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.

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 purvie(it)1l0ef2 0 612 792 reW*nQ0.00000912 0 612 792 reW*nBT/F2 12