

**CCCWFU CCOP RESEARCH BASE
PROTOCOL AMENDMENT CHANGE FORM**

Study Title: 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

Protocol #: 98308

Date of Submission to IRB: 11/07/08

IRB Number: 00006819

IRB Approval Date: 11/10/08

Principal Investigator: Kevin High

Protocol Amendment # 4

PI Signature: _____

RB PIO Fax #: 716-6275

Brief description of each change in the study protocol and rational. (Additional pages may be used as needed):

1. Changed Amendment #3 to Amendment #4 in header.

2. Updated Participating Sites: Added Carle Cancer, Geisinger Clinic, Hematology Oncology Associates, Main Line, Sioux Community Cancer Consortium, St. Vincent Hospital, and Caldwell Memorial.

3. Section 4.1.3 Deleted "18-25 week...drug" and "Amount based...randomization". Added "enough study.....until 4/30/09. Packaging: Deleted "56 capsules" and "84 capsules"

4. Section 4.2 Treatment Plan: 3rd paragraph 5th line deleted "time of....2009" and added "within 2 weeks ofand continue"

5. Section 8.2 added: "Completed shipping kit form"

6. Section 10.1: Deleted "of registration" added "After the site.....Biologics, Inc". Table: Deleted "Post Randomization" added "After starting drug" Added "Appendix 10". Added "x" in Baseline column on Current Medication form line. 5: Changed 10 ml to 5 ml

7. Section 12.1: Added "Baseline" to last line of table.

8. Appendix 13: Added "If there are....716-9134. Blood: Changed 10 ml to 5 ml.

Consent Form Changes

Brief description of each change in the consent form and rational.

1.

2.

3.

4.

5.