



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Operations Office

Date: May 12, 2009

To: Primary CRA's, Nursing Board Members

From: Deb Barton, Ph.D.
Tracee Shevlin

Re: N07C2, The Use of Wisconsin Ginseng (panax quinquefolius) to Improve Cancer-Related Fatigue: A Randomized, Double-Blind, Placebo-Controlled Phase III Study

As a result of Addendum 1 (which changed the lab from MCTS to MML), the saliva kits for N07C2 now have generic labels that do not include any pre-printed information. It is **CRITICAL** that the labels be prepared and put on the salivettes **BEFORE** giving the patient the kit and that the patient is instructed to use the correct salivette for each collection. The current kits do NOT contain these instructions, so please make sure EVERYONE in your institution who is participating in this trial has this information. Failure to label the salivettes as instructed will make the saliva unable to be analyzed in any way since it will not be known which tube equates to what time of day. We are updating the instructions for future kits with this information.

CRITICAL STEP: Preparing the labels for the Salivettes.

1. Write the Study ID (N07C2), patient's initials, and patient Registration ID on EACH of the six labels provided in the kit. In addition, one label each should have the following information written on it:
 - D1 wake**
 - D1 30 min**
 - D1 bedtime**
 - D2 wake**
 - D2 30 min**
 - D2 bedtime**
2. Place these six labels on the Salivettes.
3. Assure the supplies are properly labeled and provide the patient with the Salivettes and Appendix IX "Saliva Collection Instructions" of the protocol.
4. **Instruct the patient to use all the D1 salivettes on the first day, beginning with the one labeled "wake", then the one 30 min and finally, at the end of the day, the one labeled "bedtime". Follow the same process on the second day with the D2 salivettes.**

Do not hesitate to contact me if you have any questions. Thanks for your attention to this important matter. Deb Barton 507-255-3812; barton.debra@mayo.edu or Tracee Shevlin 507-538-6647; shevlin.tracee@mayo.edu.