

NORTH CENTRAL CANCER TREATMENT GROUP
NCCTG PRE-REGISTRATION (STEP 1) ELIGIBILITY CHECKLIST N078D

02/04/2011
Page 1 of 2

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

Phase I patients only: Prior to checking eligibility and pre-registering a patient, contact the Registration Office (507/284-4130) for study status and dose level and to insure that a place on the protocol is open to the patient.

To pre-register a patient, call (507/284-4130) or fax (507/284-0885) a completed (Step 1) pre-registration eligibility checklist to the Registration Office between 8 a.m. and 4:30 p.m. Central time Monday through Friday.

Phase II patients only: To pre-register a patient, access the NCCTG web page at <https://ncctg.mayo.edu/training> and enter the remote registration/randomization application.

Registration date (date on) (mm/dd/yyyy) ___/___/_____

Patient study ID number (provided at time of Reg/Random) _____

NCCTG member (participant sponsor) _____

NCCTG treating location _____

NCCTG treating physician _____

Institution patient number (local subject number) _____

IRB approval date (mm/dd/yyyy) ___/___/_____

Person Completing Form:

Last Name: **(print)** _____ First Name: **(print)** _____

Phone: _____ Fax: _____ Email: _____

Patient initials (last, first, middle) _____
(For Mayo Rochester patients, include first four letters of last name.)

Gender (check one) ___ Male ___ Female ___ Unknown

Date of birth (mm/dd/yyyy) ___/___/_____

ZIP code _____

Country of Residence _____

Race (check all that apply)

- White
- Black or African American
- Native Hawaiian or Other Pacific Islander
- Asian
- American Indian or Alaska Native
- Not reported: Patient refused or not available
- Unknown: Patient unsure

Method of payment (check one)

- PI (Private Insurance)
- MR (Medicare)
- MRP (Medicare and Private Insurance)
- MD (Medicaid)
- MM (Medicaid and Medicare)
- MVA (Military or Veterans Sponsored,
Not Otherwise Specified (NOS))
- MS (Military Sponsored [including CHAMPUS & TRCARE])
- MV (Veterans Sponsored)
- SP (Self pay [no insurance])
- NP (No means of payment [no insurance])
- OTH (Other)
- UNK (Unknown)

Ethnicity (check one)

- Not Hispanic or Latino
- Hispanic or Latino
- Not reported: Refused or data not available
- Unknown: Unsure of their ethnicity

Addendum 8 & 9 dated Feb. 4, 2011 IRB approved?

___ Yes. If Yes, addendum approval date (mm/dd/yyyy) ___/___/_____

___ No. If No, End form, Addendum 8 & 9 IRB approval required.

NCCTG Pre-Registration (Step 1) Eligibility Checklist N078D

02/04/2011
Page 2 of 2

Patient study ID number _____

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be *mm/dd/yyyy*.

Pre-Registration - Inclusion Criteria

Yes No NA

Central pathology review. This review is mandatory prior to registration to confirm eligibility. It should be initiated as soon after surgery as possible.	___	___	___
Provide informed written consent.	___	___	___

All responses in above section must be "Yes."

Pre-Registration Check

Yes No NA

Consent form signed and dated. Date informed consent signed ___/___/_____	___	___	___
Authorization for use and disclosure of protected health information (<i>U.S.A. institutions only</i>) signed and dated. If not a USA institution (<i>check NA</i>) If a USA institution - Date of authorization ___/___/_____	___	___	___
The site has reviewed and understands the process listed in Section 17.0 and must account for sufficient time to complete pre-registration and registration steps.	___	___	___

All responses in above section must be "Yes" unless specified as "NA."

Assigned Treatment

___ Pre-registration allowed

Person registering Signature _____ Registration Office specialist initials _____

Physician Signature _____ Date (*mm/dd/yyyy*) ___/___/_____