

**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<sup>®</sup>) to Prevent Respiratory Infection and Reduce Antibiotic Use in Patients with Chronic Lymphocytic Leukemia**

**Protocol #: 98308**

**Date of Submission to IRB:**

**IRB Number: IRB00006819**

**IRB Approval Date:**

**Principal Investigator: Kevin High**

**Protocol Amendment # 2**

**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):

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| 1. Added "Exempt" to header. Page vii – added "Any CTSU Participating Member"  |
| 2. Table of Contents: Added "2.3 Exploratory...Objectives". Deleted "Pathology...Bank" Added "Laboratory Specimen...Procedures". "Deleted: "Correlative...Studies". Added 10.1, 10.2, and 12.1. Revised numbering. |
| 3. Schema page: added "336" under Enrollment. Added "336" to sample size. Deleted "140..arm" added "See Section 14.1"  |
| 4. Page 3: Added "3.2 and formatted numbering" Added "ginseng" to section 3.2.3.   |
| 5. Section 4.1.2: Added "Used drug....policies and procedures". Added "4.1.3 Packaging and Labeling"   |
| 6. Added Section 8. Laboratory Specimen....Procedures  |
| 7. Added "Serum pregnancy Test" to Section 10. Added "6. A negative....of registration." Deleted 5 "Will only...endpoint" Added "One 10ml .....See Appendix 13".   |
| 8. Section 14.1 added additional paragraph at end "In addition...effect with 90% power."   |

**Consent Form Changes**

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

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|---|
| 1. In section "How Many People" Changed number of total enrolled to "three hundred and thirty-six (336)"                            |
| 2. In section "What is Involved" Added paragraph "Immune function testing...for immune function testing."                           |
| 3. "Reproductive Risks" Deleted "two negative pregnancy...days apart" Added "a negative serum pregnancy.....prior to registration". |
| 4. Page 2: Changed 2-3 tablespoons to 2-3 teaspoons.  |
| 5.  |

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|   |
|---|
| 1. Page iii: Second line. Changed “aligned” to “affiliated”. Deleted “(or its...CCOP sites)”. 2 <sup>nd</sup> Bullet added “8”. Fourth bullet: added “signed consents”                  |
| 2. Schema: Moved SGOT and Total Bilirubin from Exclusion Criteria to Inclusion Criteria. Added “Untreated CLL” to Inclusion Criteria  |
| 3. Page 3: Added 3.1.8 “Untreated CLL”  |
| 4. Section 4.6: Deleted “In the absence...event(s)”.  |
| 5. Section 12.1: Replaced “CTSU Participants” with “Submission Schedule” In Table: Deleted “EOS” from Telephone line and added “Post Treatment”. Added Section 12.2 “CTSU...procedures” |
| 6. Added 13.5 to page 17.   |
| 7. Section 14.5 Second paragraph: Added “it is recommended that”  |
| 8.  |

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| 1. |
| 2. |
| 3. |
| 4. |
| 5. |