

**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: 12/10/08

IRB Number: 00006819

IRB Approval Date: 12/17/08

Principal Investigator: Kevin High

Protocol Amendment # 5

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 #4 to Amendment #5 in header and included approval date of 12/17/08.
2. Title page: Added "Amendment #5 – 12-17-08"
3. Page xi: Treatment Phase box: added "initiated no later than Dec 31 st and continue"
4. Page xi: Added "Note: Biologics, Inc will be closed...January 1 st and 2 nd ."
5. Page 3: Section 3.2.1: added "Patients with previous...5 years are allowed."
6. Page 8: Section 4.2: last paragraph: Added "All subjects MUST...please plan accordingly." Added "Biologics, Inc will be closed... January 1 st and 2 nd ."
7. Page 9: Section 4.4: Added "Biologics, Inc will be closed...January 1 st and 2 nd ." <ul style="list-style-type: none"> • Deleted "from enrollment" • Added "must be initiated no later than December 31, 2008 and continue"
8. Page 11: Section 10.1: Added "and all subjects must initiate drug no later than December 31 st ." Added "Biologics, Inc will be closed...January 1 st and 2 nd ."
9. Appendix 8 Changes: Requested changes by CTSU were completed. <ul style="list-style-type: none"> • Deleted "and randomization...Arm 2." • Added: "therefore, a randomization...confirmation e-mail." • Deleted: "The process of randomization...the appropriate treatment."

Consent Form Changes

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

1. none
2.
3.
4.
5.