POLICY

The IRB must conduct continuing review of approved protocols for purposes of renewal of the IRB approval period, at intervals appropriate to the degree of risk. Please see SOP 307 (Approval Period and Determination of Expiration) for the policy regarding the approval period of a study. Investigators are required to submit a continuing review application in the ERICA system prior to the expiration of the study.

When considering whether or not to renew a study, the IRB revisits the same criteria used to grant initial approval. The IRB will not approve protocols submitted for continuing review, if due to interim changes in IRB policies and procedures, the IRB would not approve that same protocol as a new proposal.

During continuing review, the IRB determines whether the study can be renewed at the same risk/benefit ratio, or if new information has changed that determination. As an outcome of continuing review, the IRB may require that the research be modified or halted altogether. Additionally, the IRB may need to impose new precautions or revise those it had previously imposed on the research protocol. The IRB will re-assess the approval period for each continuing review application. Determinations are made using the board member checklist.