

North Central Cancer Treatment Group

N0871, A Phase II Study of Carboplatin (CBDCA), Paclitaxel (TAXOL), and Everolimus (RAD001) in Previously Untreated Patients with Measurable Disease with Cancer of Unknown Primary (CUP)

Addendum 9 – February 10, 2012

Summary

- An updated Investigators Brochure (IB) for Everolimus dated November 7, 2011 has been received. Therefore, the consent form has been updated accordingly.
- Administrative/editorial changes.

Replacement pages are included. Please incorporate into the protocol and keep this addendum with your protocol.

Title Page Addendum 8 has been added and the NCI version date has been revised.

Protocol Resources

Page 2: Tamra ~~Chomjak~~ is now known as Tamra **Losinski**.

Section 14.0 **Body Fluid Biospecimens**

Page 44: The shipping instructions in Section 14.254 have been updated as follows:
Ship specimens via Priority Overnight service, Monday – Thursday ONLY, to the BAP ~~Shared Resource~~ **Freezer**. Do not send sample on weekends or the day before or day of an observed national holiday.

Appendix I **Consent Form**

Page 9: Due to the receipt of the updated IB for Everolimus, the last bullet under the Rare but serious risk section has been deleted as follows:

- ~~Re-activation of hepatitis infection (if you have previously been diagnosed with hepatitis, which is a type of infection in the liver) (deleted as hepatitis also listed under the Less Likely section)~~