

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 9 – February 3, 2012

**Summary**

This addendum is in response to a Request for Amendment (RA) from the National Cancer Institute (NCI) dated December 29, 2011 concerning Sorafenib. The Drug Information section and the Phase II consent form have been updated accordingly.

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

**Title page** Addendum 9 has been added and the NCI version date has been updated.

**Section 15.0 Drug Information**  
Page 59-62: Due to the receipt of the RA for Sorafenib, Section 15.11 has been replaced in its entirety.

**Appendices IA & IB Consent Forms**

Page 8: Due to the receipt of the RA for Sorafenib, the “Rare but serious” section of the consent forms have been updated as follows:

**Rare but serious:**

- Collection of signs and symptoms that indicate sudden heart disease in which the heart does not get enough oxygen. Sudden symptoms such as chest pain, shortness of breath, or fainting could indicate heart disease and should be reported right away. Signs such as abnormal EKG and blood tests can confirm damage to the heart.
- Decrease in heart's ability to pump blood during the "active" phase of the heartbeat (systole)
- Heart attack caused by a blockage of a blood vessel supplying part of the heart
- **Gastrointestinal perforation: A tear or hole in the stomach or gut that can lead to serious complications and may require surgery to repair** ~~Hole in a part(s) of the digestive tract~~ (*wording expanded*)
- Serious potentially life-threatening type of allergic reaction that may cause breathing difficulty, dizziness, low blood pressure, and loss of consciousness
- Bleeding in the brain
- Collection of symptoms including headache, confusion, seizures, and vision loss associated with imaging findings (MRI, CT Scan)
- Severe reaction of the skin and gut lining that may include rash and shedding or death of tissue
- Potentially life-threatening condition affecting less than 10% of the skin in which cell death causes the epidermis (outer layer) to separate from the dermis (middle layer)