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1. PURPOSE

- 1.1. This policy describes the obligations of investigators conducting <Human Research> overseen by this [Organization].

2. POLICY

- 2.1. Do not commence research until you have the IRB approval letter and obtained all other required approvals, such as radiation safety approval, biosafety approval, and approvals of departments or divisions that require approval of the use of their resources.
 - 2.1.1. If there are any questions about whether you are conducting research involving human subjects, contact the IRB before commencing the study.
- 2.2. Comply with all requirements and determinations of the IRB.
- 2.3. Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
- 2.4. Ensure that research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
 - 2.4.1. Principal Investigator (PI) Eligibility
 - 2.4.1.1. To be eligible to serve as a principal investigator, an individual must hold one of the following titles: professor, associate professor, assistant professor, or research professor. Although it is not common, other designated full-time, benefited professional positions may be granted PI Status at the discretion of the Vice Chancellor for Research and Innovation.
 - 2.4.1.2. Full-time benefited individuals holding titles other than professor, associate professor, assistant professor, and research professor must obtain approval from the Vice Chancellor for Research and Innovation or his/her designee to submit an IRB protocol. Please contact IRB@uml.edu for A Request for PI Status Form.
- 2.5. Personally conduct or supervise the research.
- 2.6. Conduct the research in accordance with the relevant current protocol approved by the IRB.
- 2.7. Protect the rights, safety, and welfare of subjects involved in the research.
- 2.8. Submit proposed modifications to the IRB prior to their implementation.
 - 2.8.1. Do not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- 2.9. Submit continuing reviews when requested by the IRB.
- 2.10. Submit a closure form to close research (end the IRB's oversight) when:
 - 2.10.1. The protocol is permanently closed to enrollment
 - 2.10.2. All subjects have completed all protocol related interventions and interactions
 - 2.10.3. For research subject to federal oversight other than FDA:
 - 2.10.3.1. No additional identifiable private information about the subjects is being obtained
 - 2.10.3.2. Your analysis of private identifiable information is completed
- 2.11. If research approval expires, stop all research activities and immediately contact the IRB.
- 2.12. Promptly report to the IRB the information items listed in "POLICY: Prompt Reporting Requirements (HRP-071)."



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- 2.13. Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”)
- 2.14. Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments”) without prior IRB approval.
- 2.15. For studies regulated by a federal department or agency, follow any additional obligations, as applicable.

3. REFERENCES

- 3.1. 21 CFR §56.103(a)
- 3.2. 21 CFR §56.108(a)
- 3.3. 21 CFR §50.20
- 3.4. 21 CFR §50.25
- 3.5. 21 CFR §50.27
- 3.6. 45 CFR §46.116
- 3.7. 45 CFR §46.117
- 3.8. FDA Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572)
- 3.9. AAHRPP Evaluation Instrument for Accreditation