1 PURPOSE
   1.1 This procedure establishes the process for the IRB Chair to determine whether current subjects may continue in expired research.
   1.2 The process begins when the IRB Chair is notified of a request by an investigator of a request for current subjects to continue in expired research.
   1.3 The process ends when the IRB Chair has communicated a decision and documented the decision in writing.

2 REVISIONS FROM PREVIOUS VERSION
   2.1 Replacement of a Designated Reviewer with IRB Chair; replaces version dated 7/7/11.

3 POLICY
   3.1 None.

4 RESPONSIBILITIES
   4.1 The IRB Chair is responsible to follow these procedures.

5 PROCEDURE
   5.1 Determine from the investigator which subjects need to continue in the expired research, what procedures are being requested to continue, and why.
   5.2 Under no circumstances can new subjects be enrolled.
   5.3 Determine which subjects can continue in the research based on these principles:
      5.3.1 In general, research procedures should be safely discontinued.
      5.3.2 In general, the only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care, these should be provided as such.
      5.3.3 In general, research procedures conducted to collect data with no direct benefit to the subject should not continue.
      5.3.4 In some cases, an ethical issue may be raised where the above general principles may not be followed.
   5.4 Communicate with the investigator using “TEMPLATE LETTER: Continuation of Subjects in Expired Research.”
   5.5 Update the protocol history in the IRB database.
   5.6 Follow “SOP: IRB Records” to file any relevant protocol materials or correspondence to and from the IRB.

6 MATERIALS
   6.1 IRB database
   6.2 SOP: IRB Records
   6.3 TEMPLATE LETTER: Continuation of Subjects in Expired Research

7 REFERENCES
   7.1 None