

UMES Policy on Communicating IRB Actions to Investigators

IRB approval of a new application, continuing review application, changes in research application, or other study changes is provided in writing to the principal investigator. An approval notice is provided on letterhead and requires the signature of the IRB chairperson.

IRB disapproval of a new application, continuing review application, changes in research application, or other study changes is provided in writing to the principal investigator by the IRB Chairperson. The disapproval notice will: be provided on letterhead with the signature of the IRB Chairperson, identify what has been disapproved and the reason for disapproval. The investigator will have the opportunity to respond in writing to the IRB Chairperson. The response of the investigator should be provided to the IRB Chairperson within 21 days of the date the disapproval notice was provided to the investigator. The IRB Chairperson will in turn present the documentation to the IRB for reconsideration.