

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

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

From: Chair, IRB # 1
Institutional Review Board

Date: 10/8/2008

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.
Amendment 2 for IRB Study #IRB00006819

Study Documents:

Protocol Version: 98308 Cold-fX Protocol Amend 2; Informed Consent Version: 98308 Consent - Amend 2 Clean (approved); Investigator's Brochure: Investigator Brochure - Cold-Fx

The Institutional Review Board voted approval of the amendments listed below at its meeting of 10/7/2008. This action of the full Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Total sample size increased from 280 to 336.
- Added additional information on immune function testing that was mentioned in previous paragraph of consent.
- Administrative editorial and clarifying changes made to protocol and consent.
- Schema Page: Moved SGOT, SGPT, AND Total Bilirubin from Exclusion Criteria to Inclusion Criteria.
- Added Negative Serum Pregnancy test within 10 days of registration to Study Parameter table.
- Section 12 Table: Telephone contact line: Deleted EOS and added Post Treatment

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.



Richard Weinberg, M.D.