1. PURPOSE: To ensure the timely expiration of protocols when the continuing review has not been approved by the expiration date set at the previous continuing review.

2. POLICY: Any protocol that does not obtain approval by the continuing review date last stipulated by the IRB will be expired in the IRB database and the Principal Investigator (PI) will be sent an expiration letter. Specifically, when a protocol has expired on a Sunday, Monday, Tuesday, Wednesday, or Thursday, an expiration letter will be sent to the PI on the day after expiration. When a protocol expires on a Friday or Saturday, an expiration letter will be sent to the Principal Investigator on Friday. When a protocol expires on a holiday, an expiration letter will be sent out on the closest business day prior to the holiday.

3. SPECIFIC POLICIES: Every business day, the designated IRB staff will run a report form the IRB database for Full Board and Expedited protocols requiring continuing review. Each study’s expiration is verified by checking the database again to ensure the continuing review has not been completed. Once verified, they will change the status of the study to “Expired”, and send out an Expiration Notice through the IRB database.

Expiration Notices are not sent for studies under review by external IRBs, studies which do not require continuing review under the 2018 Requirements, or for Exempt Protocols.

4. RESPONSIBILITY:
   It is the responsibility of the IRB Managers, Lead IRB Trainer, and IRB Specialists to implement this SOP.
   It is the responsibility of the Director and Assistant Director to implement and monitor this SOP.

5. APPLICABLE REGULATIONS AND GUIDELINES:
   45 CFR 46.103(b)(4)
   21 CFR 56.108

6. ATTACHMENTS: None