



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Date: September 10, 2010

To: Primary Clinical Research Associates

From: Sara Braun
Research Protocol Specialist III

Re: Correction to Rituximab Risk List affecting the following studies:

N0682, A Phase II Clinical Trial of Denileukin Diftitox in Combination with Rituximab in Previously Untreated Follicular B-cell Non-Hodgkin's Lymphoma

N078D, Phase I/II Trial of Rituximab, Cladribine, and Temsirolimus (RCT) Therapy in Newly Diagnosed Mantle Cell Lymphoma (MCL)

CTEP has issued a correction to the Risk List for the drug Rituximab which was incorporated into the following studies in response to an Action Letter:

N0682: Addendum 7 - Effective date June 25, 2010

N078D: Addendum 5 - Effective date June 25, 2010

Under the "Rare but serious risks for Rituximab", CTEP has issued the following correction:

- Disease affecting brain tissue, caused by ~~the JC virus (specifically the JC virus: Jacob~~ **Cruetzfeld virus**

CTEP has instructed the Research Base to make this correction with the next addendum for each of these studies. Since your site is allowed to add risks or re-word risks in the model consent form, you may choose to make this correction to your local consent form now or you can wait for the next addendum. Please keep this e-mail for your records.

If you have any questions, please feel free to contact me at 507-538-8226 or braun.sara@mayo.edu.