

FORMS PACKET

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

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✓ designates revised/new forms

*Generic forms completion instructions are available on the NCCTG web site under “the CRA link in the Remote Registration and Data Entry section and are titled “Remote Data Entry Screen Instructions (Forms Completion).”

The specific forms instructions take precedence over the generic forms instructions, so it is very important to review them in addition to the generic forms instructions.

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

02/04/2011
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N078D: Phase I/II Trial of Rituximab, Cladribine, and Temsirolimus (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*) ___/___/_____

NORTH CENTRAL CANCER TREATMENT GROUP
NCCTG REGISTRATION (STEP 2) ELIGIBILITY CHECKLIST N078D

02/05/2010
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N078D: Phase I/II Trial of Rituximab, Cladribine, and Temozolomide (RCT) Therapy in Newly Diagnosed Mantle Cell Lymphoma (MCL).

Phase I patients only: To register a patient, call (507/284-4130) or fax (507/284-0885) a completed 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 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

Patient study ID number _____

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

Registration - Inclusion Criteria

Yes No NA

Histologically confirmed MCL. The diagnosis must be confirmed by NCCTG pre-registration pathology review by Dr. Paul Kurtin or his designate (see Section 17.1). It is recommended that the biopsy be an excisional biopsy, but adequate core-needle biopsies will be accepted as long as they are considered adequate for registration by Dr. Kurtin or his designate. The tumor must be cyclin D-1 positive by immunohistochemistry or have evidence of a t(11;14) translocation by FISH or cytogenetics.	____	____	____
Measurable or assessable disease defined as at least one of the following: <ul style="list-style-type: none"> • A lymph node or tumor mass that is ≥ 2.0 cm in at least one dimension by PET/CT, CT, MRI, or plain radiograph imaging. • Splenic enlargement may be used as a measurable parameter if the spleen is palpable ≥ 3 cm below the left costal margin. • Diffuse infiltration of an organ such as the stomach, bone marrow, peripheral blood, liver, lungs, or bowel by lymphoma without a discrete mass would constitute assessable, but not measurable, disease. 	____	____	____
≥ 18 years of age. Age = _____	____	____	____
ECOG performance status (PS) of 0, 1, 2, or 3. Performance Status = _____.	____	____	____
Life expectancy ≥ 12 weeks.	____	____	____
The following laboratory values obtained ≤ 14 days prior to registration: Earliest laboratory test date ____/____/____; latest laboratory test date ____/____/____. NOTE: These dates pertain to the following labs only.	____	____	____
• ANC ≥ 1500 ANC = _____	____	____	____
• PLT $\geq 100,000$ PLT = _____	____	____	____
The following laboratory values obtained ≤ 28 days prior to registration: Earliest laboratory test date ____/____/____; latest laboratory test date ____/____/____. NOTE: These dates pertain to the following labs only.	____	____	____
• Serum creatinine ≤ 2.0 mg/dL Serum Creatinine = _____	____	____	____
• Serum total bilirubin (or direct bilirubin if total is abnormal) \leq institutional upper limit of normal (ULN) with or without secondary liver involvement. Is total bilirubin $>ULN$? (this question may be answered yes or no) ____ Yes \rightarrow Direct bilirubin = _____ ____ No \rightarrow Total bilirubin = _____; ULN = _____	____	____	____
• SGOT ≤ 3 x institutional ULN (exception: if there is liver involvement, SGOT must be ≤ 5 x institutional ULN.) Liver involvement? (This question may be answered "Yes" or "No") ____ Yes. \rightarrow (SGOT ≤ 5 x institutional ULN) SGOT = _____; ULN = _____. ____ No. \rightarrow (SGOT ≤ 3 x institutional ULN) SGOT = _____; ULN = _____.	____	____	____
Negative pregnancy test done ≤ 7 days prior to registration, for women of childbearing potential only. If not a woman of childbearing potential or male (<i>check NA</i>) If a woman of childbearing potential – Negative pregnancy test date ____/____/____	____	____	____
Willingness to return to NCCTG enrolling institution for follow-up.	____	____	____
Willingness to provide the blood specimens as required by the protocol (see Sections 6.33 and 14.1).	____	____	____
Willingness to provide tissue specimens as required by the protocol (see Sections 6.34 and 17.1).	____	____	____
Willingness to abstain from eating grapefruit or drinking grapefruit juice for the duration of the study.	____	____	____

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

Patient study ID number _____

Registration - Exclusion Criteria

Yes No NA

Any prior therapy for mantle cell non-Hodgkin lymphoma including radiation therapy. <u>Exception:</u> Patient may have undergone a splenectomy for diagnosis, cytopenia, or systematic splenomegaly.	___	___	
Active or uncontrolled infection.	___	___	
Any of the following cardiac conditions: <ul style="list-style-type: none"> • Uncontrolled high blood pressure • Unstable angina • Active congestive heart failure • Myocardial infarction ≤6 months • Serious uncontrolled cardiac arrhythmia 	___	___	
Known CNS involvement.	___	___	
Any of the following because this study involves an investigational agent whose genotoxic, mutagenic and teratogenic effects on the developing fetus and newborn are unknown: <ul style="list-style-type: none"> • Pregnant women or women of reproductive ability who are unwilling to use effective contraception while taking the drug and for 12 months after stopping treatment. • Nursing women • Men who are unwilling to use a condom (even if they have undergone a prior vasectomy) while having intercourse with any woman, while taking the drug and for 12 months after stopping treatment. 	___	___	
Medical or psychiatric conditions which, in the opinion of the investigator, make the patient a poor risk for participation.	___	___	
Known to be HIV positive. HIV testing is not required but should be done if clinically indicated. HIV patients are excluded because of concerns regarding excess risk of complications of immunosuppressive therapy regimens. HIV-positive patients receiving combination anti-retroviral therapy are excluded from the study because of possible pharmacokinetic interactions with temsirolimus.	___	___	
Concurrent malignancy ≤5 years ago. Exceptions: carcinoma in situ of the cervix, resected basal cell or squamous cell carcinomas of the skin, or prostate cancer that is in remission following a radical retropubic prostatectomy or radiation therapy. If there is a history of prior malignancy, they must not be receiving other specific treatment (other than hormonal therapy) for their cancer.	___	___	
Known hypersensitivity to rituximab or its components, or to murine proteins.	___	___	
Receiving any other investigational agent which would be considered as a treatment for the primary neoplasm.	___	___	
Prior treatment with an mTOR inhibitor.	___	___	
Autologous or allogeneic stem cell transplant planned as part of initial therapy.	___	___	
Receiving enzyme-inducing antiepileptic drugs (EIAEDs; e.g., phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, phenobarbital, or primidone); any other potent CYP3A4 inducer such as rifampin, glucocorticoids at greater than adrenal replacement levels, or St. John's wort; or receiving strong CYP3A4 inhibitors. Note: See Appendix II for a more complete list of drugs which may interact with temsirolimus metabolism. Note: If these agents are discontinued, temsirolimus therapy can begin ≥7 days after discontinuation of such agent.	___	___	

All responses in above section must be “No” unless specified as “NA.”

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

Yes No NA

A mandatory blood translational research component is part of this study; the patient will be automatically registered onto this component (Sections 3.29b and 14.1).	___	___	
A mandatory tissue translational research component is part of this study; the patient will be automatically registered onto this component (Sections 3.29c and 17.1)	___	___	
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.	___	___	
Treatment cannot begin prior to registration and must begin ≤10 days after registration.	___	___	

Patient study ID number _____

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

Yes No NA

Pretreatment tests/procedures (see Section 4.0) must be completed ≤14 days prior to registration. Earliest pretreatment test date ___/___/____; latest pretreatment test date ___/___/____. NOTE: The earliest pretreatment test date must be less than or equal to the earliest laboratory test date and the latest pretreatment test date must be greater than or equal to the latest laboratory test date.	____	____	
<u>Exceptions to the above dates:</u> Exception pretreatment tests can be performed ≤28 days prior to registration (see Section 4.0). Earliest exception test date ___/___/____; latest exception test date ___/___/____.	____	____	
All required baseline symptoms (see Section 10.3) must be documented and graded.	____	____	
Study drug availability checked.	____	____	
Blood draw kit availability checked.	____	____	

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

At the time of registration/randomization, the following will also be recorded:			
• Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat cancer.	____	____	
• Patient has given permission to keep blood sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).	____	____	
• Patient has given NCCTG permission to give blood sample(s) to outside researchers.	____	____	
• Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat cancer.	____	____	
• Patient has given permission to keep tissue sample(s) for use in future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer’s disease, or heart disease).	____	____	
• Patient has given NCCTG permission to give tissue sample(s) to outside researchers.	____	____	
Patient has agreed to be enrolled on N0392.	____	____	

All responses in above section may be “Yes” or “No”.

Grouping Factor:

- ____ Phase I
- ____ Phase II (includes patients treated at MTD in Phase I)

Descriptive Factor

Dose Level (to be assigned by the Registration Office):

- ____ Dose Level 1
- ____ Dose Level 2
- ____ Dose Level 3
- ____ Dose Level 4
- ____ Dose Level 5

Assigned Treatment

____ A) 2-CDA + RITUX + CCI779*

*Temsirolimus: Dose = _____ mg/d

Person registering Signature _____ Registration Office specialist initials _____

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

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**PREREGISTRATION
SCREENING FAILURE FORM**

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Date aware of preregistration screening failure: (mm/dd/yyyy) ___/___/___

Primary reason screening failed? (check one)

3 Did not meet eligibility criteria

1 Investigator decision

2 Patient decision

4 Other reason, specify _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

ON-STUDY FORM

Patient ID: Patient Initials: L F M

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 2

Institution Number:

Are data amended? (check one) Yes No (if data are amended, please circle in red when using paper form)

Institution:

Description of Primary Disease

MedDRA code: 10026799 [Mantle Cell Lymphoma]

Prior Treatment and History

Date of Initial Pathologic Diagnosis: (mm/dd/yyyy) _ _ / _ _ / _ _ _ _

Disease Description

Staging - Ann Arbor Classification: Clinical Stage (check one) 1 I 2 II 3 III 4 IV

WHO Classification

- 2 Non-Hodgkin Lymphoma
9 Mantle Cell Lymphoma

Extra Nodal Sites

Extra nodal site involvement? (check one) 1 Yes 2 No

If Yes: Site: (check all that apply)

Method of Evaluation: (check one)

- Lung: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Liver: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Bone marrow: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Bone: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Pleura: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Kidney: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Skin (cutaneous): 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Parotid gland: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Submandibular gland: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Thymus: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Thyroid: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Testes: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Ovary: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Stomach: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Small bowel: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Colon: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Brain-parenchymal: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Spine-parenchymal: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
CNS-epidural: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
CNS-leptomeninges: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
CNS- vitreal: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown
Other, specify: 1 Clinical (includes clinical exam, x-ray, etc.) 2 Pathologic 9 Unknown

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

ON-STUDY FORM

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 2

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Symptomatic Stage: (check one)

1 A, asymptomatic

2 B, symptomatic

9 Unknown

Height (cm): ____ .

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

BASELINE

BLOOD SPECIMEN SUBMISSION FORM

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

INSTRUCTIONS:

*Complete this form for all patients and enter into the remote data entry system within 14 days of study entry.
See Section 14 of the protocol for specimen requirements and shipment.*

Was a research blood specimen collected? (check one)

1 Yes. If Yes: Date of collection: (mm/dd/yyyy) ___/___/_____

Date Specimen Shipped: (mm/dd/yyyy) ___/___/_____

2 No. If No, reason: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

BASELINE
ADVERSE EVENTS FORM

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Required Baseline Adverse Events from Section 10.0 of Protocol		
CTC Adverse Events Term (CTCAE v3.0)	MedDRA Code (v. 10.0)	CTC Adverse Event Grade
Neutrophils/granulocytes (ANC/AGC)	10029366	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Platelets	10035528	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Viral hepatitis	10047446	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection) (ANC $\leq 1.0 \times 10^9/L$, fever $\geq 38.5^\circ$)	10016288	<input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Rash/desquamation	10037853	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Cholesterol, serum-high (hypercholesteremia)	10040190	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Triglyceride, serum-high (hypertriglyceridemia)	10040424	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4
Weight loss	10047900	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**BASELINE
TISSUE SPECIMEN SUBMISSION FORM**

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Protocol Number: N078D
Patient ID: _____ Patient Initials: _____
L F M
Institution Number: _____
Institution: _____

INSTRUCTIONS:

- Complete this form **for all patients** and enter into the remote data entry system within 30 days of study entry.
- See Section 17 of the protocol for specimen requirements and shipment.
- Include a copy of this form with tissue submission (see Section 17).

Was a research tissue specimen obtained? (check one)

- 1 Yes. If Yes: Date of collection: (mm/dd/yyyy) ___/___/_____
Date Specimen Shipped: (mm/dd/yyyy) ___/___/_____
2 No. If No, reason: _____

Institution Contact Information: (Please Print)

Contact Person at Institution (CRA/Nurse):

Institution Name: _____

Street Address: _____

City: _____

State: _____

Zip Code: _____

Phone Number: _____

Fax Number: _____

E-mail Address: _____

PLACE LABEL HERE

MAYO CLINIC CANCER CENTER

**Quantitative Flow Cytometry Form
(Baseline)**

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data amended, please circle in red when using paper forms)

Baseline

Quantitation of blood cells by flow cytometry

Date of test: (mm/dd/yyyy) ___/___/_____

Total T (CD3)	cells/ μ L	_____ . _____
Total B-cells (CD19)	cells/ μ L	_____ . _____
Total NK cells (CD16 + CD56)	cells/ μ L	_____ . _____
Total helper (CD4)	cells/ μ L	_____ . _____
Total T suppressor (CD8)	cells/ μ L	_____ . _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**CONCURRENT TREATMENT FORM
(BASELINE)**

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

Evaluation Date: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __

Is patient currently taking any Substrates listed in Appendix II? (check one) 1 Yes 2 No (go to next question)

If Yes, enter all applicable Substrates (including prescription, over-the-counter, and alternative medications) that are listed in Appendix II.

Concomitant Treatment

Is patient currently taking any Inhibitors listed in Appendix II? (check one) 1 Yes 2 No (go to next question)

If Yes, enter all applicable Inhibitors (including prescription, over-the-counter, and alternative medications) that are listed in Appendix II.

Concomitant Treatment

Is patient currently taking any Inducers listed in Appendix II? (check one) 1 Yes 2 No

If Yes, enter all applicable Inducers (including prescription, over-the-counter, and alternative medications) that are listed in Appendix II.

Concomitant Treatment

I. CRA / RN	PLACE LABEL HERE	NORTH CENTRAL CANCER TREATMENT GROUP
	Protocol # <u>N078D</u> Patient ID # _____ Initials: _____ L F M Local ID # _____ Institution _____	PATHOLOGY REPORTING FORM
	Date of Operative Procedure: (mm/dd/yyyy) ___/___/_____ Type of procedure: (check one) 1 <input type="checkbox"/> Biopsy 2 <input type="checkbox"/> Resection	

II. Completed by central pathology reviewer	DIAGNOSTIC CODE: <u>214</u> 2. Non-Hodgkin Lymphoma 214. Mantle Cell Lymphoma Subtype: (check one) 1 <input type="checkbox"/> Mantle zone 2 <input type="checkbox"/> Nodular 3 <input type="checkbox"/> Diffuse 4 <input type="checkbox"/> Blastoid variant Cyclin D-1 immunopositive stain: (check one) 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Not done t(11;14) by FISH: (check one) 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Not done t(11;14) by conventional cytogenetics: (check one) 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Not done
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III. Signatures	_____ NCCTG Pathology Reviewer _____ Date <input type="checkbox"/> 1. Agree with original local diagnosis <input type="checkbox"/> 2. Minor disagreement with original local diagnosis <input type="checkbox"/> 3. Substantial disagreement with original local diagnosis Comments: _____	_____ Research Base Advisor _____ Date <input type="checkbox"/> 1. Agree with original local diagnosis <input type="checkbox"/> 2. Minor disagreement with original local diagnosis <input type="checkbox"/> 3. Substantial disagreement with original local diagnosis Comments: _____	_____ Committee Chairperson _____ Date <input type="checkbox"/> 1. Agree with original local diagnosis <input type="checkbox"/> 2. Minor disagreement with original local diagnosis <input type="checkbox"/> 3. Substantial disagreement with original local diagnosis Comments: _____
	Block/Slide number(s) to be used for research/banking: _____		

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

PATHOLOGY SUBMISSION FORM

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**** This form must be submitted to the NCCTG Operations Office at the time slides/blocks are sent to the NCCTG reviewer (see Pathology section of the protocol) ****

Date specimen shipped: (mm/dd/yyyy) ___/___/_____

Reviewer: Dr. Paul Kurtin and colleagues, Hilton 11, Mayo Clinic Rochester - Rochester, MN

Number of slides sent: ___

Accession number(s) (on the slides sent):

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Number of blocks sent: ___

Accession number(s) (on the blocks sent):

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

COMMENTS:

Institution Contact Information: (Please Print)

Contact Person at Institution (CRA/Nurse): _____

Institution Name: _____

Street Address: _____

City: _____

State: _____

Zip Code: _____

Phone Number: _____

Fax Number: _____

E-mail Address: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**PRETREATMENT
MEASUREMENT FORM**

Pg. 1 of 2

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Assessment Date: (mm/dd/yyyy) __ __ / __ __ / __ __ __ __

(Assessment date is the date reflecting type of assessment, not the physician interpretation date)

INSTRUCTIONS

1. Record measurable disease (*refer to protocol*).
2. Record up to six indicator lesions. These should be the six largest dominant nodes or nodal masses.
3. Measure measurable tumor areas in cm. using longest perpendicular diameters. State both diameters.
4. Record measurements at on study, scheduled reevaluation, and progression.
5. Maintain same type of assessment throughout study.

Measurable Lesion Site(s) (Dominant Node Sites)	Type of Assessment			Measurement (cm)
	CT	MRI	PET/CT*	
1	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x
2	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x
3	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x
4	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x
5	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x
6	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x

*PET/CT - Only CT portion of scan can be used for measurement.

Evaluable/ Nonmeasurable Lesion Site(s) (extranodal sites)	Type of Assessment					
	CT	PET/CT*	Peripheral blood flow cytometry	Bone marrow biopsy	Colonoscopy	EGD
1	2 <input type="checkbox"/>	15 <input type="checkbox"/>	1 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>
2	2 <input type="checkbox"/>	15 <input type="checkbox"/>	1 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>
3	2 <input type="checkbox"/>	15 <input type="checkbox"/>	1 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>
4	2 <input type="checkbox"/>	15 <input type="checkbox"/>	1 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>
5	2 <input type="checkbox"/>	15 <input type="checkbox"/>	1 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>

*PET/CT - Only CT portion of scan can be used for measurement.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

**PRETREATMENT
MEASUREMENT FORM**

Pg. 2 of 2

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Unexplained persistent fever >38°C (or >100.4° F) in the previous month? (check one) 1 Yes 2 No

Recurring drenching night sweats during the previous month? (check one) 1 Yes 2 No

Unexplained weight loss >10% of body weight in the previous 6 months? (check one) 1 Yes 2 No

Bone Marrow (when applicable, submit copy of report): (check one) 1 Positive 2 Negative 3 Not applicable

LDH	U/L	_____ .
LDH	ULN	_____ .
ALC	10 ⁹ /L	_____ . ____
WBC	10 ⁹ /L	_____ . ____

Spleen

Is there spleen involvement? (check one) 1 Yes 2 No 3 Unknown

If Yes: Date of spleen evaluation: (mm/dd/yyyy) ____/____/____

Splenomegaly by scan or x-ray? (check one) 1 Yes 2 No 3 Not examined

If Yes, Method of Evaluation: (check one) 1 CT scan
2 PET/CT (only CT portion of scan can be used for measurement)
3 Other, specify _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**ACTIVE MONITORING
MEASUREMENT FORM**

Pg. 1 of 2

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Current Cycle Number: ____

Assessment Date: (mm/dd/yyyy) __ __/__ __/____

(Assessment date is the date reflecting type of assessment, not the physician interpretation date)

INSTRUCTIONS

1. Record measurable disease (*refer to protocol*).
2. Record up to six indicator lesions. These should be the six largest dominant nodes or nodal masses.
3. Measure measurable tumor areas in cm. using longest perpendicular diameters. State both diameters.
4. Record measurements at on study, scheduled reevaluation, and progression.
5. Maintain same type of assessment throughout study.

- Objective Status (*check one*)
- 19 N/A (*not applicable this cycle*).
 - 1 CR** (*complete response*)
 - 2 PR** (*partial remission*)
 - 5 SD (*stable disease*)
 - 6 PD** (*progressive disease*) (*Complete End of Active Treatment and Event Monitoring forms*)

Measurable Lesion Site(s) (Dominant Node Sites)	Type of Assessment			Measurement (cm)
	CT	MRI	PET/CT*	
1	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x
2	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x
3	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x
4	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x
5	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x
6	2 <input type="checkbox"/>	3 <input type="checkbox"/>	15 <input type="checkbox"/>	x

*PET/CT - Only CT portion of scan can be used for measurement.

**Submit documentation to verify CR, PR, and PD.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**ACTIVE MONITORING
MEASUREMENT FORM**

Pg. 2 of 2

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Evaluable/ Nonmeasurable Lesion Site(s) (extranodal sites)	Type of Assessment						Change				
	CT	PET/ CT*	Peripheral blood flow cytometry	Bone marrow biopsy	Colonoscopy	EGD	5 = Not Done	1 = Total Disappearance	2 = Definite Decrease	3 = Stable	4 = Definite Increase
1	2 <input type="checkbox"/>	15 <input type="checkbox"/>	1 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	5	1	2	3	4
2	2 <input type="checkbox"/>	15 <input type="checkbox"/>	1 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	5	1	2	3	4
3	2 <input type="checkbox"/>	15 <input type="checkbox"/>	1 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	5	1	2	3	4
4	2 <input type="checkbox"/>	15 <input type="checkbox"/>	1 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	5	1	2	3	4
5	2 <input type="checkbox"/>	15 <input type="checkbox"/>	1 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	6 <input type="checkbox"/>	5	1	2	3	4

*PET/CT - Only CT portion of scan can be used for measurement.

Unexplained persistent fever >38°C (or >100.4° F) in the previous month? (check one) 1 Yes 2 No

Recurring drenching night sweats during the previous month? (check one) 1 Yes 2 No

Bone Marrow (when applicable, submit copy of report): (check one) 1 Positive 2 Negative 3 Not applicable

LDH	U/L	_____ .
LDH	ULN	_____ .
ALC	10 ⁹ /L	_____ . ____
WBC	10 ⁹ /L	_____ . ____

Spleen

Is there spleen involvement? (check one) 1 Yes 2 No 3 Unknown

If Yes: Date of spleen evaluation: (mm/dd/yyyy) ___/___/_____

Splenomegaly by scan or x-ray? (check one) 1 Yes 2 No 3 Not examined

If Yes, Method of Evaluation: (check one) 1 CT scan
2 PET/CT (only CT portion of scan can be used for measurement)
3 Other, specify _____

PLACE LABEL HERE

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/TREATMENT FORM

Pg. 1 of 2

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Use one form per cycle, one column per agent.

Current Cycle Number: _____

Weight (kg): _____ . _____

(used for this cycle, round to the nearest tenth)

ECOG Performance Status: (check one) 0 1 2 3 4

(used for this cycle)

BSA (m²): (used for this cycle) _____ . _____

Was this cycle of treatment held (Day 1)? (check one)

1 Yes, planned 2 No 3 Yes, unplanned

If Yes, planned or unplanned; Primary reason treatment held: (check one)

186 Blood/Bone marrow 38 Nonhematologic
97 Infection 99 Other (not per protocol) _____

Agent	Rituximab (RITUX) day 1	Cladribine (2-CDA) days 1-5	Temsirolimus (CCI779) days 1, 8, 15, 22 ±1 day
Agent Start Date this cycle (mm/dd/yyyy)	____/____/____	____/____/____	____/____/____
Dose Level day one this cycle (If agent was not given this cycle, enter the dose level received on last day of treatment.)	mg/m ²	mg/m ² /d	mg
Total Dose this cycle (If agent was not given this cycle, enter 0 for total dose.)	mg	mg	mg
Was DOSE LEVEL adjusted from previous cycle? (mg/m ²)	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No
If Yes, PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. (Check one)	38 <input type="checkbox"/> Nonhematologic 99 <input type="checkbox"/> Other (not per protocol), specify _____	186 <input type="checkbox"/> Blood/Bone marrow 99 <input type="checkbox"/> Other (not per protocol), specify _____	38 <input type="checkbox"/> Nonhematologic 186 <input type="checkbox"/> Blood/Bone marrow 99 <input type="checkbox"/> Other (not per protocol), specify _____
Did this patient have dose limiting toxicity this cycle? (See Section 7.32 in protocol). (If Yes, check all that apply)			1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No <input type="checkbox"/> Grade 4 ANC (<500) for ≥ 5 days <input type="checkbox"/> Grade 4 ANC (<500) associated with fever (>100.5 F) and/or active infection <input type="checkbox"/> PLT <25,000 <input type="checkbox"/> Grade 4 infection <input type="checkbox"/> ≥ grade 3 nonhematologic adverse event

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

EVALUATION/TREATMENT FORM

page 2 of 2

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Current Cycle Number: _____

Temsirolimus (CCI779) Days scheduled: (check one)

- 1 Day 1 3 Days 1, 8, 15
- 2 Days 1, 15 4 Days 1, 8, 15, 22

Agent: CCI779

Was dose omitted (day 1)? (check one)

- 1 Yes. If Yes, primary reason dose omitted: (check one) 2 No
- 186 Blood/bone marrow 99 Other (not per protocol), specify _____
- 3 NA (CCI779 has been discontinued or not required for current dose level; primary reason previously reported)

Was dose omitted (day 8)? (check one)

- 1 Yes. If Yes, primary reason dose omitted: (check one) 2 No
- 186 Blood/bone marrow 99 Other (not per protocol), specify _____
- 3 NA (CCI779 has been discontinued or not required for current dose level; primary reason previously reported)

Was dose omitted (day 15)? (check one)

- 1 Yes. If Yes, primary reason dose omitted: (check one) 2 No
- 186 Blood/bone marrow 99 Other (not per protocol), specify _____
- 3 NA (CCI779 has been discontinued or not required for current dose level; primary reason previously reported)

Was dose omitted (day 22)? (check one)

- 1 Yes. If Yes, primary reason dose omitted: (check one) 2 No
- 186 Blood/bone marrow 99 Other (not per protocol), specify _____
- 3 NA (CCI779 has been discontinued or not required for current dose level; primary reason previously reported)

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**CONCURRENT TREATMENT FORM
(ACTIVE MONITORING PHASE)**

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Current Cycle Number: _____

Evaluation Date: (mm/dd/yyyy) ___/___/_____

Is patient currently taking any Substrates listed in Appendix II? (check one) 1 Yes 2 No (go to next question)

If Yes, enter all applicable Substrates (including prescription, over-the-counter, and alternative medications) that are listed in Appendix II.

Concomitant Treatment

Is patient currently taking any Inhibitors listed in Appendix II? (check one) 1 Yes 2 No (go to next question)

If Yes, enter all applicable Inhibitors (including prescription, over-the-counter, and alternative medications) that are listed in Appendix II.

Concomitant Treatment

Is patient currently taking any Inducers listed in Appendix II? (check one) 1 Yes 2 No

If Yes, enter all applicable Inducers (including prescription, over-the-counter, and alternative medications) that are listed in Appendix II.

Concomitant Treatment

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

**ACTIVE MONITORING
BLOOD SPECIMEN SUBMISSION FORM**

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____
L F M

Institution Number: _____

Institution: _____

Current Cycle Number: 2

INSTRUCTIONS:

*Complete this form **for all patients** and enter into the remote data entry system within 7 days of specimen collection. See Section 14 of the protocol for specimen requirements and shipment.*

Was a research blood specimen collected? *(check one)*

1 Yes. If Yes: Date of collection: *(mm/dd/yyyy)* __ __/__ __/____

Date Specimen Shipped: *(mm/dd/yyyy)* __ __/__ __/____

2 No. If No, reason: _____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 2

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Current Cycle Number (nadir/adverse events associated with this cycle): _____

Date of Evaluation: (mm/dd/yyyy) ____/____/____

Test	Nadir/Worst Date (Date of lab test) (mm/dd/yyyy)	Nadir/Worst Value (The nadir is the lowest value of counts occurring between two treatments. If the only count available is taken the day of retreatment, use that value as the nadir.)	Is nadir below LLN? (check one)	CTC AE Attribution Code (If Grade >0) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*(Enter 1 for Yes or 2 for No)
Platelets (PLT) K/uL or 10 ⁹ /L	____/____/____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to WBC)	[1] [2] [3] [4] [5]	_____
Hemoglobin (Hgb) g/dL	____/____/____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to Adverse Event)	[1] [2] [3] [4] [5]	_____
Absolute Neutrophil Count (ANC) K/uL or 10 ⁹ /L	____/____/____	_____	1 <input type="checkbox"/> Yes → 2 <input type="checkbox"/> No → (Go to ANC)	[1] [2] [3] [4] [5]	_____

CTC Adverse Event Term (CTCAE v3.0)	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (highest grade this cycle) INCLUDE GRADE 0's	CTC AE Attribution Code (If Grade > 0) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*(Enter 1 for Yes or 2 for No)
--	---	--	--	---

Required Adverse Events from Section 10.0 of Protocol

Viral hepatitis	10047446	[0] [1] [2] [3] [4] [5] (death)	[1] [2] [3] [4] [5]	_____
Febrile neutropenia (fever of unknown origin without clinically or microbiologically documented infection) (ANC ≤ 1.0 x 10 ⁹ /L, fever ≥ 38.5°)	10016288	[0] [3] [4] [5] (death)	[1] [2] [3] [4] [5]	_____
Rash/desquamation	10037853	[0] [1] [2] [3] [4] [5] (death)	[1] [2] [3] [4] [5]	_____
Cholesterol, serum-high (hypercholesteremia)	10040190	[0] [1] [2] [3] [4] [5] (death)	[1] [2] [3] [4] [5]	_____
Triglyceride, serum-high (hypertriglyceridemia)	10040424	[0] [1] [2] [3] [4] [5] (death)	[1] [2] [3] [4] [5]	_____
Weight loss	10047900	[0] [1] [2] [3]	[1] [2] [3] [4] [5]	_____

* See Section 10.0 of the protocol.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT FORM

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 2

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

Current Cycle Number (*adverse events associated with this cycle*): _____

Were (*other*) adverse events assessed during this report period?

- 1 Yes, and reportable adverse events occurred 3 Yes, but no reportable adverse events occurred (*Stop here*)
 2 No (*Stop here*)

Adverse Events beyond those required in Section 10.0 of the protocol. Record grade 2 with attribution of possible, probable or definite and all grade 3, 4 and 5 regardless of attribution.**

Other CTC Adverse Event Terms not listed (CTCAE v3.0)	MedDRA Code (<i>v. 10.0</i>) (<i>must be completed</i>)	CTC Adverse Event Grade (<i>highest grade this cycle</i>)	CTC AE Attribution Code (<i>If Grade > 0</i>) 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Has an adverse event expedited report been submitted?*(<i>Enter 1 for Yes or 2 for No</i>)
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 (death)	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	_____

* See Section 10.0 of the protocol.
 ** Both hematologic (*except for the nadirs listed on page 1*) and nonhematologic Adverse Events must be graded on this form as applicable.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM

Patient ID: _____ Patient Initials: _____

Submit Once Per Patient

L F M

Institution Number: _____

ALL ITEMS MUST BE COMPLETED

Institution: _____

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Last Date (any modality of) protocol therapy was given: (mm/dd/yyyy) ___/___/_____
(date of last treatment dose on this study or date decision made not to initiate protocol treatment)

Off Treatment Date: (mm/dd/yyyy) ___/___/_____
(date decision was made to end active treatment or not to initiate protocol treatment)

This patient will now go to: (check one)
(See Schema and Section 13.0 of the protocol)

- 1 Observation *(follow test schedule and enter cycle data)*
- 2 Event Monitoring *(follow Event Monitoring schedule)*
- 9 Off Study *(cancels only)*

Reason Treatment Ended <i>(check one)</i>	COMMENTS
1 <input type="checkbox"/> Treatment Completed Per Protocol Criteria	
2 <input type="checkbox"/> Patient Withdrawal/Refusal After Beginning Protocol Therapy	Specify:
24 <input type="checkbox"/> Patient Withdrawal/Refusal Prior To Beginning Protocol Therapy <i>(cancel)</i>	Specify:
3 <input type="checkbox"/> Adverse Event/Side Effects/Complications	Specify:
4 <input type="checkbox"/> Disease Progression, Relapse During Active Treatment*	Complete Event Monitoring Form
5 <input type="checkbox"/> Alternative Therapy	Specify:
6 <input type="checkbox"/> Patient Off-Treatment For Other Complicating Disease	Specify:
7 <input type="checkbox"/> Death On Study	Complete Event Monitoring Form
8 <input type="checkbox"/> Other	Specify:

* Submit documentation to verify progression. See Section 11.0 and Section 18.0 of protocol.

PLACE LABEL HERE

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/OBSERVATION FORM

ALL ITEMS MUST BE COMPLETED

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Use one form per cycle.

Current Cycle Number: _____

Weight (kg): _____ . _____

(used for this cycle, round to the nearest tenth)

ECOG Performance Status: *(check one)* 0 1 2 3 4

(used for this cycle)

Observation*

Day 1 of this observation cycle: *(mm/dd/yyyy)* __ __ / __ __ / __ __ __ __



End of observation? *(check one)* 1 Yes 2 No

*When observation ends amend the last existing Evaluation/Observation Form by checking "Yes" for the End of observation question above.

PLACE LABEL HERE

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NORTH CENTRAL CANCER TREATMENT GROUP

EVENT MONITORING FORM

ALL ITEMS MUST BE COMPLETED

Pg. 1 of 2

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

Were you able to obtain any information about the patient since the last report?*

1 Yes. If Yes, complete rest of form.

2 No. If No, date of last attempt to contact patient: (mm/dd/yyyy) ___/___/_____ (End form)

Vital Status

1 Alive Date of last contact or date of death: (mm/dd/yyyy) ___/___/_____

2 Dead

Primary Cause of Death: (check one) 1 Due to this disease 2 Due to other cause, specify _____

4 Due to protocol treatment

(adverse event related to treatment)

Disease Follow-up Status

Has the patient had a documented clinical assessment for this cancer (since submission of the last event monitoring form)?*

2 No. If No, Go to Notice of New Primary.

1 Yes. If Yes, Cancer Follow-up Status Date: (mm/dd/yyyy) ___/___/_____

Notice of First Relapse/Progression in the Event Monitoring Phase

Has the patient developed a first relapse or progression that has not been previously reported (in event monitoring phase)?

2 No 1 Yes. If Yes, Date of Relapse/Progression:** (mm/dd/yyyy) ___/___/_____

Notice of First Subsequent Treatment

Has the patient received subsequent treatment for this cancer that has not been previously reported?

2 No 3 Unknown 1 Yes. If Yes, Start date of subsequent treatment: (mm/dd/yyyy) ___/___/_____

Specify subsequent treatment: _____

Notice of New Primary

Has a new primary cancer or MDS (myelodysplastic syndrome) been diagnosed that has not been previously reported?

2 No 3 Unknown 1 Yes. If Yes, New Primary Cancer Date: (mm/dd/yyyy) ___/___/_____

Site of New Primary: _____

Late Adverse Event (post completion of active monitoring)

Has the patient experienced (prior to treatment for progression or relapse or a second primary, and prior to non-protocol treatment) any severe (grade ≥ 3) long term toxicity that has not been previously reported:

- Adverse events at least possibly attributed to treatment on this study.
- Death within 30 days of treatment.
- Death any time at least possibly treatment related.

2 No 3 Unknown 1 Yes. If Yes, Submit page 2 of the Event Monitoring Form for Late Adverse Event Reporting.

*If this is the first event monitoring form check yes, enter cancer follow-up status date and complete the rest of the form.

**Submit documentation to verify PD.

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

**EVENT MONITORING FORM
(LATE ADVERSE EVENT REPORTING)**

ALL ITEMS MUST BE COMPLETED

Pg. 2 of 2

Are data amended? (check one) Yes No
(if data are amended, please circle in red when using paper form)

The CTC AE v.3.0 will be used to evaluate the following adverse events:

CTC Adverse Event Term	MedDRA Code (v. 10.0) (must be completed)	CTC Adverse Event Grade (Highest Grade)	CTC AE Attribution Code 1 = Unrelated 2 = Unlikely 3 = Possible 4 = Probable 5 = Definite	Late Adverse Event Onset Date (mm/dd/yyyy)
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____
	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> (death)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	___/___/_____

PLACE LABEL HERE

NORTH CENTRAL CANCER TREATMENT GROUP

Protocol Number: N078D

Patient ID: _____ Patient Initials: _____

L F M

Institution Number: _____

Institution: _____

NOTIFICATION FORM
Grade 4 or 5 Non-AER Reportable Events/Hospitalization
ALL ITEMS MUST BE COMPLETED

INSTRUCTIONS:

- Use this form to report all known information on non-AER reportable grade 4 or 5 adverse events or any hospitalization during active treatment.
- Verify reporting requirements listed within the study protocol, prior to entering into the remote data entry system.
- If AER has been submitted for this event do not enter this form.
- Fill out all information known.
- Enter into the remote data entry system within 5 working days of notification.
- These events must also be reported on the Nadir/Adverse Event Form.

Date membership CRA aware of event(s): (mm/dd/yyyy) ___/___/_____

Name of Person Completing Form: _____ Phone: (_____) _____ - _____

Current Cycle Number: _____ Assigned Treatment Arm: _____

Event ≥ Grade 4: (check one) 1 Yes 2 No

Date of First Occurrence of Adverse Event (mm/dd/yyyy)	CTC Adverse Event Term (only one event per line)	CTC Adverse Event Grade	In your opinion, is this related to the study medication?*
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown
___/___/_____		<input type="checkbox"/> 4 <input type="checkbox"/> 5	4 <input type="checkbox"/> Yes: Unlikely 1 <input type="checkbox"/> Yes: Possible, probable, or definite 2 <input type="checkbox"/> No 3 <input type="checkbox"/> Unknown

*Answer YES if attribution is unlikely, possible, probable or definite; answer NO if unrelated; answer UNKNOWN if you are not sure. Verify if expedited reporting (e.g. ADEERS) is required (see protocol), based on relationship to study treatment.

Hospitalization: (check one) 1 Yes 2 No

If Yes: Hospital Admission Date: (mm/dd/yyyy) ___/___/_____

Reason(s) for Hospitalization:

- 1 Adverse Event, specify type and grade: _____
- 2 Prophylactic, specify: _____
- 3 Other reason, specify _____

Biospecimen Accessioning Processing
Fax Supply Order Form – No Cover Sheet Necessary
Fax to Research Kit Building @ 507-538-4103

NOTE: Form must be either typed or printed legibly and filled out completely.
Study ID: N078D _____

Investigator: _____

Order Placed By: _____ Phone #: () _____

Email: _____ Fax #: () _____

Complete Address (kits sent to):

ALLOW AT LEAST TWO WEEKS TO RECEIVE THE KITS.

NOTE: Kits will be sent via FedEx® Ground at no additional cost to the participating institutions. Kits will not be sent via rush delivery service unless the participating institution provides their own FedEx® account number or alternate billing number for express service. **The study will not cover the cost for rush delivery of kits.**

Date Needed: _____
(Please be specific)

Fed Ex account number (Rush deliveries only) _____

Type of Kits

of Kits Needed

N078D Research Blood Kit _____

Total Kits _____

Questions? Contact the Biospecimen Resource Manager listed on the Protocol Resource page of the protocol.