

Office of Research  
INSTITUTIONAL REVIEW BOARD.

MEMORANDUM

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

From: Chair,  
Institutional Review Board

Date: 8/3/2009

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.

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

This is to confirm for your record that the Institutional Review Board reviewed your progress report and consent form, containing compounded HIPAA authorization language, if applicable, for the above-named protocol. IRB approval was activated on 8/3/2009 and will expire on 8/12/2010. If the protocol is to remain active longer, a written request for renewal, together with a summary progress report, and a copy of the current consent form, if applicable, should be submitted to the Board at least one month prior to expiration.

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.



Richard Weinberg, M.D.