



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Date: July 13, 2007

To: Primary Clinical Research Associates

From: Janis Wobschall
Protocol Development Coordinator

Re: N0572: A Phase I/II trial of Sorafenib and CCI-779 in Recurrent Glioblastoma

It has been determined that the consent form Appendix IC (Phase II Patients not Undergoing Surgery) distributed with NCCTG Addendum 3 July 6, 2007 did not include all of the changes noted in the addendum summary. The addendum summary document correctly lists all changes.

A corrected version of Appendix IC is attached with this e-mail and is posted on the NCCTG web site.

The corrections made are as follows:

- Under “What will happen in the study” section, a new row was added entitled “Cycle 1/Day 1” for research blood draw. Note: This has been deleted from the “Weekly (first 4 weeks) then every other week (subsequent cycles)” row.
- Under the “Very Common” risks for CCI-779, “Fainting” has been deleted.
- Under the “Common” risks for CCI-779, “Abnormal amount of protein in the blood that is needed for blood clotting” and “Higher acid levels in blood” have been added.
- Under the “Also reported” risks for CCI-779, “Hole in the bowel” and “Temporary unconsciousness” have been deleted.
- Under the “Also reported” risks for CCI-779, “Fainting” has been added.

Please note that the effective date of July 6, 2007 will remain the same.

If you have any questions, please feel free to contact me at 507/284-4852.

JW/dg
Enclosure