

Office of Research  
INSTITUTIONAL REVIEW BOARD.

**MEMORANDUM**

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

From: Chair, IRB # 2  
Institutional Review Board

Date: 8/15/2008

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.

Study Documents:

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

The Institutional Review Board (IRB) has approved the above-named protocol and study documents. IRB approval was activated on 8/12/2008. A written request for renewal together with a summary progress report must be submitted to the Board at least one month prior to 8/12/2009.

Written informed consent will be obtained; Individual Authorization will be obtained.

Federal regulations and Board policy require that you promptly report to the Board for review/approval:

- Proposed changes in the research activity (e.g., protocol amendments; consent form revision; advertisements). Changes may not be initiated without IRB review and approval, unless necessary to eliminate an immediate hazard to subjects.
- Serious adverse events and unanticipated problems involving risks must be reported to the Board, institutional officials, FDA, sponsor and other regulatory agencies as required by the protocol, local policy and state or federal regulation.

Please provide a final report to the Board when the project is completed and Board approval can be terminated.

This IRB is in compliance with the requirements in Part 56, Subchapter D, Part 312 of the 21 Code of Federal Regulations published January 27, 1981 and Part 46, Subpart A of 45 CFR published January 26, 1981.

A handwritten signature in black ink, appearing to read "Gregory Hawkins". The signature is written in a cursive style with a large initial "G" and "H".

Gregory Hawkins, Ph.D.