

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Kevin High, M.D.
Int Med-Infectious Disease

From: Chair, IRB # 3
Institutional Review Board

Date: 12/18/2008

Subject: Human Protocol: IRB00006819
A Phase III Randomized, Double-Blind, Placebo Controlled Trial of North American Ginseng Extract (CVT-E002; COLD-fX®) to Prevent Respiratory Infection and Reduce Antibiotic Use in Patients with Chronic Lymphocytic Leukemia.
Sponsor Title: Amendment 5

Study Documents:

Protocol Version: 98308 Amend 5 Clean; Informed Consent Version: Amend 3 - Consent clean (approved); Investigator's Brochure: Investigator Brochure - Cold-Fx; Advertisements: 98308 WFU Recruitment Letter

The Institutional Review Board voted approval of the amendments listed below at its meeting of 12/17/2008. This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Administrative/editorial revisions throughout protocol.

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.



Anthony Liguori, Ph.D.