Subject: Procedure for the Notification of IRB Continuing Review

Procedure:
This procedure outlines the guidelines for the notification to the Investigator of continuing review for previously approved human subjects research by the Institutional Review Board (IRB).

I. Investigator Responsibilities.
   A. The Investigator is responsible for completing the “Application for Continuing Review or Study Closure” according to HRPP policies and procedures.
   B. If a study expires, the Investigator will cease all research activities as instructed in the expiration notice. The Investigator will immediately submit continuing review requirements or notify the IRB of study closure.

II. IRB Committee Responsibilities.
   The IRB Committee will conduct its review in accordance with applicable HRPP Policies and Procedures.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. During the last week of each month the RCA sends out continuing review notifications. The Study Contact is copied on this correspondence. The Application for Continuing Review includes the following information from the database:
      1. IRB number;
      2. Current status;
      3. Expiration date;
      4. Date of previous review;
      5. Principal Investigator;
      6. Title of the study; and
      7. Proposed subject enrollment approved by the IRB.
   B. During the last week of each month, the RCA will access the database team view for continuing reviews and determine which continuing reviews are due to expire in five weeks. The RCA generates and distributes a four-week reminder to the Investigators that have not yet responded to the earlier eight to nine-week notice. The study contact is copied on this correspondence.
   C. During the second and last weeks of each month, the RCA will assess the database team view for continuing reviews and determine which continuing reviews are due to expire in five weeks. The RCA will contact the Investigator and/or the Study Contact by telephone and email, and notify them that the study is due to expire within two weeks. If the RCA is unable to reach the Investigator, the RCA will attempt to contact the Investigator by pager or cellular phone. The RCA will inform the Investigator of the probable outcome if the appropriate continuing review forms are not received in the IRB within 2 business days to allow time for adequate review.