MEMORANDUM

To: Edward Shaw, M.D.
Radiation Oncology

From: Assistant Director, Institutional Review Board

Date: 5/6/2013

Subject: Human Protocol: BG03-161
A Phase II Randomized Placebo Controlled, Double Blinded Trial to Evaluate the Effects of Fruit and Vegetable Extracts on Intermediate Biomarkers in Head and Neck Cancer Patients
Amendment 5 for IRB Study #BG03-161 (Personnel Change Request)

Study Documents:
Protocol Version: 60A02 Am 17 Protocol wo tracking; Informed Consent Version: Updated Consent CR 2007 60A02 (approved); Advertisements: BG03-161 Advertisement; Other Documents: University of Miami 2010 Approval Letter

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

Dr. Akman will be removed from the study team by a personnel amendment.

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.

Brian Moore

[Signature]