

North Central Cancer Treatment Group

N054C: Phase II Study of Sorafenib/Bevacizumab as Salvage Therapy in Patients with Metastatic Colorectal Cancer

Update 1 – May 13, 2009

Summary

- In Section 8.3 the dose modification table has been replaced for clarification
- At the request of NCI, the CAEPR for bevacizumab, dated June 19, 2007 has been added to Section 15.0 and the consent form has been revised accordingly
- The consent form has been revised for sorafenib due to review of the sorafenib version 2.2 CAEPR, dated December 17, 2008
- Administrative/Editorial Changes

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

Title Page

Page 1:

The NCI version date has been updated.

The activation date has been entered in the Document History and for Study Participants Dater Activated.

Addendum 1 (approved by CTEP on May 1, 2009) and Update 1 (submitted with the activation Status Change) have been added to the title page with an effective date of May 13, 2009.

Section 12.0

Page 40:

Descriptive Factors

The blank line following “Date:” has been removed to avoid confusion. The date bevacizumab was last received will be collected on the On Study form and should not be entered here.

Section 18.0

Page 88:

Records and Data Collection Procedures

The row for the Patient Compliance Questionnaire has been deleted as the form is no longer being used.