

North Central Cancer Treatment Group

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

Addendum 9 – February 4, 2011

**Summary**

- Revision to Section 7.321 to clarify rituximab DLT's
- Added "Nonhematologic adverse event attributed to rituximab" in the "At Time of Retreatment" in the rituximab portion of Section 8.0.
- Editorial/Administrative Changes.

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

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

**Section 7.0** **Adverse Event (AE) Reporting and Monitoring**  
 Page 20 Section 7.321 has been revised to add Footnote 3 for clarifying Nonhematologic DLT's, as follows:

**3. Rituximab infusion related adverse events will not be considered dose-limiting.**

**Section 8.0** **Dosage Modification Based on Adverse Events**  
 Page 23 The following row has been added for correction under the "At Time of Retreatment" in the rituximab portion of Section 8.0:

<p><b>Nonhematologic adverse event attributed to rituximab</b></p>	<p>• <b>Grade 4 infusion related adverse events</b></p>	<p><b>Rituximab</b></p>	<p><b>Stop rituximab infusion immediately and omit any remaining dose for current cycle. May resume rituximab at subsequent cycle with 50% dose reduction if toxicity has resolved. If 50% dose is well tolerated (&lt; grade 3 toxicity) may escalate back to 100% dose with subsequent cycles.</b></p>
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