

North Central Cancer Treatment Group

N0745: Phase I/II Randomized Trial of Sorafenib and Bevacizumab as First-Line Therapy in Patients with Locally Advanced or Metastatic Hepatocellular Carcinoma

Addendum 8 – November 4, 2011

Summary

- Dr. Shaji Kumar, Research Base Laboratory Cochair has been removed from title page.
- Dr. Zoran Gatalica, Pathology – NCCTG has been removed from the title page and Section 17.
- Administrative changes.

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

Title page Addendum 8 has been added and the NCI version date has been updated.

Drs. Shaji Kumar and Zoran Gatalica have been removed.

Section 14.0 **Body Fluid Biospecimen Submission**

Page 54: Sections 14.255 and 14.256 have been updated to reflect current shipping instructions as follows:

14.254 Use kit **shippers with** mailing labels for shipment to BAP.

14.255 BAP ~~Receiving Freezer~~ will forward specimens immediately to the NCCTG Research Base Biospecimens Accessioning and Processing (BAP) Shared Resource, ~~Stable 13-10A~~ **Hilton CL-21**, Attention: BAP Supervisor.

Section 17.0 **Pathology Considerations/Tissue Biospecimens**

Page 95: Due to the removal of Dr. Zoran Gatalica from the protocol, Section 17.25 has been revised as follows:

17.25 Review is being performed ~~by an external reviewer not located~~ at the NCCTG Research Base at Mayo Clinic Rochester. Please ship specimens and appropriate materials as indicated below:

17.251 ~~The Pathology Submission Form must be sent to the NCCTG Operations Office at Mayo Clinic Rochester. Please do not send this form to the external reviewer listed below~~ **Mayo Clinic Rochester (MCR) patients only: please forward pathology material to Dr. Thomas C. Smyrk, Hilton 11, for review.**

- 17.252 ~~Mayo Clinic Rochester (MCR) patients only: please forward pathology material to Dr. Thomas C. Smyrk, Hilton 11, for review~~ **For all other NCCTG memberships, including MCJ AND MCA, materials should be sent to the NCCTG Research Base:**

**NCCTG Operations Office
Attn: PC Office (Study N0745)
RO_FF_03_24-CC/NW Clinic
200 First Street SW
Rochester, MN 55905**

- 17.253 ~~For all other NCCTG memberships, including MCJ and MCA, materials should be sent to the Caris Life Sciences Primary CRA:~~ **The NCCTG Operations Office will forward the diagnostic slides to Dr. Thomas C. Smyrk, Hilton 11, for central review to confirm diagnosis of Hepatocellular carcinoma.**

~~Rhonda Boblett
N0745 NCCTG Pathology Review
Caris Life Sciences
4207 East Cotton Center Blvd.
Phoenix, AZ 85040~~

- ~~17.254 Rhonda Boblett will accession the pathology materials and forward the materials to Dr. Thomas C. Smyrk for central review to confirm diagnosis of hepatocellular carcinoma.~~