March 26, 2010

FORMS PACKET

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

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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.

Pre-Registration Eligibility Checklist

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

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

Has the patient ever been on a prior study entered through this Randomization Center? ____ Yes ____ No

If yes: Last protocol number _________________; previous patient ID number _______________________

Patient study ID number _____________________ Registration date (date on) __ __/__ __/__ __ __ __

NCCTG member (participant sponsor) ____

NCCTG treating location ____

NCCTG treating physician ____

Institution patient number (local subject number) __________________________

IRB approval date *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Patients 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 ___________________________________

Method of payment *(check one)*
- ___ PI *(Private)*
- ___ 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)*

Race *(check all that apply)*
- ___ White
- ___ Black or African American
- ___ Native Hawaiian or Other Pacific Islander
- ___ Asian
- ___ American Indian or Alaskan Native
- ___ Not reported: Patient refused or not available
- ___ Unknown: Patient unsure

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*.

Pre-registration - Inclusion Criteria	Yes No
Central pathology review submission. This review is mandatory prior to registration to confirm eligibility. It should be initiated as soon after surgery as possible.	____ ____

All responses in above section must be "Yes."

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

	Yes No NA
Consent form signed and dated. Date of consent __ __/__ __/__ __ __ __.	____ ____
Authorization for use and disclosure of protected health information signed and dated. **Non-USA institution only** *(check NA)* vs. 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.	____ ____
Blood draw kit availability checked.	____ ____

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

Assigned Treatment

_____ Pre-registration

Person registering ________________________________ Random. specialist _______
Signature initials

Physician ____ _____-_____-_____
Signature M D Y

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

To register a patient, access the NCCTG web page at https://ncctg.mayo.edu/training and enter the remote registration/randomization application.

Has the patient ever been on a prior study entered through this Randomization Center? ____ Yes ____ No

If yes: Last protocol number ________________; previous patient ID number ______________________

Patient study ID number ____________________ Registration date (date on) *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

NCCTG member (participant sponsor) ____

NCCTG treating location ____

NCCTG treating physician ____

Institution patient number (local subject number) _________________________

IRB approval date *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Patients 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 __________________________________

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)*

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

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

Criterion	Yes	No	NA
Follicular grade 1 or 2 B-cell non-Hodgkin's lymphoma. The diagnosis must be confirmed by NCCTG pre-registration pathology review (See section 17.2 and 18.1).	____	____	
Willingness to provide translational research components (Section 6.23). • Research blood draws (Section 14.2).	____	____	
• FFPE tumor tissue blocks/slides submitted prior to registration (Section 17.3).	____	____	
Previously untreated for NHL (no prior chemotherapy, immunotherapy, vaccines or radiation therapy for NHL).	____	____	
Stage III or IV.	____	____	
≥ 18 years of age. Age = __________.	____	____	
Must have measurable disease defined as at least one lesion whose longest diameter can be accurately measured as ≥ 20 mm (i.e. ≥2 cm). See Section 11.0 for the evaluation of measurable disease. Measurable masses (such as enlarged lymph nodes) must have a clearly defined bidimensional diameter of at least 2 x 2 cm on physical examination or ≥ 2.0 cm in one of the dimensions by 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.	____	____	
ECOG Performance Status 0, 1, or 2. ECOG PS = _____	____	____	
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.	____	____	
• WBC ≥ 3400 x 10^6 cells/L. WBC = __________.	____	____	
• PLT ≥ 100,000 x 10^6/L. PLT = __________.	____	____	
• HgB ≥ 10.0 g/dL. HgB = __________.	____	____	
• Total bilirubin ≤ 1.5 x institutional upper normal limit (UNL). Total bilirubin = __________; UNL = __________.	____	____	
• Alkaline phosphatase ≤ 3 x UNL. Alkaline phosphatase = __________; UNL = __________.	____	____	
• AST ≤ 3 x UNL. AST = __________; UNL = __________.	____	____	
• Creatinine ≤ 1.5 x UNL. Creatinine = __________; UNL = ___________.	____	____	
• Albumin ≥ 3 g/dl. Albumin = __________.	____	____	
Negative serum pregnancy test done ≤ 7 days prior to registration, for women of childbearing potential only. Not a woman of childbearing potential *(check NA)* vs. negative pregnancy test date __ __/__ __/__ __ __ __	____	____	____
Life expectancy of ≥ 1 year.	____	____	

All responses in above section must be "Yes."

Registration - Contraindications

Criterion	Yes	No	NA
Any of the following: • Pregnant women • Nursing women • Men or women of childbearing potential who are unwilling to employ adequate contraception methods during the study. The immunologic effects of denileukin diftitox and rituximab may be harmful to a developing fetus or nursing infant. Denileukin diftitox has potential toxicities and the developing fetus is felt to be at risk if these toxicities occur.	____	____	
≥ 5000 circulating tumor cells per microliter.	____	____	
Central nervous system (CNS) lymphoma.	____	____	

Patient study ID number ________________________

Registration – Contraindications continued

	Yes No
HIV infection. We anticipate that treatment with rituximab and denileukin diftitox will suppress intratumoral regulatory T-cells and reverse the inhibition of the antitumor immune response. Patients with HIV infection will be excluded from the study as they are generally immune suppressed by the HIV infection and are unlikely to respond to this strategy.	____ ____
Active malignancies other than lymphoma.	____ ____
Presence of active uncontrolled infection.	____ ____
Known hypersensitivity to denileukin diftitox or any of its components: diphtheria toxin, interleukin-2, or excipients.	____ ____

All responses in above section must be "No."

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 translational research component is part of this study. The patient will be automatically registered onto this component (Section 3.22, 14.2 and 17.3).	____ ____
Prior to accepting the registration, the application will verify the following: • Patient eligibility	____ ____
Treatment on this protocol must commence at the accruing membership under the supervision of an NCCTG member physician.	____ ____
Treatment cannot begin prior to registration (if not done at pre-registration) and must begin ≤14 days after registration.	____ ____
Pretreatment tests/procedures must be completed ≤14 days prior to registration (see Section 4.0). 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.	____ ____
Exceptions to the above dates: Exception pretreatment test/procedures can be performed ≤28 days prior to registration (see Section 4.0). Earliest exception test/procedure date __ __/__ __/__ __ __ __; latest exception test/procedure 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."

Patient study ID number _________________________

Registration Check –continued

At the time of registration, the following will also be recorded: • Patient has given permission to store and use blood sample(s) for future research to learn about, prevent, or treat cancer.	____ ____
• Patient has given permission to store and use blood sample(s) for future research to learn about, prevent, or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).	____ ____
• Patient has given permission to store and use tissue sample(s) for future research to learn about, prevent, or treat cancer.	____ ____
• Patient has given permission to store and use 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 samples(s) to outside researchers.	____ ____
An optional translational research component is part of this study; there will be an option to select if the patient is to be registered onto this component (Section 17.4). • Patient has given permission to give fresh tumor tissue sample for optional research testing.	____ ____
Patient has agreed to be enrolled on N0392 (N0392 must be open at site and offered to patient).	____ ____

All responses in above section may be "Yes" or "No".

Assigned Treatment Arm

__________ A) RITUX + ONTAK

Person registering ________________________________ Random. specialist _______
Signature initials

Physician ____ _____-_____-_____
Signature M D Y

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ________________________ Patient Initials: _____________
L F M

Institution Number: ____

Institution: ____

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)

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 ________________________________

I. CRA / RN

PLACE LABEL HERE

Protocol # N0682

Patient ID # ______________________ Initials: ________________
L F M

Local ID # ______________________ Institution ______________

DATE OF OPERATIVE PROCEDURE (MO-DAY-YEAR)

☐☐ ☐☐ ☐☐☐☐ ☐ Type of procedure
1. Biopsy
2. Resection

NORTH CENTRAL CANCER TREATMENT GROUP

PATHOLOGY REPORTING FORM
LYMPHOMA

Primary Pathologist: ______________________ No. of slides sent: ________

Clinic/Hospital: __________________________ Date sent: ______________

Reviewer: ____

Surg path No.: ____

II. Completed by central pathology reviewer

DIAGNOSTIC CODE ☐☐☐☐

1. Hodgkin's disease
   - 111. Lymphocyte predominance, nodular variant
   - 112. Nodular sclerosis
   - 113. Mixed cellularity
   - 114. Lymphocyte rich classical
   - 115. Lymphocyte depletion
   - 116. Unclassifiable (state reason): ___________________________

2. Non-Hodgkin's Lymphomas

   B-Cell Neoplasms

   - 211. Precursor B-lymphocytic leukemia/lymphoma
   - 212. B-cell chronic lymphocytic leukemia/small lymphocytic lymphoma
   - 213. Lymphoplasmacytic lymphoma
   - 214. Mantle cell lymphoma
   - 215. Splenic marginal zone lymphoma
   - 216. Extranodal marginal zone B-cell lymphoma of MALT type
   - 217. Nodal marginal zone B-cell lymphoma
   - 218. Follicular lymphoma (Grade using cell counting method of Berard)
     - a. Grade 1
     - b. Grade 2
     - c. Grade 3
   - 219. Diffuse large B-cell lymphoma
   - 220. Burkitt's lymphoma
   - 221. High grade B-cell lymphoma, Burkitt-like

   T-cell and NK-cell Neoplasms

   - 222. Precursor T-lymphoblastic leukemia/lymphoma
   - 223. Extranodal NK/T-cell lymphoma nasal type
   - 224. Enteropathy type T-cell lymphoma
   - 225. Hepatosplenic T-cell lymphoma (gamma delta and alpha beta types)
   - 226. Subcutaneous panniculitis-like T-cell lymphoma
   - 227. Mycosis fungoides/Sezary syndrome
   - 228. Anaplastic large cell lymphoma T/null cell type, primary cutaneous
   - 229. Anaplastic large cell lymphoma T/null cell type, systemic
   - 230. Angioimmunoblastic T-cell lymphoma
   - 231. Peripheral T-cell lymphoma, not otherwise, characterized

3. Composite lymphomas* (specify components):

   ____
   ____
   ____

4. Unclassifiable (specify reason)

   ____
   ____
   ____

* The designation of "composite lymphoma" should only be used in those cases composed of two lymphomas demonstrated to be of two separate lineages. For example, diffuse small lymphocytic lymphoma and Hodgkin's disease occurring in the same lymph node would be a composite lymphoma. In contrast, diffuse large cell lymphoma and follicular small cleaved cell lymphoma would usually be considered transformation, not a composite lymphoma.

IMMUNOLOGIC PHENOTYPE

___ 1. B-cell by direct immunologic or molecular genetic method
___ 2. T-cell by direct immunologic or molecular genetic method
___ 3. Uncertain

PHENOTYPE METHOD

___ 1. Immunoperoxidase staining of tissue sections
   a. Frozen sections
   b. Paraffin sections
___ 2. Immunoperoxidase staining of cytology preparations
___ 3. Flow cytometry on cell suspensions
___ 4. Molecular genetics

III. Signatures

______________________ Reviewer	______________________ Research Base Advisor	______________________ Committee Chairman
______________________ Date	______________________ Date	______________________ Date
___ 1. Agree with diagnosis ___ 2. Minor disagreement ___ 3. Substantial disagreement	___ 1. Agree with diagnosis ___ 2. Minor disagreement ___ 3. Substantial disagreement	___ 1. Agree with diagnosis ___ 2. Minor disagreement ___ 3. Substantial disagreement
Comments: ______________ ______________________	Comments: ______________ ______________________	Comments: ______________ ______________________

Block/Slide number(s) to be used for research/banking: ______________________________________

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

ON-STUDY 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)

Description of Primary Disease

MedDRA code for primary tumor site: [10016896]

Prior Treatment and History

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

Disease Description

WHO Classification

Non-Hodgkin Lymphoma *(check one)*

1 ☐ Follicular lymphoma - I
2 ☐ Follicular lymphoma - II
3 ☐ Low grade or indolent follicular lymphoma unable to classify further (no follicular grade 3)

Lymphatic Tissue Assessment

Lymph Node *(check all that apply)*	Method of Evaluation 1=Clinical *(includes clinical exam, x-ray, etc.)* 2=Pathologic 9=Unknown
☐ Orbital	☐
☐ Cervical	☐
☐ Occipital	☐
☐ Pre-auricular	☐
☐ Waldeyer's ring	☐
☐ Paratracheal	☐
☐ Supraclavicular	☐
☐ Infraclavicular	☐
☐ Epithrochlear	☐
☐ Pectoral	☐
☐ Axillary / Brachial	☐
☐ Mediastinal	☐
☐ Hilar	☐
☐ Splenic hilar	☐
☐ Porta hepatis	☐
☐ Celiac axis / Retrocrural	☐
☐ Para-aortic	☐
☐ Porta caval	☐
☐ Mesenteric	☐
☐ Common pelvic	☐
☐ External / internal iliac	☐
☐ Inguinal / Femoral	☐
☐ Popliteal	☐
☐ Spleen	☐
☐ Other, specify ________________	☐

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ______ Patient Initials: ______ L F M

Institution Number: ______

Institution: ______

NORTH CENTRAL CANCER TREATMENT GROUP

ON-STUDY 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)

Disease Description - continued

Extra Nodal Sites

Extra nodal site involvement? 1 ☐ Yes 2 ☐ No

↓

Site *(check all that apply)*	Method of Evaluation 1=Clinical *(includes clinical exam, x-ray, etc.)* 2=Pathologic 9=Unknown	Site *(check all that apply)*	Method of Evaluation 1=Clinical *(includes clinical exam, x-ray, etc.)* 2=Pathologic 9=Unknown
☐ Lung	☐	☐ Thyroid	☐
☐ Liver	☐	☐ Testes	☐
☐ Bone marrow	☐	☐ Ovary	☐
☐ Bone	☐	☐ Stomach	☐
☐ Pleura	☐	☐ Small bowel	☐
☐ Kidney	☐	☐ Colon	☐
☐ Skin (cutaneous)	☐	☐ Brain-parenchymal	☐
☐ Parotid gland	☐	☐ Spine-parenchymal	☐
☐ Submandibular gland	☐	☐ CNS-epidural	☐
☐ Thymus	☐	☐ CNS-leptomeninges	☐
		☐ CNS - vitreal	☐
		☐ Other, specify ______	☐

Bulky Disease

Any lymph node with a diameter greater than 10 cm? 1 ☐ Yes 2 ☐ No 3 ☐ Unknown

Mediastinal mass with a diameter greater than 10 cm? 1 ☐ Yes 2 ☐ No 3 ☐ Unknown

Symptomatic Stage

1 ☐ A, asymptomatic

2 ☐ B, symptomatic

9 ☐ Unknown

Descriptive Factors

Follicular Lymphoma International Prognostic Index Adverse Factors: *(check one)*

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Age: *(check one)* 1☐ ≤60 yr 2☐ >60 yr

Ann Arbor Stage: *(check one)* 1☐ III 2☐ IV

Serum LDH: *(check one)* 1 ☐ Normal or below 2 ☐ Above normal

Hemoglobin level: *(check one)* 1☐ ≥ 12 g/dL 2☐ <12 g/dL

Number of nodal siters: *(check one)* 1☐ ≤ 4 2☐ > 4

Height (cm): __ __ __ **.**

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ________________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

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	MedDRA Code (*v. 10.0*)	CTC Adverse Event Grade
Allergic reaction/hypersensitivity ***(including drug fever)***	10020751	0 1 2 3 4
Acute vascular leak syndrome	10007196	0 2 3 4
Retinopathy	10038923	0 1 2 3 4
Albumin, serum low (hypoalbuminemia)	10040123	0 1 2 3
Viral hepatitis	10047446	0 1 2 3 4

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ______________________________________

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT 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)

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

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

Test	Date of Nadir *(Date of lab test)* *(mm/dd/yyyy)*	Nadir 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 this nadir below the 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)*
PLT K/uL or10^9/L	__ __/__ __/__ __ __ __	__ __ __ .	1 ☐ Yes ⟶ 2 ☐ No⟶ *(Go to WBC)*	1 2 3 4 5	____
WBC K/uL or10^9/L	__ __/__ __/__ __ __ __	__ __ . __	1 ☐ Yes ⟶ 2 ☐ No⟶ *(Go to Hgb)*	1 2 3 4 5	____
Hgb g/dL	__ __/__ __/__ __ __ __	__ __ . __	1 ☐ Yes ⟶ 2 ☐ No⟶ *(Go to ANC)*	1 2 3 4 5	____
ANC K/uL or10^9/L	__ __/__ __/__ __ __ __	__ __ . __ __	1 ☐ Yes ⟶ 2 ☐ No⟶ *(Go to Adverse Event)*	1 2 3 4 5	____

CTC Adverse Event Term	**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				
Allergic reaction/hypersensitivity *(including drug fever)*	10020751	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Acute vascular leak syndrome	10007196	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Retinopathy	10038923	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Albumin, serum low (hypoalbuminemia)	10040123	0 1 2 3 4 5 (death)	1 2 3 4 5	____
Viral hepatitis	10047446	0 1 2 3 4 5 (death)	1 2 3 4 5	____

* See Section 10.0 of the protocol.

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ________________ Patient Initials: __________
L F M

Institution Number: ______________________

Institution: ______________________

NORTH CENTRAL CANCER TREATMENT GROUP

NADIR/ADVERSE EVENT 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)

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	**MedDRA Code** ***(v. 10.0)*** *(must be completed)*	CTC Adverse Event Grade *(highest grade this cycle)*	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)*
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 5	____
	☐☐☐☐☐☐☐☐	1 2 3 4 5 (death)	1 2 3 4 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

Protocol Number: N0682

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ______________________________________

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

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 sent: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

2 ☐ No. If No, reason: ____

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ________________________ Patient Initials: _____________
L F M

Institution Number: ____

Institution: ____

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)

Current Cycle Number: ____

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 sent: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

2 ☐ No. If No, reason: ____

PLACE LABEL HERE

Protocol Number: N0682____________________

Patient ID: ________________________ Patient Initials: _____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

BASELINE
TISSUE SPECIMEN SUBMISSION FORM
(TISSUE BLOCKS/SLIDES)
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 28 days of study entry. See Section17 of the protocol for specimen requirements and shipment.*

Were FFPE tissue blocks/slides obtained? *(check one)*

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

Date specimen sent: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

2 ☐ No. If No, reason: ____

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ______________________ Patient Initials: ___________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

ACTIVE MONITORING
TISSUE SPECIMEN SUBMISSION FORM
(FRESH TUMOR TISSUE/TUMOR BIOPSY)
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: ____

INSTRUCTIONS:
*Complete this form **for all patients** and enter into the remote data entry system within 5 days of specimen collection. See Section 17 of the protocol for specimen requirements and shipment.*

Did this patient provide written consent to give fresh tissue/repeat biopsy specimen(s) for research? *(check one)*

1 ☐ Yes. If Yes, complete rest of form.

2 ☐ No. If No, end form.

Was a research fresh tissue/repeat biopsy specimen obtained? *(check one)*

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

Date specimen sent: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

2 ☐ No. If No, reason: ____

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ________________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

PRETREATMENT
MEASUREMENT 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)

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
	PE	CT	MRI	ULT	CXR	(cm)
1	1☐	2☐	3☐	4☐	5☐	x
2	1☐	2☐	3☐	4☐	5☐	x
3	1☐	2☐	3☐	4☐	5☐	x
4	1☐	2☐	3☐	4☐	5☐	x
5	1☐	2☐	3☐	4☐	5☐	x
6	1☐	2☐	3☐	4☐	5☐	x

Question	Response
Unexplained persistent fever >38°C (or >100 degrees F) in the previous month?	1 ☐ Yes 2 ☐ No
Recurring drenching night sweats during the previous month?	1 ☐ Yes 2 ☐ No
Unexplained weight loss >10% of body weight in the previous six months?	1 ☐ Yes 2 ☐ No
Bone Marrow *(when applicable, submit copy of report)*	1 ☐ positive 2 ☐ negative 3 ☐ not applicable

Test	Unit	Value
LDH	U/L	__ __ __ __ .
LDH	ULN	__ __ __ __ .
ALC	10^9/L	__ __ . __

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ______________________ Patient Initials: ___________
L F M

Institution Number: _______________________________________

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

ACTIVE MONITORING
MEASUREMENT 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)

Cycle: ___

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)* ⟶ Go to "Unexplained persistant fever." 1 ☐ CR**(complete response) 26 ☐ CRu** *(clinical response unconfirmed)* 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)
	PE	CT	MRI	ULT	CXR	
1	1☐	2☐	3☐	4☐	5☐	x
2	1☐	2☐	3☐	4☐	5☐	x
3	1☐	2☐	3☐	4☐	5☐	x
4	1☐	2☐	3☐	4☐	5☐	x
5	1☐	2☐	3☐	4☐	5☐	x
6	1☐	2☐	3☐	4☐	5☐	x

Unexplained persistent fever >38°C (or >100 degrees F) in the previous month?	1 ☐ Yes 2 ☐ No
Recurring drenching night sweats during the previous month?	1 ☐ Yes 2 ☐ No
Bone Marrow (when applicable, submit copy of report)	1 ☐ Positive 2 ☐ Negative 3 ☐ Not applicable

LDH	U/L	__ __ __ __ .
LDH ULN	U/L	__ __ __ __ .
ALC	10^9/L	__ __ . __ __

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

PATHOLOGY SUBMISSION FORM

(NOTE: This form is used to update the Outstanding Materials Report)

**** 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 Sent: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Reviewer: Dr. William Macon, Mayo Clinic Rochester - Rochester, MN

Number of slides sent: ___ ___

Accession numbers on the slides sent:

____________________	____________________
____________________	____________________
____________________	____________________
____________________	____________________
____________________	____________________

Number of blocks sent: ___ ___

Accession numbers on the blocks sent:

____________________	____________________
____________________	____________________
____________________	____________________
____________________	____________________
____________________	____________________

Comments:

Institution Contact Information: (Please Print)

CRA/Nurse Contact:______________________

Institution Name:_________________________

Street Address: _________________________

____

City:__________________________________

State: __________ Zip: __________________

Phone Number: _________________________

Fax Number: ____________________________

E-mail Address:__________________________

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ________________ Patient Initials: __________
L F M

Institution Number: ______________________

Institution: ______________________

NORTH CENTRAL CANCER TREATMENT GROUP

EVALUATION/TREATMENT 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, 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(m^2): *(used for this cycle)* ___ . ___ ___ ___

Was this cycle of treatment held *(delayed)*? *(check one)*
1 ☐ Yes, planned 2 ☐ No 3 ☐ Yes, unplanned

If Yes, planned or unplanned, Primary reason treatment held *(delayed)*: *(check one)*
- 154 ☐ Albumin, serum-low (hypoalbuminemia)
- 55 ☐ Leukocytes
- 38 ☐ Other nonhematologic adverse event
- 87 ☐ Platelets
- 99 ☐ Other (not per protocol) ______________

Agent	Rituximab (RITUX)	Denileukindiftitox (ONTAK)
Agent Start Date this cycle *(mm/dd/yyyy)*	__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __
Dose Level day one this cycle	mg/m^2	mcg/kg
Total Dose *(mg)* this cycle *(required)*	mg	mcg
Was **DOSE LEVEL** adjusted this cycle?	1 ☐ Yes 2 ☐ No	1 ☐ Yes 2 ☐ No
If Yes, PRIMARY REASON for Dose Adjustment per Section 8.0. Not BSA changes. *(If Yes, check one Primary Reason.)*	99 ☐ Other (not per protocol) __________	95 ☐ Neutrophils/granulocytes (ANC/AGC) 87 ☐ Platelets 154 ☐ Albumin, serum-low (hypoalbuminemia) 38 ☐ Other nonhematologic adverse event 55 ☐ Leukocytes 99 ☐ Other (not per protocol) __________

PLACE LABEL HERE

Protocol Number: N0682

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: N0682

Patient ID: ________________________ Patient Initials: _____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

END OF ACTIVE TREATMENT/CANCEL NOTIFICATION FORM
Submit Once Per Patient

ALL ITEMS MUST BE COMPLETED

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

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

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

EVENT MONITORING 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)

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)* __ __/__ __/__ __ __ __

Specify: ____

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 *(myelodyplastic 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 $\geq$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/Not evaluated 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 assessment date and complete the rest of the form.
**Submit documentation to verify PD.

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ______________ Patient Initials: ________ (L F M)

Institution Number: ______________________

Institution: ______________________

NORTH CENTRAL CANCER TREATMENT GROUP

EVENT MONITORING FORM
(LATE ADVERSE EVENT REPORTING)
ALL ITEMS MUST BE COMPLETED

Are data amended? ***(check one)*** ☐ **Yes** ☐ **No**

(if data are amended, please circle in red when using paper form)

The CTC AE Version 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)*
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __
	☐☐☐☐☐☐☐☐	3 4 5 (death)	1 2 3 4 5	__ __/__ __/__ __ __ __

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ____________________________________

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

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.***
- ***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 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?[1]
__ __/__ __/__ __ __ __		4 5	1☐Yes 2☐No 3☐Unknown
__ __/__ __/__ __ __ __		4 5	1☐Yes 2☐No 3☐Unknown
__ __/__ __/__ __ __ __		4 5	1☐Yes 2☐No 3☐Unknown
__ __/__ __/__ __ __ __		4 5	1☐Yes 2☐No 3☐Unknown
__ __/__ __/__ __ __ __		4 5	1☐Yes 2☐No 3☐Unknown

1. Answer YES if attribution is unlikely, possible, probable or definite; answer NO if unrelated; answer UNKNOWN if you are not sure.

Hospitalization: 1☐ Yes 2☐ No

Hospital Admission Date: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

Reason(s) for Hospitalization:

1☐ Adverse Event, specify type and grade: ____

____

2☐ Prophylactic, specify: ____

____

3☐ Other reason, specify ____

____

PLACE LABEL HERE

Protocol Number: N0682

Patient ID: ______________________ Patient Initials: ____________
L F M

Institution Number: ____

Institution: ____

NORTH CENTRAL CANCER TREATMENT GROUP

PET SCAN
SUBMISSION/RESULT 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)

Current cycle number: __ __

Complete this form **for all patients** within 7 days of PET scan..

PET scan date: *(mm/dd/yyyy)* __ __/__ __/__ __ __ __

PET scan result: *(check one)*

1 ☐ Positive *(check one)*
- ☐ less FDG-avid compared to baseline
- ☐ more FDG-avid compared to baseline
- ☐ NA *(baseline)*

New areas of FDG positivity? *(check one)* ☐ Yes ☐ No ☐ NA *(baseline)*

2 ☐ Negative

Comments: ____

____

____

____

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: __N0682__________

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**
N0682 Research Blood Kit	______
_____________________________	______
Total Kits	______

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

N0682 REIMBURSEMENT REQUEST

Today's Date: ____________________

NCCTG Patient ID (one patient per form): _______________________

Institution to be reimbursed:

Name of institution: ____

Address of institution: ____

____

____

Institutional TAX ID #: ____________________________

Contact CRA: ________________________________

Phone: ________________________________

email: ________________________________

Item(s) to be reimbursed	Number per patient	Max $ allowed	Date obtained or completed	Amount requested
General Biopsy	1	$624.00		$
		Total amount requested:		$

Submit to: NCCTG Operations Office, PL4
Attn: CRO Finance Coordinator
200 First Street SW
Rochester, MN 55905

Questions: Send email to CROFinance@mayo.edu

Form Version Date: 03/03/2008