

WFU# 07-02-03 <b>CCOP Research Base # 98308</b> A Phase III Double Blind, Placebo Controlled Trial of North American Ginseng Extract (CVT-002; COLD-fx) to Prevent Respiratory Infection and Reduce Antibiotic Use in Patients with Chronic Lymphocytic Leukemia	Site MR#:	Site Name:
	Patient Initials:	Staff Completing Form:
	PID:	Date:
<b>CTSU SITES ONLY:</b> <input type="checkbox"/> CTEP Assigned Site Code _____ <input type="checkbox"/> Investigator Associate Code _____		

### Appendix 2: Eligibility Checklist/ Registration Form

<b>MD Group*</b>	<b>IRB Code*</b>
<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>
<b>Protocol and Patient ID</b>	<b>Registration and Consent Date (MM/DD/YYYY)</b>
Protocol ID: <input style="width: 90%;" type="text"/> New Patient ID: <input style="width: 90%;" type="text"/>	Registration Date: <input style="width: 90%;" type="text"/> Consent Date: <input style="width: 90%;" type="text"/> Health Authorization Date: <input style="width: 90%;" type="text"/>
<b>MD Number*</b>	<b>ICD-9 Code*</b>
<input style="width: 90%;" type="text"/>	<input style="width: 90%;" type="text"/>

### Patient Information

First Name/Initial <input style="width: 90%;" type="text"/>	Last Name/ Initial <input style="width: 90%;" type="text"/>
SSN (the last 4 digits) <input style="width: 90%;" type="text"/>	DOB (MM/DD/YYYY) <input style="width: 90%;" type="text"/>
Height (in) <input style="width: 90%;" type="text"/>	Weight (lbs) <input style="width: 90%;" type="text"/>
Zip Code <input style="width: 90%;" type="text"/>	County of Residence <input style="width: 90%;" type="text"/>
Eligible <span style="float: right;">Yes/ No</span>	Gender <span style="float: right;">Male/ Female</span>
Race: <input type="checkbox"/> White <input type="checkbox"/> Black Asian <input type="checkbox"/> Native American or Alaskan <input type="checkbox"/> Native Hawaiian or Pacific Islander <input type="checkbox"/> Unknown	Ethnicity: <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Unknown
Insurance (check all that apply) <input type="checkbox"/> Medicare <input type="checkbox"/> Medicaid <input type="checkbox"/> Private <input type="checkbox"/> None	
Any part of care at VA? <span style="float: right;">Yes/ No</span>	Site Contact Person <input style="width: 90%;" type="text"/>
Site Contact Phone Number (XXX-XXX-XXXX) <input style="width: 90%;" type="text"/>	Site Contact e-mail <input style="width: 90%;" type="text"/>
* Information can be obtained from online registration screen.	

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### Protocol Specific

1. Patient daytime phone number (XXX-XXX-XXXX)	<input type="text"/>
2. Patient alternate phone number (XXX-XXX-XXXX)	<input type="text"/>
3. Patient's mailing address for delivery of study medication (no PO Box)	<input type="text"/>
4. Age $\geq$ 18?	Yes / No
5. Phenotypic evidence of CLL (Fax report) (check all that apply) _____ Flow Cytometry _____ Bone marrow biopsy	
6. Date of Diagnosis (mm/dd/yyyy)	____ / ____ / ____
7. Life expectancy >12 months?	Yes / No
8. Rai Stage (Select One) 0, I, II, III, IV	
9. Has received Influenza vaccine prior to registration? If yes, date Influenza vaccine was given ____/____/____ If no, will patient receive Influenza vaccine prior to start of protocol therapy?	Yes / No  Yes / No
10. History of HealthCare Professional Diagnosed Herpes Zoster If yes, give date ____ / ____ / ____	Yes / No
11. Current or history of HIV, cirrhosis, CVD malignancy other than CLL? (non-melanoma skin cancers and carcinoma in-situ of the cervix allowed)	Yes / No
12. Creatinine < 2.0 mg/dl (or Creatinine clearance > 50 ml/min if serum creatinine > 2.0)? (Fax report)	Yes / No
13. ECOG? (Zubrod)	0, 1, 2
14. SGOT (AST), SGPT (ALT) <2.5 x ULN? (Fax Report)	Yes / No
15. Total Bilirubin < 1.5 x ULN (Fax Report)	Yes / No
16. Current IGG Level _____ (Fax Report)	> or < 500
17. Pregnant or breast-feeding? _____ N/A Negative serum pregnancy test within 1 week prior to registration for women of childbearing potential. Date (mm/dd/yyyy) (Fax Report)	Yes / No

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18. Allergy to Ginseng products?	Yes / No
19. Current or prior treatment within the last 3 months with chlorambucil?	Yes / No
20. Current treatment with corticosteroids $\geq$ equivalent 20 mg/day prednisone?	Yes / No
21. Current or prior treatment with fludarabine, alemtuzumab, rituximab, IV, IVG, hematopoietic stem cell transplantation?	Yes / No
22. Current use of Warfarin?	Yes / No
23. Current Prophylaxis with TMP-SMX?	Yes / No
24. Current use of antibiotic Prophylaxis other than TMP-SMX?	Yes / No
25. Use of other herbal ginseng products within 1 month prior to protocol therapy?	Yes / No
26. Seasonal or environmental allergies requiring the use of antihistamines, intranasal or systemic corticosteroid?	Yes / No
27. Received any of the following vaccines in the past?	
Pneumococcal	Yes / No
Herpes Zoster	Yes / No
Tetanus	Yes / No

### Online Registration:

**(CTSUS Participants: see § below)** The Eligibility Checklist / Registration Form must be completed and submitted online (<http://www1.wfubmc.edu/cancer/researchBase/Registration/>) for the patient to be registered. Once the patient information has been entered a confirmation page will appear. Print a copy of the confirmation page for your records.

A copy of the online Eligibility Checklist / Registration Form, signed consent form, initial flow sheet, pathology report, lab and scan reports, if required, should be faxed to the Data Management Center to 336-713-6476 or mailed. These forms should be retained in the patient's study file and will be evaluated during an institutional NCI/CCCWFU CCOP Research Base site member audit.

**§ CTSUS Participants:** The Eligibility Checklist / Registration Form and CTSUS Patient Enrollment Transmittal Form must be completed and faxed to the CTSUS Patient Registrar at 1-888-691-8039 for the patient to be registered. See appendix 8 of the protocol for details. A copy of the online Eligibility Checklist / Registration Form, signed consent form, initial flow sheet, pathology report, lab and scan reports, if required, should be submitted to the CCCWFU CCOP Research Base Data Management Center as outlined in Appendix 8 of the protocol.