St. Luke's - Roosevelt Hospital Center
Institute for Health Sciences
Institutional Review Board
432 West 58th Street, Room 207, New York, NY 10019

MEMO — Approval of New Study by Expedited Review

To: Michael Tirgan, MD
From: Charles W. Paley, MD, IRB Co-Chair
Theodore Bania, MD, IRB Co-Chair
Date: December 9, 2011
IRB #: 11-184
Re: Approval by Expedited Review
Title: Keloid Radiation Registry

The Institutional Review Board has reviewed and approved the above-cited protocol by expedited review. This study is eligible for expedited review because it involves "research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies."

The IRB found that the research poses no greater than minimal risk to the children (45CFR 46.404), that permission from one parent or guardian is required and that children age 12 and older need to sign an assent form for this study. Furthermore, the IRB determined that this study is eligible for a waiver of signature on the consent form under 45CFR 46.117(c)(2)

The Board considers that the selection of subjects is equitable.

This approval will be reflected in the minutes of the IRB meeting of December 21, 2011.

The IRB has approved the following individuals to be responsible for obtaining informed consent:

1. Michael Tirgan, MD

Revisions, modifications or amendments to this protocol and/or consent form 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 operation 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 **December 8, 2012**. You will receive a notice of reminder one-month prior to that time.

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

All correspondence concerning this matter should be submitted electronically to irbSubmit@chpnet.org. If you should have any questions, please contact the IRB Coordinator at 523-4370 or 23-4368.