1. PURPOSE
   1. This guidance document describes the potential outcomes of study expiration.
2. GUIDANCE
   1. The Continuing Review Form (HRP-202) should be submitted to the IRB at least 30 days prior to the <End Approval Date>.
      1. Investigators will receive two notices as an alert of the upcoming <End Approval Date>.
   2. If the Continuing Review Form (HRP-202) is submitted prior to the study’s <End Approval Date>, but approval expires prior to the IRB’s approval for continuation, there is a lapse in approval, and all research activities must stop until the study is reapproved.
      * 1. If it is in the best interested of the study participants to continue on the study during this lapse, the PI must email [OHRIRB@gwu.edu](mailto:OHRIRB@gwu.edu) describing the reason that participants should be permitted to continue.
           1. The IRB may determine that current participants may continue on the study for a brief period if it is in their best interest;
           2. New enrollment is not permitted.
   3. If the PI fails to submit the Continuing Review Form (HRP-202) prior to the <End Approval Date>, the study is expired and all research activities, including non-interventional activity such as identifiable data analysis, must stop.
      1. Within 90 days of expiration, the PI may submit a Continuing Review Form (HRP-202) to restart the study.
         1. Note that this is NOT a grace period in which study activities may continue; all study activities must stop after <End Approval Date>.
         2. In the Continuing Review Form (HRP-202), the PI must include:
            1. A statement that no study activities (including analysis of identifiable data) have been carried out after <End Approval Date>.
            2. An explanation as to why IRB approval lapsed, and a plan to prevent further lapses.
      2. After 90 days, a new application (HRP-200) must be submitted and approved in order to restart the study.
      3. If a new application (HRP-200) is submitted for the research,the PI must submit a Study Closure Form (HRP-206) for the expired study.
      4. The Study Closure Investigator Guidance (HRP-806) should be followed.
3. REFERENCES
   1. 21 CFR §56
   2. 45 CFR §46