

To:

Date:

From: Nicholas Ferraio, MS, MPA
Acting Director Operations & Regulatory Affairs

Re: **5-Year Renewal**

Study Name:

RSRB Number:

The RSRB office has notified the PCRO that your study is currently awaiting an RSRB 5-year review.

The PCRO conducts an abbreviated Scientific Review of 5-year renewals, designed to evaluate only the changes since the initial review. In order to process your renewal in a timely manner, the PCRO is requesting the following information/answers about your study:

- Completion of the *Department of Pediatrics Clinical Research Proposal Sign-Off Form* (if not already submitted).
- A current Resume/CV.
- Has your project received an accepted form of external scientific review (see attached list) within the last year?
 Yes No

- Has the science in this field changed significantly since your Initial RSRB Review? Yes No If YES, go to next question.
 - If the science has changed significantly since your Initial RSRB Review, have your Yearly Progress Reports and/or Amendments submitted to the RSRB reflected these changes? Yes No
 - If the science has changed significantly, please also provide a brief (no more than one paragraph) explanation of the changes and the protocol changes made to accommodate them.

Please return the requested information to Nicholas Ferraio at P.O. Box 777 or via email to nicholas_ferraio@urmc.rochester.edu.