UMES Policy on IRB Assurance of Compliance with DHHS Policy

UMES will provide written assurance documents to the Office of Human Research Protection to comply with the requirement of 45 CFR 46.103. Assurance documents will be maintained and renewed in accordance with regulations. UMES will apply Department of Health and Human Services regulations, including Subparts A, B, C, and D (as applicable) to all federally funded research. The fundamental commitment to the protection of human participants applies to all human subjects research conducted by UMES, regardless of funding source or site of the research.

UMES may rely on other organizations to provide IRB review. Such reliance shall be documented in written IRB review agreements, and the terms of the agreements shall be reflected in UMES's assurance documents, as applicable.

In accordance with 45 CFR 46.109, the UMES IRB, and any IRB delegated by UMES to review research, have the authority to:

1. Approve, require modifications to secure approval, or disapprove, all human subjects research activities overseen and conducted by the organization.
2. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants.
3. Observe, or have a third party observe the consent process.
4. Observe, or have a third party observe, the conduct of the research.

Officials of the Organization may not approve research if it has not been approved by the IRB. Officials of the Organization may disapprove research that has been approved by the IRB.