St. Luke's – Roosevelt Hospital Center
Institute for Health Sciences
Institutional Review Board
432 West 58th Street, Room 207, New York NY 10019
Telephone (212) 523-4370, (212) 523-7253 Fax (212) 523-7442

Memo – Approval of Continuing Review by Expedited Review

To: Richard L. Whelan, MD.

From: Theodore Bania, MD., IRB Co-Chair
Charles W. Paley, MD., IRB Co-Chair

Date: June 27, 2013

IRB# 09-113

Title: Tumor, Preoperative Blood Sample, and Clinical Data Banking for Cancer, Physiology, Immunology and Other Research Studies

The Institutional Review Board reviewed and approved your request for continuing review of the above-cited study. Your protocol was reviewed by Expedited Review since initial review and there have been no changes in the risks to the subjects. Approval will be reflected in the minutes of the IRB meeting on **July 17, 2013.**

The IRB has approved the following individuals responsible for obtaining Informed Consent:

1. Richard Whelan, MD.
2. Alison Estabrook, MD.
3. Vesna Cekic, RN.
4. Paul Tartter, MD.
5. Sharon Rosenbaum-Smith, MD.
6. Eric Moore, MD.
7. Faiz Bhora, MD.
8. Cliff Connery, MD.
9. Hiromichi Miyagaki, MD.

Revisions, modifications or amendment to this protocol and/or patient information may not be made unless reported to the IRB. The only exception would be if these changes were necessary to eliminate apparent immediate hazards to the human subjects. In this case, prompt notification of the IRB is required. Any serious unanticipated adverse events or unexpected reactions including death, loss of limb, need for major operations, etc. should be reported by the Principal Investigator in writing to the IRB within 48 hours of occurrence or receipt of report of occurrence.

Your study will be due for continuing review on or before **June 20, 2014.** Written courtesy reminder attempts by the IRB are sent at least one month prior to the end of the previous approval period; however, maintaining continued approval of your research project is the investigator's responsibility.

FDA regulations require that you notify the IRB when your study is completed.

All correspondence concerning this matter should be submitted electronically to the IRB office via irbsubmit@chpnet.org. If you should have any questions, please contact the IRB Coordinator at 212-523-4370 or 212-523-7253.