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MARQUETTE UNIVERSITY Office of Research Compliance	IRB-610	Audits and Protocol Monitoring	July 2018	1 of 2

1. PURPOSE
   1.1. This policy establishes the criteria and process for auditing and monitoring human subjects research projects.

2. REVISIONS FROM PREVIOUS VERSION
   2.1. None

3. POLICY
   3.1. The Marquette University Institutional Review Board (IRB) is responsible for ongoing oversight of approved protocols to ensure the protection of human subjects and compliance with federal regulations and IRB policies. The IRB has the authority to audit or review, or appoint a designee to audit or review, IRB approved research.

   3.2. The Research Compliance Officer shall at all times act as a designee. Directed audits are conducted in response to identified concerns that require an IRB determination.

   3.3. Protocol monitoring is conducted randomly to review compliance with IRB approved research.

   3.4. Monitoring and/or auditing activities may include, but are not limited to the following:
   - Examine research records, including copies of signed consent forms.
   - Observe the informed consent form process.
   - Review advertisements and other recruitment materials and methods.
   - Examine procedures to verify that changes have not been implemented without IRB approval.

   3.5. Principal Investigators are contacted in advance to schedule any audit or monitoring activity.

   3.6. Upon completion of each review, a written report is prepared and provided to the PI, the IRB, and the Vice President for Research and Innovation.

   3.7. If deficiencies, problems or concerns are identified, the PI is required to respond in writing, stating corrective actions taken.

   3.8. If deficiencies, problems or concerns are identified, the IRB may temporarily halt subject recruitment, require additional oversight, or recommend other corrective actions as deemed necessary.

3.9. The IRB may suspend or terminate research if the audit/monitoring indicates that human subjects were exposed to unexpected serious risk or harm, or that federal regulations or IRB policies were not adhered to.