU offers human subjects research training through the Collaborative Institutional Training Initiative (CITI). It is the responsibility of the PI and/or faculty advisor to determine which CITI learner group members of the research team who are engaged in the above activities must complete. The IRB does not require proof of training of non-Marquette research staff unless MU is being relied upon as the

reviewing IRB. The PI is responsible for ensuring that the non-Marquette personnel are trained appropriately.

3.3. The approval of non-exempt human subjects 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 subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, §46.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with §46.117.

(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) For purposes of conducting the limited IRB review required by §46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1)-(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §46.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(9) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

3.4. 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. Recruitment materials may be stamped with the IRB approval date. 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. Noncompliant materials may not be posted or otherwise disseminated.

3.5. Additional requirements: that must be satisfied, not listed under 45 C.F.R. 46.111, include the following**:** HIPAA requirements, FERPA requirements, Marquette policy, Marquette colleges and departments, Local and state law, Department of Defense, and other ancillary agencies.