

Office of Research  
Institutional Review Board

MEMORANDUM

To: Jennifer J. Hu, Ph.D.  
Cancer Biology

From: Acting Chairman, Board #1  
Institutional Review Board

Date: May 4, 2004

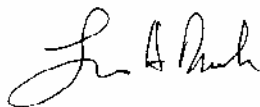
Subject: Human Protocol: BG03-161  
A Phase II Randomized Placebo Controlled, Double Blinded Trial to Evaluate the Effects of Fruit and Vegetable Extracts on Intermediate Biomarkers in Head and Neck Cancer Patients (CCCWFU 60A02) – Amendment #4

The Institutional Review Board voted approval of the amendments listed below at its meeting of May 4, 2004. This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Inclusion of Section 4.4, Post-Treatment Use of Fruit and Vegetable Extracts: Patients will be given the option to continue taking Juice Plus free of charge for five years, following completion of the 12-week study.
- Administrative and editorial changes.
- Consent form revised accordingly.

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.



Lisa Roach

cc: Megan Whelen