

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

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

From: Chair, IRB # 3
Institutional Review Board

Date: 1/22/2009

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 6

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 1/21/2009.
This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Notification that study is closed to enrollment due to meeting accrual goal. Subject follow-up and data analysis continues.

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.