UMES Policy on Single Case Reports and Case Series

It is the policy of the Organization that a single case report or case series (three or fewer cases) does not constitute human subjects research requiring review and approval by the UMES IRB. If an investigator wishes to have the project formally assessed by the UMES IRB to see if it meets UMES's definition of a single case report or case series, the investigator must submit a new protocol application to the IRB, requesting a Not Human Subjects Research review. If the project qualifies, the IRB will send an acknowledgment letter to the investigator stating:

"The IRB received your request concerning a single case report or case series you wish to publish. The UMES IRB has determined that a case report or case series involving three or fewer patients do not produce generalizable knowledge, nor is it an investigation of an FDA-regulated product. IRB review and approval are not required for this activity."

Investigators should inform the Office of Human Subjects Research if a journal does not accept the IRB's decision by contacting the Chairperson via email.

Case reports/series for publication must be prepared in accordance with the requirements of the HIPAA privacy regulations. Any use or disclosure of PHI must be authorized by the patient, or, if the patient is deceased, the patient's family. Publication of a case report containing PHI is a disclosure of PHI. The Privacy Officer or designated HIPAA authority at the applicable location within the Organization by which the PHI was initially collected should be consulted prior to submission of the case report/series to ensure proper authorization was obtained if necessary.

For guidance please see: 1) Case Report Publication Guidance: IRB Review and HIPAA Compliance; and 2) Guidance for Investigators HIPAA Requirements for Case Reports