

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

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

From: Vice Chair, Institutional Review Board

Date: 9/8/2008

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 1 for IRB Study #IRB00006819

Study Documents:

Protocol Version: 98308 Cold-Fx Protocol; Informed Consent Version: 98308 Cold-Fx Amend 1 (approved); Investigator's Brochure: Investigator Brochure - Cold-Fx

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:

- Administrative and editorial protocol revision.
- Consent form revision to more clearly identify risks (More Common/Less Frequent) (no subjects enrolled to date).

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.



Scott Rhodes, Ph.D.