

## APPENDIX 8

### CANCER TRIALS SUPPORT UNIT (CTSU) PARTICIPATION PROCEDURES

#### REGISTRATION/RANDOMIZATION

Prior to the recruitment of a patient for this study, investigators must be registered members of the CTSU. Each investigator must have an NCI investigator number and must maintain an “active” investigator registration status through the annual submission of a complete investigator registration packet (FDA Form 1572 with original signature, current CV, Supplemental Investigator Data Form with signature, and Financial Disclosure Form with original signature) to the Pharmaceutical Management Branch, CTEP, DCTD, NCI. These forms are available on the CTSU registered member Web site or by calling the PMB at 301-496-5725 Monday through Friday between 8:30 a.m. and 4:30 p.m. Eastern time.

Each CTSU investigator or group of investigators at a clinical site must obtain IRB approval for this protocol and submit IRB approval and supporting documentation to the CTSU Regulatory Office before they can enroll patients. Study centers can check the status of their registration packets by querying the Regulatory Support System (RSS) site registration status page of the CTSU member web site at <http://members.ctsu.org>

All forms and documents associated with this study can be downloaded from the WFU-07-02-03 Web page on the CTSU registered member Web site (<https://members.ctsu.org>). Patients can be registered only after pre-treatment evaluation is complete, all eligibility criteria have been met, and the study site is listed as ‘approved’ in the CTSU RSS.

#### Requirements for WFU-07-02-03 site registration:

- CTSU IRB Certification
- CTSU IRB/Regulatory Approval Transmittal Sheet

#### Pre-study requirements for patient enrollment on WFU-07-02-03

- Patient must meet all inclusion criteria, and no exclusion criteria should apply
- Patient has signed and dated all applicable consents and authorization forms
- The Specimen Kit Shipping Information for CTSU Sites document must be completed and faxed to the number indicated on the form prior to registering your first patient. The form is located under the Site Registration Documents section of the WFU 07-02-03 web page.

#### CTSU Procedures for Patient Enrollment

1. Contact the CTSU Patient Registration Office by calling 1-888-462-3009 between 9:00 a.m. and 5:30 p.m. Eastern Time, Mon-Fri. Leave a voicemail to alert the CTSU Patient Registrar that an enrollment is forthcoming. Registrations received after 5:00 pm ET will be processed the next business day. For immediate registration needs (e.g. within one hour) call the registrar cell phone at 1-301-704-2376 during registration office hours.

2. Complete the following forms:

- CTSU Patient Enrollment Transmittal Form
- Eligibility Checklist / Registration Form

3. Fax these forms to the CTSU Patient Registrar at 1-888-691-8039 between the hours of 9:00 a.m. and 5:30 p.m., Mon-Fri, Eastern Time (excluding holidays); however, please be aware that registrations received after 5:00 p.m. will be processed the next day. The CTSU registrar will check the investigator and site information to ensure that all regulatory requirements have been met. The registrar will also check that forms are complete and will follow-up with the site to resolve any discrepancies.
4. Once investigator eligibility is confirmed and enrollment documents are reviewed for compliance, the CTSU registrar will access the CCCWFU Research Base registration web site and enter the patient enrollment data on-line. A confirmation of registration will be forwarded to the enrolling site indicating the patient ID# to be used on all future forms and correspondence. Note that this is a double-blind, placebo-controlled trial; therefore a randomization assignment will not be provided in the confirmation e-mail.

Treatment will continue from the time of enrollment through April 30, 2009. This allows for a consistent period of time during which all subjects will be on protocol (Jan 1- April 30). (See section 4.2 of protocol)

## DATA SUBMISSION AND RECONCILIATION

1. All case report forms (CRFs) associated with this study must be downloaded from the WFU-07-02-03 Web page located on the CTSU registered member Web site (<https://members.ctsu.org>). Sites must use the current form versions and adhere to the instructions and submission schedule outlined in the protocol.
2. Submit all completed CRFs, clinical reports, and transmittals directly to the CCCWFU Research Base Data Management Center (DMC) as indicated in the cover pages of the protocol. Do not send study data to the CTSU. A completed CCCWFU Research Base DMC Data Submission Checklist should accompany all data submissions. Your institution's standard fax transmittal cover sheet should accompany all data submissions.
3. Quality Control (QC) reports containing data query and delinquency information will be generated on a monthly basis by the CCCWFU CCOP Research Base DMC and posted on the CTSU members' website for retrieval and reconciliation by clinical site staff. Sites will be notified when new reports are posted. Please send query responses and delinquent data to the CCCWFU CCOP Research Base DMC and do not copy CTSU Data Operations. Each site should have a designated CTSU Administrator and Data Administrator. Only the Administrator or Data Administrator will have access to QC reports and must keep their CTEP account contact information current. This will ensure timely communication between the site and the CCCWFU CCOP Research Base.

## **SPECIAL MATERIALS OR SUBSTUDIES**

### Protocol Pilot Phase Specimen Collection

All sites will participate in the pilot phase of this study for testing of Influenza and RSV Serology as outlined in Section 8 of the protocol. Sites must request specimen kits prior to enrollment of their first patient.

## **SERIOUS ADVERSE EVENT REPORTING** (Section 14 of protocol)

1. CTSU sites must comply with the expectations of their local Institutional Review Board (IRB) regarding documentation and submission of adverse events. Local IRBs must be informed of all reportable serious adverse reactions.
2. CTSU sites will assess and report adverse events according to the guidelines and timelines specified in the protocol.
3. Do not send adverse event reports to the CTSU.

## **DRUG PROCUREMENT** (Section 4 of protocol)

Cold FX (CVT-E002) and matching placebo are manufactured by CV Technologies and provided free of charge to study participants. Biologics, Inc. will distribute the Cold FX or placebo directly to the site following patient registration for each patient enrolled in the study.

You may navigate to the Agent Accountability Record (Med Log) by using the following link <http://ctep.cancer.gov/forms/accountability.pdf> .

## **REGULATORY AND MONITORING**

### Study Audit

To assure compliance with Federal regulatory requirements [CFR 21 parts 50, 54, 56, 312, 314 and HHS 45 CFR 46] and National Cancer Institute (NCI)/ Cancer Therapy Evaluation Program (CTEP) Clinical Trials Monitoring Branch (CTMB) guidelines for the conduct of clinical trials and study data validity, all protocols approved by NCI/CTEP that have patient enrollment through the CTSU are subject to audit.

Responsibility for assignment of the audit will be determined by the site's primary affiliation with a Cooperative Group or CTSU. For Group-aligned sites, the audit of a patient registered through CTSU will become the responsibility of the Group receiving credit for the enrollment. For CTSU

Independent Clinical Research Sites (CICRS), the CTSU will coordinate the entire audit process.

For patients enrolled through the CTSU, you may request the accrual be credited to any Group for which you have an affiliation provided that Group has an active clinical trials program for the primary disease type being addressed by the protocol.

Details on audit evaluation components, site selection, patient case selection, materials to be reviewed, site preparation, on-site procedures for review and assessment, and results reporting and follow-up can be found in the CTMB Monitoring Guidelines and are available for download from the CTEP web page <http://ctep.cancer.gov/monitoring/guidelines.html>.

### **Health Insurance Portability and Accountability Act of 1996 (HIPAA)**

The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule referenced in HHS 45 CFR 164.501. Templated language addressing NCI-U.S. HIPAA guidelines are provided in the HIPAA Authorization Form located on the CTSU website.

The HIPAA Privacy Rule does not affect participants from outside the United States. Authorization to release Protected Health Information is NOT required from patients enrolled in clinical trials at non-US sites.

### **Clinical Data Update System (CDUS) Monitoring**

This study will be monitored by the Clinical Data Update System (CDUS). The CCCWFU CCOP Research Base Data Management Center fulfills this obligation by electronic submission of cumulative quarterly reports to DCP/CTEP.