CALGB 9732

Etoposide & Cisplatin vs.
Etoposide / Cisplatin plus Paclitaxel
in Extensive Small Cell Lung Cancer

PROTOCOL TREATMENT FORMS

Submit forms according to the DATA SUBMISSION SCHEDULE listed at the beginning of this book and specified in section 5.4 of the 9732 protocol.

04/09/98

The following forms are a part of a Case Report Form book (CRF) designed to make the data submission easier for 9732. Each form necessary for data reporting is already printed in the CRF and is arranged in a logical order that follows the planned patient treatment schedule. ***There should be no need to photocopy extra pages***, with the exception of the Long-Term Follow-Up Form (page 41) which will need to be photocopied for submission on each occasion that follow-up is required.

The intent of this CRF is to allow each page to be filled out as soon as possible after the patient is evaluated and/or treated. This should make for more timely data submission and less data delinquencies.

Every effort has been made to minimalize the number of questions asked on each form. ***Therefore, please do not leave any questions blank. Complete each question on every form entering a "-1" when the answer is unknown or not applicable.***

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

The CALGB Data Management Center
(919) 286-0045

9732 PROTOCOL TREATMENT FORMS Data Submission Schedule

DATA COMPLETION INSTRUCTIONS:

Submit all forms according to the schedule outlined below. Information in the upper right-hand box of each form must be completed for the form to be accepted. Do not leave any entries on a form blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box. Retain a copy of all forms submitted for your records and send the originals to:

CALGB Data Management Center
2200 W. Main St., Suite 340
Durham, NC 27705

ON-STUDY / TREATMENT DATA		**SUBMISSION SCHEDULE**
Eligibility Checklist (page iii) 9732 On-Study Form 9732 Measurement Form 9732 Remarks Addenda Pathology report of diagnosis	***Pages iii, 1-3***	Within two weeks of protocol entry
Dosing Form for Cycle 1 Toxicities Observed From Cycle 1	***(Fax to the CALGB DMC at the completion of Cycle 1)***	
9732 Remarks Addenda Dosing Form for Cycle 2 Toxicities Observed From Cycle 2	***(Fax to the CALGB DMC at the completion of Cycle 2)***	
Response / Relapse Form For Cycles 1 & 2 9732 Measurement Form	***Pages 4-11***	Within two weeks of completion of Cycle 2
Dosing Form for Cycle 3 Toxicities Observed From Cycle 3 9732 Remarks Addenda Dosing Form for Cycle 4 Toxicities Observed From Cycle 4 Response / Relapse Form For Cycles 3 & 4 9732 Measurement Form	***Pages 12-19***	Within two weeks of completion of Cycle 4
Dosing Form for Cycle 5 Toxicities Observed From Cycle 5 9732 Remarks Addenda Dosing Form for Cycle 6 Toxicities Observed From Cycle 6 Response / Relapse Form For Cycles 5 & 6 9732 Measurement Form C-300 Off Treatment Notice *(Submit once treatment is completed, or if treatment is ended prematurely)*	***Pages 20-28***	Within two weeks of completion of Cycle 6

9732 PROTOCOL TREATMENT FORMS Data Submission Schedule

AT THE COMPLETION OF TREATMENT, OR IF A PATIENT ENDS TREATMENT PREMATURELY, SUBMIT:

C-300 Off Treatment Notice ***Page 28***	If the patient ends treatment prematurely for any reason, or the patient is taken off study prior to the assessment of response, relapse or death.

POST TREATMENT: FOLLOW UP EVERY 4 MONTHS FOR 1 YEAR

Response / Relapse Forms for Post Treatment Period Toxicities Observed Post Treatment 9732 Remarks Addendas 9732 Measurement Forms ***Pages 29-40***	Every four months after the completion of treatment for one year.

LONG TERM FOLLOW-UP: FOLLOW-UP EVERY 6 MONTHS FOR 3 YEARS, THEN EVERY YEAR THEREAFTER UNTIL DEATH

C-400 Long Term Follow Up ***Pages 41-42***	Every 6 months for 3 years beginning 18 months after treatment has ended.
Relapse Form Form For Long Term Follow-Up 9732 Measurement Form ***Pages 43-44***	Submit in case of relapse and/or death during the Long-Term Follow-Up period.
C-215 Secondary Malignancy ***Page 45***	At the discovery of a secondary malignancy.
C-113 Notification of Death ***Page 46***	At death.

Clear

CALGB CONFIRMATION OF REGISTRATION

CALGB 9732: Etoposide / Cisplatin Vs. Etoposide / Cisplatin + Paclitaxel for Extensive Small Cell Lung Cancer
A PHASE III STUDY

IRB Approval ___/___/___

					CALGB Patient Number	Consent Form ___/___/___
					Institution/Adjunct _____/_____	
					Physician of Record _____	

Provider of Information/Phone Number _____

																			Patient Name
								Hospital Chart Number											
									Social Security Number										

Prior CALGB Protocols (1-No, 2-Yes) if yes, list protocols: _____

		Race		Sex				Birthdate
		(1-White, 2-Hispanic, 3-Black, 4-Oriental, 5-Native Hawaiian, 6-Native American, 7-Indian, 8-Filipino, 9-Other, 10-Patient refusal, 1-Institution refusal,-1-Unknown)		(1-M, 2-F)		M	D	Y

		Method of Payment					—			Zip Code

(1-Private Insurance, (e.g.: Blue Cross, CHAMPUS, Aetna, Kaiser Permanente, and employer sponsored insurers); 2-Medicare;3-Medicare and Private Insurance; 4-Medicaid; 5-Medicaid and Medicare; 6-Military or Veterans Administration Sponsored; 7-Self Pay (no insurance); 8-No means of payment (no insurance);-1-Unknown)

Diagnosis_____								Date of Diagnosis
					M	D	Y	

STATIFICATION FACTORS

☐ Performance Status (1= 0-1; 2=2)

☐ Gender (1=male, 2=female)

☐ Is this patient a part of the Expanded Participation Project? (1=no, 2=yes)

TREATMENT

☐ 1. Etoposide / Cisplatin
2. Etoposide / Cisplatin + Paclitaxel

								Date of Registration	_____
					M	D	Y		Registrar

9732 ELIGIBILITY CHECKLIST

CALGB Study	9732
CALGB Patient ID:	_____
Amended Data?:	_____ Yes

INSTRUCTIONS: All patients must satisfy the criteria found in Section 3.0 of the protocol. It is the responsibility of the institutional PI and CRA to review ALL eligibility criteria. Please submit this form with the required on-study data to the CALGB Data Management Center, 2200 W. Main St., suite 340, Durham, NC 27705.

Patient's Name:_____ Patient Hospital Number:_____

SECTION I: ELIGIBILITY CRITERIA:

___Yes ___No Patient has histologically or cytologically documented Extensive Small Cell Lung Cancer?
___Yes ___No Has no active concomitant malignancy?
___Yes ___No Has had no prior chemotherapy for Small Cell Lung Cancer?
___Yes ___No Has had no prior pelvic or mediastinal radiotherapy?
___Yes ___No Patient has measurable or evaluable disease? (See section 3.5 of 9732 protocol.)*
___Yes ___No Performance status 0-1?
___Yes ___No IRB Approval < 1 year?
___Yes ___No Patient signed an informed consent?
___Yes ___No Patient > 18 years old?

___***Yes*** ___***No*** ***For each column of questions, are ALL the answers marked in the FIRST column? If the answer is YES, go to Section II. If the answer is NO, the patient is INELIGIBLE.***

SECTION II: LABORATORY CRITERIA: (to be completed< 16 days before registration)

___Yes ___No Granulocytes $\geq$ 1,500/µl
___Yes ___No Platelet count $\geq$ 100,000/µl
___Yes ___No SGOT (AST) < 2X upper limit of normal
___Yes ___No Bilirubin (total) $\leq$ 1.5 mg/dl
___Yes ___No Serum Creatinine $\leq$ 1.5 mg/dl

___***Yes*** ___***No*** ***Were the answers to ALL QUESTIONS in each section above marked in the first column? If the answer is YES, the patient is ELIGIBLE. If the answer is NO, the patient is INELIGIBLE.***

REQUIRED LAB TESTS/RADIOLOGIC STUDIES: These studies are part of the pre-study work up and need to be completed prior to registration.

To be completed < 16 days before registration:
CBC with differential and platelets
SGOT (AST), Creatinine, BUN, Alk. Phos.
Bilirubin, LDH, Tot. Protein, Albumin
Uric Acid, Glucose, Phosphate, Ca^{++}, Mg^{++}

To be completed < 28 days before registration;
CT Scan/MRI of chest/liver/adrenals
CT or MRI of brain
Bone scan
PA/LAT Chest X-Ray

To be completed < 42 days before registration:
EKG

Any exam of an uninvolved organ **NOT USED** for tumor measurements.

A pathology report indicating the patient's diagnosis is required with the first data submission.

Completed by:_____ **Date**_____/_____/_____
Print or type name

9732 ON STUDY FORM

CALGB Form:	C-522
CALGB Study No:	9732
CALGB Patient ID:	_____
Amended Data?	_____Yes

INSTRUCTIONS: Complete all information in the upper right-hand box. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

PATIENT INFORMATION

☐.☐☐ Body Surface Area (m^2)

☐ Assessment of disease
1=measurable
2=evaluable

☐ Extent of Disease
1=Extensive
2=Limited *(ineligible)*

☐ Performance Status
0=Fully active
1=ambulatory
2=In bed < 50% of the time
3=In bed > 50% of the time *(ineligible)*
4=Completely bedridden *(ineligible)*

CURRENT SITES OF INVOLVEMENT (1=not involved, 2=involved, 3=equivocal**)**

☐ Supraclavicular/Scalene nodes
☐ Contralateral lung
☐ Pleura
☐ Liver
☐ Adrenals
☐ Bone
☐ Bone marrow
☐ Brain
☐ Other
specify_____

SYMPTOMS

☐ CNS Symptoms (1=no, 2=yes)
☐ Chest Pain (1=no, 2=yes)
☐ Dyspnea (1=no, 2=yes)

☐ Duration of symptoms prior to diagnosis
1= ≤ 3 months
2= 3-6 months
3= ≥ 6 months

☐ Weight loss in previous 6 months:
1=none or < 5 % of body weight
2=5-10 % of body weight
3=> 10 % of body weight

PRE-STUDY LAB WORK *(Date: month, day and four digit year)*

☐☐.☐ WBC ($x10^3$) ___/___/_____
☐☐.☐ ANC ($x10^3$) ___/___/_____
☐☐☐ Platelets ($x10^3$) ___/___/_____
☐☐.☐ Hemoglobin (g/dl) ___/___/_____
☐.☐ Albumin (mg/dl) ___/___/_____

☐.☐ Creatinine (mg/dl) ____/___/____
☐☐☐ SGOT (AST) (mg/dl) ____/____/____
☐☐☐☐ LDH (units) ____/____/_____
LDH normal range:_____
☐.☐ Bilirubin (mg/dl) ____/____/_____

PREVIOUS RADIOTHERAPY

☐ ***(1=no, 2=yes If yes, specify below)***

Site	Dates of treatment From:	To:

9732 REMARKS ADDENDA

CALGB Study No: 9732
CALGB Patient ID: _____
Amended Data? _____Yes

INSTRUCTIONS: This form is to be used to detail patient history, physical findings and to describe adverse events or toxicities noted while the patient is on study. Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name_____

Dates Covered: _____ /_____ /_____ to _____/_____/_____

9732 MEASUREMENT FORM

CALGB Form:	C-276
CALGB Study No:	9732
CALGB Patient ID:	_____
Amended Data?	_____Yes

INSTRUCTIONS:. Document all tumor and lymph node measurements for the appropriate time-frame listed below. For MEASUREABLE DISEASE, record BIDIMENSIONAL measurements. For EVALUABLE DISEASE, record disease 'present' (initially), 'increase', 'unchanged', 'decrease' or 'absent' (subsequently). Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

	Baseline	After Cycle 2	After Cycle 4	After Cycle 6	Post Treatment	Post Treatment
Date of Observation (m/d/y)						
Response: CR, PR, SD, PD	N/A					
SITES MEASURED						

SUBMIT ALL OF THE PRECEDING PAGES NOW.

Include with on-study data a copy of the pathology report indicating the diagnosis.

Submit to the Data Management Center all completed on study data including the Eligibility Checklist.

Retain a copy of all forms submitted for your records and send the originals to:

CALGB Data Management Center
2200 W. Main St., Suite 340
Durham, NC 27705

Submit forms according to the schedule specified in the DATA SUBMISSION SECTION, 5.0 of the 9732 protocol, and listed at the beginning of the 9732 PROTOCOL TREATMENT FORMS book.

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045

CHEMOTHERAPY DOSING FOR CYCLE 1

INSTRUCTIONS: Complete this form following CYCLE 1 DOSING. Information in the upper right box must be completed for this form to be accepted. Do not leave any entries blank. Enter -1 to indicate that an answer is "unknown", "unobtainable", or "not done". Highlight and circle *ALL* amended data.

CALGB Form:	C-523
CALGB Study No.:	9732
CALGB Patient ID.:	_____
Amended Data?	_____Yes

Patient's Name_____ Participating Group_____

Cycle Number 1

First Day of Cycle ☐☐ ☐☐ ☐☐☐☐ (M D Y) Last Day Drugs Administered ☐☐ ☐☐ ☐☐☐☐ (M D Y)

Weight (kg) ☐☐☐.☐ BSA (m^2) ☐.☐☐

Record the Amount of Protocol Drugs Received During This Cycle *(See codes at bottom of page)*

Drug Code	Amount Received	Units ✣	Days Received	Dose Modified? ✳	If Yes Why? @	Per Prot? ✳	Dose Delayed? ✳	If Yes Why? @	If `Why?' Code=99, Specify
Cisplatin									
38	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Taxol									
09	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Etoposide									
69	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____

FOR G-CSF ADMINISTRATION

Drug Code (G-CSF)	Amount Received	Units ✣	Days Received
50	☐☐☐.☐☐	☐ ×	☐☐

CODES

✳ **1=No, 2=Yes**

✣ **Units**

1-Grams
2-Milligrams
3-Micrograms
4-Liters
5-Milliliters
6- Units
7- International Units

@ **Modification/Delay**

41 - Hematologic Tox
42 - Hepatic Dys.
43 - PNS Toxicity
44 - CNS Toxicity
45 - GI Toxicity

@ **Modification/Delay**

46 -Cardiotoxicity
47 -Pulmonary Toxicity
48 -Renal toxicity
49 -Infection/fever
99 -Other

TOXICITY DOCUMENTATION:

This form must be filled out using the **CALGB Expanded Common Toxicity Criteria.**

For all toxicities coded, refer to **CALGB Expanded Common Toxicity Criteria** for the grading of all toxicities listed on the form. Indicate if a coded toxicity is:

TREATMENT RELATED=1,
NOT TREATMENT RELATED=2, or
UNKNOWN=3 (unable to be determined if the event is or is not treatment related.)

Address every toxicity listed on the form.
If no toxicity has been observed, enter "0"in the space provided for grade of toxicity.

If "Other" toxicities are reported in a category, print entry legibly and code the event according to the above instructions.

Use the **9732 Remarks Addenda** following each toxicity page to describe relevant events involving coded toxicities.

It is not necessary to transcribe laboratory reports on to the Remarks Addenda as supportive documentation for coded toxicities.

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045

TOXICITIES OBSERVED FROM CYCLE 1

CALGB Form:	C-524
CALGB Study No.:	9732
CALGB Patient ID.:	_____
Amended Data?	_____Yes

INSTRUCTIONS: Report all toxicities observed from Cycle 1 prior to dosing on Cycle 2. Complete all information in the upper right-hand box. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box. Retain a copy for your records and send original to CALGB DMC.

Patient's Name_____ Participating Group_____

Patient Hospital Number_____ Participating Group Protocol No. _____

Main Member Institution/Adjunct_____ Participating Group Patient No._____

1 **CYCLE NUMBER**

Time Period Covered By This Form: From ☐☐ ☐☐ ☐☐☐☐ (m/d/y) To ☐☐ ☐☐ ☐☐☐☐ (m/d/y)

☐ Was an ADVERSE Drug Reaction Report filled based on an event reported below?

Coding Instructions: Use the CALGB Expanded Common Toxicity criteria to determine grade.

If no toxicity is reported for a specific category, code grade = 0

GRADE	Treatment Related (1=no, 2=yes, 3=unknown)	
		HEMATALOGIC
☐	☐	WBC
☐	☐	Platelets
☐	☐	Hemoglobin
☐	☐	Granulocytes
☐	☐	Lymphocytes
☐	☐	Other, sp_____
		GASTROINTESTINAL
☐	☐	Nausea
☐	☐	Vomiting
☐	☐	Diarrhea
☐	☐	Stomatitis
☐	☐	Anorexia
☐	☐	Other, sp_____
		LIVER
☐	☐	Bilirubin
☐	☐	SGPT (AST)
☐	☐	Alk Phos
☐	☐	Other, sp_____
		KIDNEY
☐	☐	Creatinine
☐	☐	Other, sp_____

GRADE	Treatment Related (1=no, 2=yes. 3=unknown)	
		PULMONARY
☐	☐	Dypsnea
☐	☐	Other, sp_____
		HEART
☐	☐	Cardiac dysrhythmia
☐	☐	Cardiac ischemia
☐	☐	Other, sp_____
		NEUROLOGIC
☐	☐	Neuro sensory
☐	☐	Neuro motor
☐	☐	Neuro hearing
☐	☐	Other, sp_____
		ALLERGY
☐	☐	Allergic reaction
☐	☐	Other, sp_____
		FLU LIKE SYMPTOMS
☐	☐	Fever
☐	☐	Myalgia/Arthralgia
		METABOLIC
☐	☐	Hypomagnesemia
☐	☐	Other, sp_____

9732 REMARKS ADDENDA

CALGB Study No: 9732
CALGB Patient ID: _____
Amended Data? _____Yes

INSTRUCTIONS:. This form is to be used to detail patient history, physical findings and to describe adverse events or toxicities noted while the patient is on study. Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name_____

Dates Covered:_____ /_____ /_____ to _____/_____/_____

EARLY TERMINATION OF TREATMENT:

If the patient ends treatment prematurely for any reason or the patient is taken off study prior to the assessment of response, relapse or death, submit the **Response / Relapse** and **Measurement Forms** for this cycle and the **C-300 Off Treatment Notice** (page 28.) Go to the **2 through 12 Month Post Treatment Response/Relapse Forms** (beginning on page 29) to begin post treatment follow-up every 4 months for 1 year.

If a second malignancy is discovered, submit the **C-215 Notice of Second Malignancy Form.** (page 45)

If the patient dies, submit the **C-113 Notification of Death Form** (page 46.) If death occurs while receiving protocol treatment, follow the guidelines in section 13.0 for the reporting of Adverse Events (AERs).

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045

CHEMOTHERAPY DOSING FOR CYCLE 2

INSTRUCTIONS: Complete this form following CYCLE 1 DOSING. Information in the upper right box must be completed for this form to be accepted. Do not leave any entries blank. Enter -1 to indicate that an answer is "unknown", "unobtainable", or "not done". Highlight and circle *ALL* amended data.

CALGB Form:	C-523
CALGB Study No.:	9732
CALGB Patient ID.:	_____
Amended Data?	_____Yes

Patient's Name_____ Participating Group_____

Cycle Number 2

First Day of Cycle ☐☐ ☐☐ ☐☐☐☐ (M D Y) Last Day Drugs Administered ☐☐ ☐☐ ☐☐☐☐ (M D Y)

Weight (kg) ☐☐☐.☐ BSA (m^2) ☐.☐☐

Record the Amount of Protocol Drugs Received During This Cycle *(See codes at bottom of page)*

Drug Code	Amount Received	Units ✣	Days Received	Dose Modified? ✳	If Yes Why? @	Per Prot? ✳	Dose Delayed? ✳	If Yes Why? @	If `Why?' Code=99, Specify
Cisplatin									
38	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Taxol									
09	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Etoposide									
69	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____

FOR G-CSF ADMINISTRATION

Drug Code (G-CSF)	Amount Received	Units ✣	Days Received
50	☐☐☐.☐☐	☐ ×	☐☐

CODES

✳ **1=No, 2=Yes**

✣ **Units**

1-Grams
2-Milligrams
3-Micrograms
4-Liters
5-Milliliters
6- Units
7- International Units

@ **Modification/Delay**

41 - Hematologic Tox
42 - Hepatic Dys.
43 - PNS Toxicity
44 - CNS Toxicity
45 - GI Toxicity

@ **Modification/Delay**

46 -Cardiotoxicity
47 -Pulmonary Toxicity
48 -Renal toxicity
49 -Infection/fever
99 -Other

TOXICITIES OBSERVED FROM CYCLE 2

CALGB Form:	C-524
CALGB Study No.:	9732
CALGB Patient ID.:	_____
Amended Data?	_____Yes

INSTRUCTIONS: Report all toxicities observed from Cycle 2 prior to dosing on Cycle 3. Complete all information in the upper right-hand box. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box. Retain a copy for your records and send original to CALGB DMC.

Patient's Name _____ Participating Group _____

☐ 2 **CYCLE NUMBER**

Time Period Covered By This Form: From ☐☐ ☐☐ ☐☐☐☐ (m/d/y) To ☐☐ ☐☐ ☐☐☐☐ (m/d/y)

☐ Was an ADVERSE Drug Reaction Report filed based on an event reported below?

Coding Instructions: Use the CALGB Expanded Common Toxicity criteria to determine grade.
If no toxicity is reported for a specific category, code grade = 0

GRADE	Treatment Related (1=no, 2=yes, 3=unknown)	
		HEMATOLOGIC
☐	☐	WBC
☐	☐	Platelets
☐	☐	Hemoglobin
☐	☐	Granulocytes
☐	☐	Lymphocytes
☐	☐	Other, sp_____
		GASTROINTESTINAL
☐	☐	Nausea
☐	☐	Vomiting
☐	☐	Diarrhea
☐	☐	Stomatitis
☐	☐	Anorexia
☐	☐	Other, sp_____
		LIVER
☐	☐	Bilirubin
☐	☐	SGPT (AST)
☐	☐	Alk Phos
☐	☐	Other, sp_____
		KIDNEY
☐	☐	Creatinine
☐	☐	Other, sp_____

GRADE	Treatment Related (1=no, 2=yes. 3=unknown)	
		PULMONARY
☐	☐	Dyspnea
☐	☐	Other, sp_____
		HEART
☐	☐	Cardiac dysrhythmia
☐	☐	Cardiac ischemia
☐	☐	Other, sp_____
		NEUROLOGIC
☐	☐	Neuro sensory
☐	☐	Neuro motor
☐	☐	Neuro hearing
☐	☐	Other, sp_____
		ALLERGY
☐	☐	Allergic reaction
☐	☐	Other, sp_____
		FLU LIKE SYMPTOMS
☐	☐	Febrile neutropenia
☐	☐	Myalgia/Arthralgia
☐	☐	Other, sp_____
		MISCELLANEOUS
☐	☐	Specify_____
☐	☐	Specify_____

9732 REMARKS ADDENDA

CALGB Study No: 9732
CALGB Patient ID: _____
Amended Data? _____Yes

INSTRUCTIONS: This form is to be used to detail patient history, physical findings and to describe adverse events or toxicities noted while the patient is on study. Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name_____

Dates Covered:_____ /_____ /_____ to _____/_____/_____

RESPONSE AND RELAPSE CODING:

Submit according to the data submission schedule after cycles 2, 4, and 6 as well as every 4 months during the first year after treatment has been completed. Submit the **C-400 Long-Term Follow-Up Form**, (page 41) for follow-up beginning 18 months after treatment has ended (or 6 months after the final **12 Month Post Treatment Response/Relapse Form** has been submitted.)

If the patient ends treatment prematurely for any reason or the patient is taken off study prior to the assessment of response, relapse or death, submit the **C-300 Off Treatment Notice** (page 28). Go to the **4 through 12 Month Post Treatment Forms** (beginning on page 29) to begin post treatment follow-up every 4 months for 1 year.

If the patient dies, submit the **C-113 Notification of Death Form** (page 46). If death occurs while receiving protocol treatment, follow the guidelines in section 13.0 for the reporting of Adverse Events (AERs).

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045

RESPONSE / RELAPSE FORM FOR CYCLES 1 & 2

CALGB Form:	C-525
CALGB Study #:	9732
CALGB Patient ID:	_____
Amended Data ?	_____yes

INSTRUCTIONS: Use this form to assess treatment from CYCLES 1 & 2. Complete all information in the upper right-hand box. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient's Name: _____

TIME PERIOD COVERED BY THIS FORM:

From: ☐☐ ☐☐ ☐☐☐☐ **To:** ☐☐ ☐☐ ☐☐☐☐ **(m/d/y)** ☐2 **Cycle**

☐ **Survival status**
1-Alive
2-Dead
3-Lost to follow-up

Date last known alive or date of death: ☐☐ ☐☐ ☐☐☐☐ **(m/d/y)**

☐ **Status of assigned Treatment:**
1-Therapy has been terminated permanently.
2-Therapy is being continued.

RESPONSE DATA

☐ **Best overall objective response to date:**
1-Complete response
2-Partial response
3-Regression (nonmeasurable disease)
4-Stable disease
5-Progression
6-Unevaluable

☐ **Current status of remission:**
1-Continues in remission
2-Relapsed after response or improvement
3-Died with no evidence of relapse

Date last known in remission:
☐☐ ☐☐ ☐☐☐☐ **(m/d/y)**

If any of the following have occurred during this report period, please give date(s):

Partial response/regression onset:
☐☐ ☐☐ ☐☐☐☐ **(m/d/y)**

Complete response onset:
☐☐ ☐☐ ☐☐☐☐ **(m/d/y)**

First local-regional progression/relapse:
☐☐ ☐☐ ☐☐☐☐ **(m/d/y)**

First distant disease progression/relapse:
☐☐ ☐☐ ☐☐☐☐ **(m/d/y)**

CNS metastases:
☐☐ ☐☐ ☐☐☐☐ **(m/d/y)**

☐ **Total number of cycles of chemotherapy completed to date.**

PROGRESSION / RELAPSE DATA

If a progression/relapse has occurred, document the site of relapse and the method of assessment.

Sites Of Relapse
1-Not involved
2-Involved
3-Equivocal

Assessment Method
1-Clinical (palpation radiologic scan)
2-Pathologic 3-Autopsy

☐	Hilar Nodes	☐
☐	Mediastinal Nodes	☐
☐	Supraclavicular/Scalene Nodes	☐
☐	Primary Lung	☐
☐	Contralateral lung	☐
☐	Pleura	☐
☐	Liver	☐
☐	Adrenal(s)	☐
☐	Bone	☐
☐	Bone Marrow	☐
☐	Brain	☐
☐	Other Nodal, Specify_____	☐
☐	Other, Specify_____	☐

☐ **Was progression or relapse associated with initial site(s) of disease? (1=no, 2=yes)**

☐ **Did a new primary tumor develop? (1-no; 2-yes)**

If yes, date ☐☐ ☐☐ ☐☐☐☐ **(m/d/y)**

9732 MEASUREMENT FORM

CALGB Form:	C-276
CALGB Study No:	9732
CALGB Patient ID:	_____
Amended Data?	_____Yes

INSTRUCTIONS:. Document all tumor and lymph node measurements for the appropriate time-frame listed below. For MEASUREABLE DISEASE, record BIDIMENSIONAL measurements. For EVALUABLE DISEASE, record disease 'present' (initially), 'increase', 'unchanged', 'decrease' or 'absent' (subsequently). Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

	Baseline	After Cycle 2	After Cycle 4	After Cycle 6	Post Treatment	Post Treatment
Date of Observation (m/d/y)						
Response: CR, PR, SD, PD	N/A					
SITES MEASURED						

SUBMIT ALL OF THE PRECEDING PAGES NOW.

Submit to the Data Management Center all completed data that has not been previously submitted.

Retain a copy of all forms submitted for your records and send the originals to:

CALGB Data Management Center
2200 W. Main St., Suite 340
Durham, NC 27705

Submit forms according to the schedule specified in the DATA SUBMISSION SECTION of the 9732 protocol, and listed at the beginning of the 9732 PROTOCOL TREATMENT FORMS book.

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045

CHEMOTHERAPY DOSING FOR CYCLE 3

INSTRUCTIONS: Complete this form following CYCLE 1 DOSING. Information in the upper right box must be completed for this form to be accepted. Do not leave any entries blank. Enter -1 to indicate that an answer is "unknown", "unobtainable", or "not done". Highlight and circle *ALL* amended data.

CALGB Form:	C-523
CALGB Study No.:	9732
CALGB Patient ID.:	_____
Amended Data?	_____Yes

Patient's Name_____ Participating Group_____

Cycle Number 3

First Day of Cycle ☐☐ ☐☐ ☐☐☐☐ (M D Y) Last Day Drugs Administered ☐☐ ☐☐ ☐☐☐☐ (M D Y)

Weight (kg) ☐☐☐.☐ BSA (m^2) ☐.☐☐

Record the Amount of Protocol Drugs Received During This Cycle *(See codes at bottom of page)*

Drug Code	Amount Received	Units+	Days Received	Dose Modified?*	If Yes Why?@	Per Prot?*	Dose Delayed?*	If Yes Why?@	If `Why?' Code=99, Specify
Cisplatin									
38	☐☐☐.☐☐	☐×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Taxol									
09	☐☐☐.☐☐	☐×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Etoposide									
69	☐☐☐.☐☐	☐×	☐☐	☐	☐☐	☐	☐	☐☐	_____

FOR G-CSF ADMINISTRATION

Drug Code (G-CSF)	Amount Received	Units+	Days Received
50	☐☐☐.☐☐	☐×	☐☐

CODES

* **1=No, 2=Yes**

+ **Units**

1-Grams
2-Milligrams
3-Micrograms
4-Liters
5-Milliliters
6- Units
7- International Units

@ **Modification/Delay**

41 - Hematologic Tox
42 - Hepatic Dys.
43 - PNS Toxicity
44 - CNS Toxicity
45 - GI Toxicity

@ **Modification/Delay**

46 -Cardiotoxicity
47 -Pulmonary Toxicity
48 -Renal toxicity
49 -Infection/fever
99 -Other

TOXICITIES OBSERVED FROM CYCLE 3

INSTRUCTIONS: Report all toxicities observed from Cycle 3 prior to dosing on Cycle 4. Complete all information in the upper right-hand box. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box. Retain a copy for your records and send original to CALGB DMC.

CALGB Form:	C-524
CALGB Study No.:	9732
CALGB Patient ID.:	_____
Amended Data?	_____Yes

Patient's Name_____ Participating Group_____

3 **CYCLE NUMBER**

Time Period Covered By This Form: From ☐☐ ☐☐ ☐☐☐☐ (m/d/y) To ☐☐ ☐☐ ☐☐☐☐ (m/d/y)

☐ Was an ADVERSE Drug Reaction Report filed based on an event reported below?

Coding Instructions: Use the CALGB Expanded Common Toxicity criteria to determine grade.
If no toxicity is reported for a specific category, code grade = 0

GRADE	Treatment Related (1=no, 2=yes, 3=unknown)	
		HEMATOLOGIC
☐	☐	WBC
☐	☐	Platelets
☐	☐	Hemoglobin
☐	☐	Granulocytes
☐	☐	Lymphocytes
☐	☐	Other, sp_____
		GASTROINTESTINAL
☐	☐	Nausea
☐	☐	Vomiting
☐	☐	Diarrhea
☐	☐	Stomatitis
☐	☐	Anorexia
☐	☐	Other, sp_____
		LIVER
☐	☐	Bilirubin
☐	☐	SGPT (AST)
☐	☐	Alk Phos
☐	☐	Other, sp_____
		KIDNEY
☐	☐	Creatinine
☐	☐	Other, sp_____

GRADE	Treatment Related (1=no, 2=yes. 3=unknown)	
		PULMONARY
☐	☐	Dyspnea
☐	☐	Other, sp_____
		HEART
☐	☐	Cardiac dysrhythmia
☐	☐	Cardiac ischemia
☐	☐	Other, sp_____
		NEUROLOGIC
☐	☐	Neuro sensory
☐	☐	Neuro motor
☐	☐	Neuro hearing
☐	☐	Other, sp_____
		ALLERGY
☐	☐	Allergic reaction
☐	☐	Other, sp_____
		FLU LIKE SYMPTOMS
☐	☐	Febrile neutropenia
☐	☐	Myalgia/Arthralgia
☐	☐	Other, sp_____
		MISCELLANEOUS
☐	☐	Specify_____
☐	☐	Specify_____

9732 REMARKS ADDENDA

CALGB Study No:	9732
CALGB Patient ID:	_____
Amended Data?	_____Yes

INSTRUCTIONS: This form is to be used to detail patient history, physical findings and to describe adverse events or toxicities noted while the patient is on study. Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

Dates Covered:_____ /_____ /_____ to _____/_____/_____

CHEMOTHERAPY DOSING FOR CYCLE 4

INSTRUCTIONS: Complete this form following CYCLE 1 DOSING. Information in the upper right box must be completed for this form to be accepted. Do not leave any entries blank. Enter -1 to indicate that an answer is "unknown", "unobtainable", or "not done". Highlight and circle *ALL* amended data.

CALGB Form:	C-523
CALGB Study No.:	9732
CALGB Patient ID.:	_____
Amended Data?	_____Yes

Patient's Name_____ Participating Group_____

Cycle Number 4

First Day of Cycle ☐☐ ☐☐ ☐☐☐☐ (M D Y) Last Day Drugs Administered ☐☐ ☐☐ ☐☐☐☐ (M D Y)

Weight (kg) ☐☐☐.☐ BSA (m^2) ☐.☐☐

Record the Amount of Protocol Drugs Received During This Cycle *(See codes at bottom of page)*

Drug Code	Amount Received	Units ✣	Days Received	Dose Modified? ✳	If Yes Why? @	Per Prot? ✳	Dose Delayed? ✳	If Yes Why? @	If `Why?' Code=99, Specify
Cisplatin									
38	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Taxol									
09	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Etoposide									
69	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____

FOR G-CSF ADMINISTRATION

Drug Code (G-CSF)	Amount Received	Units ✣	Days Received
50	☐☐☐.☐☐	☐ ×	☐☐

CODES

✳ **1=No, 2=Yes**

✣ **Units**

1-Grams
2-Milligrams
3-Micrograms
4-Liters
5-Milliliters
6- Units
7- International Units

@ **Modification/Delay**

41 - Hematologic Tox
42 - Hepatic Dys.
43 - PNS Toxicity
44 - CNS Toxicity
45 - GI Toxicity

@ **Modification/Delay**

46 -Cardiotoxicity
47 -Pulmonary Toxicity
48 -Renal toxicity
49 -Infection/fever
99 -Other

TOXICITIES OBSERVED FROM CYCLE 4

INSTRUCTIONS: Report all toxicities observed from Cycle 4 prior to dosing on Cycle 5. Complete all information in the upper right-hand box. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box. Retain a copy for your records and send original to CALGB DMC.

CALGB Form:	C-524
CALGB Study No.:	9732
CALGB Patient ID.:	_____
Amended Data?	_____Yes

Patient's Name_____ Participating Group_____

4 **CYCLE NUMBER**

Time Period Covered By This Form: From ☐☐ ☐☐ ☐☐☐☐ (m/d/y) To ☐☐ ☐☐ ☐☐☐☐ (m/d/y)

☐ Was an ADVERSE Drug Reaction Report filed based on an event reported below?

Coding Instructions: Use the CALGB Expanded Common Toxicity criteria to determine grade.
If no toxicity is reported for a specific category, code grade = 0

GRADE	Treatment Related (1=no, 2=yes, 3=unknown)	
		HEMATOLOGIC
☐	☐	WBC
☐	☐	Platelets
☐	☐	Hemoglobin
☐	☐	Granulocytes
☐	☐	Lymphocytes
☐	☐	Other, sp_____
		GASTROINTESTINAL
☐	☐	Nausea
☐	☐	Vomiting
☐	☐	Diarrhea
☐	☐	Stomatitis
☐	☐	Anorexia
☐	☐	Other, sp_____
		LIVER
☐	☐	Bilirubin
☐	☐	SGPT (AST)
☐	☐	Alk Phos
☐	☐	Other, sp_____
		KIDNEY
☐	☐	Creatinine
☐	☐	Other, sp_____

GRADE	Treatment Related (1=no, 2=yes. 3=unknown)	
		PULMONARY
☐	☐	Dyspnea
☐	☐	Other, sp_____
		HEART
☐	☐	Cardiac dysrhythmia
☐	☐	Cardiac ischemia
☐	☐	Other, sp_____
		NEUROLOGIC
☐	☐	Neuro sensory
☐	☐	Neuro motor
☐	☐	Neuro hearing
☐	☐	Other, sp_____
		ALLERGY
☐	☐	Allergic reaction
☐	☐	Other, sp_____
		FLU LIKE SYMPTOMS
☐	☐	Febrile neutropenia
☐	☐	Myalgia/Arthralgia
☐	☐	Other, sp_____
		MISCELLANEOUS
☐	☐	Specify_____
☐	☐	Specify_____

9732 REMARKS ADDENDA

CALGB Study No: 9732
CALGB Patient ID: _____
Amended Data? _____Yes

INSTRUCTIONS: This form is to be used to detail patient history, physical findings and to describe adverse events or toxicities noted while the patient is on study. Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

Dates Covered:_____ /_____ /_____ to _____/_____/_____

RESPONSE / RELAPSE FORM FOR CYCLES 3 & 4

CALGB Form:	C-525
CALGB Study #:	9732
CALGB Patient ID:	_____
Amended Data ?	_____yes

INSTRUCTIONS: Use this form to assess treatment from CYCLES 3 & 4. Complete all information in the upper right-hand box. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient's Name: _____

TIME PERIOD COVERED BY THIS FORM:

From: ☐☐☐☐☐☐☐☐ **To:** ☐☐☐☐☐☐☐☐ **(m/d/y)** ☐4 **Cycle**

☐ **Survival status**
1-Alive
2-Dead
3-Lost to follow-up

Date last known alive or date of death: ☐☐☐☐☐☐☐☐ **(m/d/y)**

☐ **Status of assigned Treatment:**
1-Therapy has been terminated permanently.
2-Therapy is being continued.

RESPONSE DATA

☐ **Best overall objective response to date:**
1-Complete response
2-Partial response
3-Regression (nonmeasurable disease)
4-Stable disease
5-Progression
6-Unevaluable

☐ **Current status of remission:**
1-Continues in remission
2-Relapsed after response or improvement
3-Died with no evidence of relapse

Date last known in remission:
☐☐☐☐☐☐☐☐ **(m/d/y)**

If any of the following have occurred during this report period, please give date(s):

Partial response/regression onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

Complete response onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First local-regional progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First distant disease progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

CNS metastases:
☐☐☐☐☐☐☐☐ **(m/d/y)**

☐ **Total number of cycles of chemotherapy completed to date.**

PROGRESSION / RELAPSE DATA

If a progression/relapse has occurred, document the site of relapse and the method of assessment.

Sites Of Relapse
1-Not involved
2-Involved
3-Equivocal

Assessment Method
1-Clinical (palpation radiologic scan)
2-Pathologic 3-Autopsy

☐	Hilar Nodes	☐
☐	Mediastinal Nodes	☐
☐	Supraclavicular/Scalene Nodes	☐
☐	Primary Lung	☐
☐	Contralateral lung	☐
☐	Pleura	☐
☐	Liver	☐
☐	Adrenal(s)	☐
☐	Bone	☐
☐	Bone Marrow	☐
☐	Brain	☐
☐	Other Nodal, Specify_____	☐
☐	Other, Specify_____	☐

☐ **Was progression or relapse associated with initial site(s) of disease? (1=no, 2=yes)**

☐ **Did a new primary tumor develop? (1-no; 2-yes)**

If yes, date ☐☐☐☐☐☐☐☐ **(m/d/y)**

9732 MEASUREMENT FORM

CALGB Form:	C-276
CALGB Study No:	9732
CALGB Patient ID:	_____
Amended Data?	_____Yes

INSTRUCTIONS:. Document all tumor and lymph node measurements for the appropriate time-frame listed below. For MEASUREABLE DISEASE, record BIDIMENSIONAL measurements. For EVALUABLE DISEASE, record disease 'present' (initially), 'increase', 'unchanged', 'decrease' or 'absent' (subsequently). Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

	Baseline	After Cycle 2	After Cycle 4	After Cycle 6	Post Treatment	Post Treatment
Date of Observation (m/d/y)						
Response: CR, PR, SD, PD	N/A					
SITES MEASURED						

SUBMIT ALL OF THE PRECEDING PAGES NOW.

Submit to the Data Management Center all completed data that has not been previously submitted.

Retain a copy of all forms submitted for your records and send the originals to:

CALGB Data Management Center
2200 W. Main St., Suite 340
Durham, NC 27705

Submit forms according to the schedule specified in the DATA SUBMISSION SECTION of the 9732 protocol, and listed at the beginning of the 9732 PROTOCOL TREATMENT FORMS book.

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045

CHEMOTHERAPY DOSING FOR CYCLE 5

INSTRUCTIONS: Complete this form following CYCLE 1 DOSING. Information in the upper right box must be completed for this form to be accepted. Do not leave any entries blank. Enter -1 to indicate that an answer is "unknown", "unobtainable", or "not done". Highlight and circle *ALL* amended data.

CALGB Form:	C-523
CALGB Study No.:	9732
CALGB Patient ID.:	_____
Amended Data?	_____Yes

Patient's Name_____ Participating Group_____

Cycle Number 5

First Day of Cycle ☐☐ ☐☐ ☐☐☐☐ (M D Y) Last Day Drugs Administered ☐☐ ☐☐ ☐☐☐☐ (M D Y)

Weight (kg) ☐☐☐.☐ BSA (m^2) ☐.☐☐

Record the Amount of Protocol Drugs Received During This Cycle *(See codes at bottom of page)*

Drug Code	Amount Received	Units+	Days Received	Dose Modified?*	If Yes Why?@	Per Prot?*	Dose Delayed?*	If Yes Why?@	If `Why?' Code=99, Specify
Cisplatin									
38	☐☐☐.☐☐	☐×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Taxol									
09	☐☐☐.☐☐	☐×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Etoposide									
69	☐☐☐.☐☐	☐×	☐☐	☐	☐☐	☐	☐	☐☐	_____

FOR G-CSF ADMINISTRATION

Drug Code (G-CSF)	Amount Received	Units+	Days Received
50	☐☐☐.☐☐	☐×	☐☐

CODES

* **1=No, 2=Yes**

+ **Units**

1-Grams
2-Milligrams
3-Micrograms
4-Liters
5-Milliliters
6- Units
7- International Units

@ **Modification/Delay**

41 - Hematologic Tox
42 - Hepatic Dys.
43 - PNS Toxicity
44 - CNS Toxicity
45 - GI Toxicity

@ **Modification/Delay**

46 -Cardiotoxicity
47 -Pulmonary Toxicity
48 -Renal toxicity
49 -Infection/fever
99 -Other

TOXICITIES OBSERVED FROM CYCLE 5

INSTRUCTIONS: Report all toxicities observed from Cycle 5 prior to dosing on Cycle 6. Complete all information in the upper right-hand box. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box. Retain a copy for your records and send original to CALGB DMC.

CALGB Form:	C-524
CALGB Study No.:	9732
CALGB Patient ID.:	_____
Amended Data?	_____Yes

Patient's Name_____ Participating Group_____

5 **CYCLE NUMBER**

Time Period Covered By This Form: From ☐☐ ☐☐ ☐☐☐☐ (m/d/y) To ☐☐ ☐☐ ☐☐☐☐ (m/d/y)

☐ Was an ADVERSE Drug Reaction Report filed based on an event reported below?

Coding Instructions: Use the CALGB Expanded Common Toxicity criteria to determine grade.
If no toxicity is reported for a specific category, code grade = 0

GRADE	Treatment Related (1=no, 2=yes, 3=unknown)	
		HEMATOLOGIC
☐	☐	WBC
☐	☐	Platelets
☐	☐	Hemoglobin
☐	☐	Granulocytes
☐	☐	Lymphocytes
☐	☐	Other, sp_____
		GASTROINTESTINAL
☐	☐	Nausea
☐	☐	Vomiting
☐	☐	Diarrhea
☐	☐	Stomatitis
☐	☐	Anorexia
☐	☐	Other, sp_____
		LIVER
☐	☐	Bilirubin
☐	☐	SGPT (AST)
☐	☐	Alk Phos
☐	☐	Other, sp_____
		KIDNEY
☐	☐	Creatinine
☐	☐	Other, sp_____

GRADE	Treatment Related (1=no, 2=yes. 3=unknown)	
		PULMONARY
☐	☐	Dyspnea
☐	☐	Other, sp_____
		HEART
☐	☐	Cardiac dysrhythmia
☐	☐	Cardiac ischemia
☐	☐	Other, sp_____
		NEUROLOGIC
☐	☐	Neuro sensory
☐	☐	Neuro motor
☐	☐	Neuro hearing
☐	☐	Other, sp_____
		ALLERGY
☐	☐	Allergic reaction
☐	☐	Other, sp_____
		FLU LIKE SYMPTOMS
☐	☐	Febrile neutropenia
☐	☐	Myalgia/Arthralgia
☐	☐	Other, sp_____
		MISCELLANEOUS
☐	☐	Specify_____
☐	☐	Specify_____

9732 REMARKS ADDENDA

CALGB Study No: 9732
CALGB Patient ID: _____
Amended Data? _____Yes

INSTRUCTIONS: This form is to be used to detail patient history, physical findings and to describe adverse events or toxicities noted while the patient is on study. Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

Dates Covered:_____ /_____ /_____ to _____/_____/_____

CHEMOTHERAPY DOSING FOR CYCLE 6

INSTRUCTIONS: Complete this form following CYCLE 1 DOSING. Information in the upper right box must be completed for this form to be accepted. Do not leave any entries blank. Enter -1 to indicate that an answer is "unknown", "unobtainable", or "not done". Highlight and circle *ALL* amended data.

CALGB Form:	C-523
CALGB Study No.:	9732
CALGB Patient ID.:	_____
Amended Data?	_____Yes

Patient's Name_____ Participating Group_____

Cycle Number 6

First Day of Cycle ☐☐ ☐☐ ☐☐☐☐ (M D Y) Last Day Drugs Administered ☐☐ ☐☐ ☐☐☐☐ (M D Y)

Weight (kg) ☐☐☐.☐ BSA (m^2) ☐.☐☐

Record the Amount of Protocol Drugs Received During This Cycle *(See codes at bottom of page)*

Drug Code	Amount Received	Units ✛	Days Received	Dose Modified? ✳	If Yes Why? @	Per Prot? ✳	Dose Delayed? ✳	If Yes Why? @	If `Why?' Code=99, Specify
Cisplatin									
38	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Taxol									
09	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____
Etoposide									
69	☐☐☐.☐☐	☐ ×	☐☐	☐	☐☐	☐	☐	☐☐	_____

FOR G-CSF ADMINISTRATION

Drug Code (G-CSF)	Amount Received	Units ✛	Days Received
50	☐☐☐.☐☐	☐ ×	☐☐

CODES

✳ **1=No, 2=Yes**

✛ **Units**

1-Grams
2-Milligrams
3-Micrograms
4-Liters
5-Milliliters
6- Units
7- International Units

@ **Modification/Delay**

41 - Hematologic Tox
42 - Hepatic Dys.
43 - PNS Toxicity
44 - CNS Toxicity
45 - GI Toxicity

@ **Modification/Delay**

46 -Cardiotoxicity
47 -Pulmonary Toxicity
48 -Renal toxicity
49 -Infection/fever
99 -Other

TOXICITIES OBSERVED FROM CYCLE 6

CALGB Form:	C-524
CALGB Study No.:	9732
CALGB Patient ID.:_____	
Amended Data?_____	Yes

INSTRUCTIONS: Report all toxicities observed prior to dosing on Cycle 6. Complete all information in the upper right-hand box. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box. Retain a copy for your records and send original to CALGB DMC.

Patient's Name_____ Participating Group_____

6 **CYCLE NUMBER**

Time Period Covered By This Form: From ☐☐ ☐☐ ☐☐☐☐ (m/d/y) To ☐☐ ☐☐ ☐☐☐☐ (m/d/y)

☐ Was an ADVERSE Drug Reaction Report filed based on an event reported below?

Coding Instructions: Use the CALGB Expanded Common Toxicity criteria to determine grade.
If no toxicity is reported for a specific category, code grade = 0

GRADE	Treatment Related (1=no, 2=yes, 3=unknown)	
		HEMATOLOGIC
☐	☐	WBC
☐	☐	Platelets
☐	☐	Hemoglobin
☐	☐	Granulocytes
☐	☐	Lymphocytes
☐	☐	Other, sp_____
		GASTROINTESTINAL
☐	☐	Nausea
☐	☐	Vomiting
☐	☐	Diarrhea
☐	☐	Stomatitis
☐	☐	Anorexia
☐	☐	Other, sp_____
		LIVER
☐	☐	Bilirubin
☐	☐	SGPT (AST)
☐	☐	Alk Phos
☐	☐	Other, sp_____
		KIDNEY
☐	☐	Creatinine
☐	☐	Other, sp_____

GRADE	Treatment Related (1=no, 2=yes. 3=unknown)	
		PULMONARY
☐	☐	Dyspnea
☐	☐	Other, sp_____
		HEART
☐	☐	Cardiac dysrhythmia
☐	☐	Cardiac ischemia
☐	☐	Other, sp_____
		NEUROLOGIC
☐	☐	Neuro sensory
☐	☐	Neuro motor
☐	☐	Neuro hearing
☐	☐	Other, sp_____
		ALLERGY
☐	☐	Allergic reaction
☐	☐	Other, sp_____
		FLU LIKE SYMPTOMS
☐	☐	Febrile neutropenia
☐	☐	Myalgia/Arthralgia
☐	☐	Other, sp_____
		MISCELLANEOUS
☐	☐	Specify_____
☐	☐	Specify_____

9732 REMARKS ADDENDA

CALGB Study No: 9732
CALGB Patient ID: _____
Amended Data? _____Yes

INSTRUCTIONS: This form is to be used to detail patient history, physical findings and to describe adverse events or toxicities noted while the patient is on study. Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

Dates Covered: _____/_____/_____ to _____/_____/_____

RESPONSE / RELAPSE FORM FOR CYCLES 5 & 6

CALGB Form:	C-525
CALGB Study #:	9732
CALGB Patient ID:	_____
Amended Data ?	_____yes

INSTRUCTIONS: Use this form to assess treatment from CYCLES 5 & 6. Complete all information in the upper right-hand box. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient's Name: _____

TIME PERIOD COVERED BY THIS FORM:

From: ☐☐☐☐☐☐☐☐ **To:** ☐☐☐☐☐☐☐☐ **(m/d/y)** ☐6 **Cycle**

☐ **Survival status**
1-Alive
2-Dead
3-Lost to follow-up

Date last known alive or date of death: ☐☐☐☐☐☐☐☐ **(m/d/y)**

☐ **Status of assigned Treatment:**
1-Therapy has been terminated permanently.
2-Therapy is being continued.

RESPONSE DATA

☐ **Best overall objective response to date:**
1-Complete response
2-Partial response
3-Regression (nonmeasurable disease)
4-Stable disease
5-Progression
6-Unevaluable

☐ **Current status of remission:**
1-Continues in remission
2-Relapsed after response or improvement
3-Died with no evidence of relapse

Date last known in remission:
☐☐☐☐☐☐☐☐ **(m/d/y)**

If any of the following have occurred during this report period, please give date(s):

Partial response/regression onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

Complete response onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First local-regional progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First distant disease progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

CNS metastases:
☐☐☐☐☐☐☐☐ **(m/d/y)**

☐ **Total number of cycles of chemotherapy completed to date.**

PROGRESSION / RELAPSE DATA

If a progression/relapse has occurred, document the site of relapse and the method of assessment.

Sites Of Relapse
1-Not involved
2-Involved
3-Equivocal

Assessment Method
1-Clinical (palpation radiologic scan)
2-Pathologic 3-Autopsy

☐	Hilar Nodes	☐
☐	Mediastinal Nodes	☐
☐	Supraclavicular/Scalene Nodes	☐
☐	Primary Lung	☐
☐	Contralateral lung	☐
☐	Pleura	☐
☐	Liver	☐
☐	Adrenal(s)	☐
☐	Bone	☐
☐	Bone Marrow	☐
☐	Brain	☐
☐	Other Nodal, Specify_____	☐
☐	Other, Specify_____	☐

☐ **Was progression or relapse associated with initial site(s) of disease? (1=no, 2=yes)**

☐ **Did a new primary tumor develop? (1-no; 2-yes)**

If yes, date ☐☐☐☐☐☐☐☐ **(m/d/y)**

9732 MEASUREMENT FORM

CALGB Form:	C-276
CALGB Study No:	9732
CALGB Patient ID:	_____
Amended Data?	_____Yes

INSTRUCTIONS:. Document all tumor and lymph node measurements for the appropriate time-frame listed below. For MEASUREABLE DISEASE, record BIDIMENSIONAL measurements. For EVALUABLE DISEASE, record disease 'present' (initially), 'increase', 'unchanged', 'decrease' or 'absent' (subsequently). Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

	Baseline	After Cycle 2	After Cycle 4	After Cycle 6	Post Treatment	Post Treatment
Date of Observation (m/d/y)						
Response: CR, PR, SD, PD	N/A					
SITES MEASURED						

CALGB OFF TREATMENT NOTICE

CALGB Form:	C-300
CALGB Study No.:	
CALGB Patient ID.:	_____
Check if amended data:	_____

INSTRUCTIONS: This form is submitted when **ALL** of a patient's protocol treatment *is completed or is stopped prematurely.* Information in the upper right box must be completed for this form to be accepted. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight and circle all amended data. Retain a copy for your records and send original to CALGB Data Management Center.

Patient's Name _____ Participating Group _____

Patient Hospital Number _____ Participating Group Protocol No. _____

Main Member Institution/Adjunct _____ Participating Group Patient No. _____

☐☐ REASON OFF TREATMENT (select the primary reason)

1. Treatment completed per protocol.
2. Patient had disease progression or relapse during active treatment.
3. Patient did not respond to therapy (failed induction).
4. Adverse event (complications or toxicity making it medically necessary to stop treatment).
   (Follow protocol instructions for submission of ADR forms.)
5. Patient died during treatment. Attach Death Notification Form (C-113).
   (Follow protocol instructions for submission of ADR if death occurred within 30 days of treatment.)
6. Patient refused further protocol treatment, but consented to be followed.
7. Patient refused further protocol treatment, withdrew consent to be followed. Patient is lost to follow-up.
8. Patient developed other disease. Specify _____
   (If other disease is a secondary malignancy, submit C-215 (Second Malignancy Form)).
9. Treatment never started (cancelled patient).
   Reason why treatment was not started: _____
10. Patient taken off of protocol treatment (for none of the reasons listed above) to receive non-protocol therapy during active protocol treatment.
    Specify type of non-protocol treatment: _____
11. Other (specify: _____)

☐☐ ☐☐ ☐☐☐☐ LAST DATE OF PROTOCOL TREATMENT
M D Y

COMMENTS: _____

SUBMIT ALL OF THE PRECEDING PAGES NOW.

Submit to the Data Management Center all completed data that has not been previously submitted.

Retain a copy of all forms submitted for your records and send the originals to:

CALGB Data Management Center
2200 W. Main St., Suite 340
Durham, NC 27705

Submit forms according to the schedule specified in the DATA SUBMISSION SECTION of the 9732 protocol, and listed at the beginning of the 9732 PROTOCOL TREATMENT FORMS book.

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045

TOXICITIES OBSERVED *4 MONTHS POST TREATMENT*

INSTRUCTIONS: Report all toxicities observed in the first 4 months post treatment. Complete all information in the upper right-hand box. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box. Retain a copy for your records and send original to CALGB DMC.

CALGB Form: C-524
CALGB Study No.: 9732
CALGB Patient ID.:_____
Amended Data?_____Yes

Patient's Name_____ Participating Group_____

8 **STAT USE ONLY**

Time Period Covered By This Form: From ☐☐ ☐☐ ☐☐☐☐ (m/d/y) To ☐☐ ☐☐ ☐☐☐☐ (m/d/y)

☐ Was an ADVERSE Drug Reaction Report filed based on an event reported below?

Coding Instructions: Use the CALGB Expanded Common Toxicity criteria to determine grade.
If no toxicity is reported for a specific category, code grade = 0

GRADE	Treatment Related (1=no, 2=yes, 3=unknown)	
		HEMATOLOGIC
☐	☐	WBC
☐	☐	Platelets
☐	☐	Hemoglobin
☐	☐	Granulocytes
☐	☐	Lymphocytes
☐	☐	Other, sp_____
		GASTROINTESTINAL
☐	☐	Nausea
☐	☐	Vomiting
☐	☐	Diarrhea
☐	☐	Stomatitis
☐	☐	Anorexia
☐	☐	Other, sp_____
		LIVER
☐	☐	Bilirubin
☐	☐	SGPT (AST)
☐	☐	Alk Phos
☐	☐	Other, sp_____
		KIDNEY
☐	☐	Creatinine
☐	☐	Other, sp_____

GRADE	Treatment Related (1=no, 2=yes. 3=unknown)	
		PULMONARY
☐	☐	Dyspnea
☐	☐	Other, sp_____
		HEART
☐	☐	Cardiac dysrhythmia
☐	☐	Cardiac ischemia
☐	☐	Other, sp_____
		NEUROLOGIC
☐	☐	Neuro sensory
☐	☐	Neuro motor
☐	☐	Neuro hearing
☐	☐	Other, sp_____
		ALLERGY
☐	☐	Allergic reaction
☐	☐	Other, sp_____
		FLU LIKE SYMPTOMS
☐	☐	Febrile neutropenia
☐	☐	Myalgia/Arthralgia
☐	☐	Other, sp_____
		MISCELLANEOUS
☐	☐	Specify_____
☐	☐	Specify_____

9732 REMARKS ADDENDA

CALGB Study No: 9732
CALGB Patient ID: _____
Amended Data? _____Yes

INSTRUCTIONS:. This form is to be used to detail patient history, physical findings and to describe adverse events or toxicities noted while the patient is on study. Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

Dates Covered: _____/_____/_____ to _____/_____/_____

RESPONSE / RELAPSE: *4 MONTHS POST TREATMENT*

INSTRUCTIONS: Assess any response or relapse noted during the first 4 months post treatment. Complete all information in the upper right-hand box. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box.

CALGB Form:	C-525
CALGB Study #:	9732
CALGB Patient ID:	_____
Amended Data ?	_____yes

Patient's Name: _____

TIME PERIOD COVERED BY THIS FORM:

From: ☐☐☐☐☐☐☐☐ **To:** ☐☐☐☐☐☐☐☐ **(m/d/y)** [8] **Stat Use Only**

☐ **Survival status**
1-Alive
2-Dead
3-Lost to follow-up

Date last known alive or date of death: ☐☐☐☐☐☐☐☐ **(m/d/y)**

[1] **Status of assigned Treatment:**
1-Therapy has been terminated permanently.
2-Therapy is being continued.

RESPONSE DATA

☐ **Best overall objective response to date:**
1-Complete response
2-Partial response
3-Regression (nonmeasurable disease)
4-Stable disease
5-Progression
6-Unevaluable

☐ **Current status of remission:**
1-Continues in remission
2-Relapsed after response or improvement
3-Died with no evidence of relapse

Date last known in remission:
☐☐☐☐☐☐☐☐ **(m/d/y)**

If any of the following have occurred during this report period, please give date(s):

Partial response/regression onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

Complete response onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First local-regional progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First distant disease progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

CNS metastases:
☐☐☐☐☐☐☐☐ **(m/d/y)**

[-1] **Total number of cycles of chemotherapy completed to date.**

PROGRESSION / RELAPSE DATA

If a progression/relapse has occurred, document the site of relapse and the method of assessment.

Sites Of Relapse
1-Not involved
2-Involved
3-Equivocal

Assessment Method
1-Clinical (palpation radiologic scan)
2-Pathologic 3-Autopsy

☐	Hilar Nodes	☐
☐	Mediastinal Nodes	☐
☐	Supraclavicular/Scalene Nodes	☐
☐	Primary Lung	☐
☐	Contralateral lung	☐
☐	Pleura	☐
☐	Liver	☐
☐	Adrenal(s)	☐
☐	Bone	☐
☐	Bone Marrow	☐
☐	Brain	☐
☐	Other Nodal, Specify_____	☐
☐	Other, Specify_____	☐

☐ **Was progression or relapse associated with initial site(s) of disease? (1=no, 2=yes)**

☐ **Did a new primary tumor develop? (1-no; 2-yes)**

If yes, date ☐☐☐☐☐☐☐☐ **(m/d/y)**

9732 MEASUREMENT FORM

CALGB Form:	C-276
CALGB Study No:	9732
CALGB Patient ID:	_____
Amended Data?	_____Yes

INSTRUCTIONS:. Document all tumor and lymph node measurements for the appropriate time-frame listed below. For MEASUREABLE DISEASE, record BIDIMENSIONAL measurements. For EVALUABLE DISEASE, record disease 'present' (initially), 'increase', 'unchanged', 'decrease' or 'absent' (subsequently). Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

	Baseline	After Cycle 2	After Cycle 4	After Cycle 6	Post Treatment	Post Treatment
Date of Observation (m/d/y)						
Response: CR, PR, SD, PD	N/A					
SITES MEASURED						

SUBMIT ALL OF THE PRECEDING PAGES NOW.

Submit to the Data Management Center all completed data that has not been previously submitted.

Retain a copy of all forms submitted for your records and send the originals to:

CALGB Data Management Center
2200 W. Main St., Suite 340
Durham, NC 27705

Submit forms according to the schedule specified in the DATA SUBMISSION SECTION of the 9732 protocol, and listed at the beginning of the 9732 PROTOCOL TREATMENT FORMS book.

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045

TOXICITIES OBSERVED *8 MONTHS POST TREATMENT*

INSTRUCTIONS: Report all toxicities observed in the first 8 months post treatment. Complete all information in the upper right-hand box. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box. Retain a copy for your records and send original to CALGB DMC.

CALGB Form: C-524
CALGB Study No.: 9732
CALGB Patient ID.:_____
Amended Data?_____Yes

Patient's Name_____ Participating Group_____

8 **STAT USE ONLY**

Time Period Covered By This Form: From ☐☐ ☐☐ ☐☐☐☐ (m/d/y) To ☐☐ ☐☐ ☐☐☐☐ (m/d/y)

☐ Was an ADVERSE Drug Reaction Report filed based on an event reported below?

Coding Instructions: Use the CALGB Expanded Common Toxicity criteria to determine grade.
If no toxicity is reported for a specific category, code grade = 0

GRADE	Treatment Related (1=no, 2=yes, 3=unknown)	
		HEMATOLOGIC
☐	☐	WBC
☐	☐	Platelets
☐	☐	Hemoglobin
☐	☐	Granulocytes
☐	☐	Lymphocytes
☐	☐	Other, sp_____
		GASTROINTESTINAL
☐	☐	Nausea
☐	☐	Vomiting
☐	☐	Diarrhea
☐	☐	Stomatitis
☐	☐	Anorexia
☐	☐	Other, sp_____
		LIVER
☐	☐	Bilirubin
☐	☐	SGPT (AST)
☐	☐	Alk Phos
☐	☐	Other, sp_____
		KIDNEY
☐	☐	Creatinine
☐	☐	Other, sp_____

GRADE	Treatment Related (1=no, 2=yes. 3=unknown)	
		PULMONARY
☐	☐	Dyspnea
☐	☐	Other, sp_____
		HEART
☐	☐	Cardiac dysrhythmia
☐	☐	Cardiac ischemia
☐	☐	Other, sp_____
		NEUROLOGIC
☐	☐	Neuro sensory
☐	☐	Neuro motor
☐	☐	Neuro hearing
☐	☐	Other, sp_____
		ALLERGY
☐	☐	Allergic reaction
☐	☐	Other, sp_____
		FLU LIKE SYMPTOMS
☐	☐	Febrile neutropenia
☐	☐	Myalgia/Arthralgia
☐	☐	Other, sp_____
		MISCELLANEOUS
☐	☐	Specify_____
☐	☐	Specify_____

9732 REMARKS ADDENDA

CALGB Study No:
CALGB Patient ID: _____
Amended Data? _____Yes

INSTRUCTIONS:. This form is to be used to detail patient history, physical findings and to describe adverse events or toxicities noted while the patient is on study. Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

Dates Covered: _____/_____/_____ to _____/_____/_____

RESPONSE / RELAPSE: *8 MONTHS POST TREATMENT*

CALGB Form:	C-525
CALGB Study #:	9732
CALGB Patient ID:	_____
Amended Data ?	_____yes

INSTRUCTIONS: Assess any response or relapse noted during the first 8 months post treatment. Complete all information in the upper right-hand box. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient's Name: _____

TIME PERIOD COVERED BY THIS FORM:

From: ☐☐☐☐☐☐☐☐ **To:** ☐☐☐☐☐☐☐☐ **(m/d/y)** [8] **Stat Use Only**

☐ **Survival status**
1-Alive
2-Dead
3-Lost to follow-up

Date last known alive or date of death: ☐☐☐☐☐☐☐☐ **(m/d/y)**

[1] **Status of assigned Treatment:**
1-Therapy has been terminated permanently.
2-Therapy is being continued.

RESPONSE DATA

☐ **Best overall objective response to date:**
1-Complete response
2-Partial response
3-Regression (nonmeasurable disease)
4-Stable disease
5-Progression
6-Unevaluable

☐ **Current status of remission:**
1-Continues in remission
2-Relapsed after response or improvement
3-Died with no evidence of relapse

Date last known in remission:
☐☐☐☐☐☐☐☐ **(m/d/y)**

If any of the following have occurred during this report period, please give date(s):

Partial response/regression onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

Complete response onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First local-regional progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First distant disease progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

CNS metastases:
☐☐☐☐☐☐☐☐ **(m/d/y)**

[-1] **Total number of cycles of chemotherapy completed to date.**

PROGRESSION / RELAPSE DATA

If a progression/relapse has occurred, document the site of relapse and the method of assessment.

Sites Of Relapse
1-Not involved
2-Involved
3-Equivocal

Assessment Method
1-Clinical (palpation radiologic scan)
2-Pathologic 3-Autopsy

☐	Hilar Nodes	☐
☐	Mediastinal Nodes	☐
☐	Supraclavicular/Scalene Nodes	☐
☐	Primary Lung	☐
☐	Contralateral lung	☐
☐	Pleura	☐
☐	Liver	☐
☐	Adrenal(s)	☐
☐	Bone	☐
☐	Bone Marrow	☐
☐	Brain	☐
☐	Other Nodal, Specify_____	☐
☐	Other, Specify_____	☐

☐ **Was progression or relapse associated with initial site(s) of disease? (1=no, 2=yes)**

☐ **Did a new primary tumor develop? (1-no; 2-yes)**

If yes, date ☐☐☐☐☐☐☐☐ **(m/d/y)**

9732 MEASUREMENT FORM

CALGB Form:	C-276
CALGB Study No:	9732
CALGB Patient ID:	_____
Amended Data?	_____Yes

INSTRUCTIONS:. Document all tumor and lymph node measurements for the appropriate time-frame listed below. For MEASUREABLE DISEASE, record BIDIMENSIONAL measurements. For EVALUABLE DISEASE, record disease 'present' (initially), 'increase', 'unchanged', 'decrease' or 'absent' (subsequently). Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

	Baseline	After Cycle 2	After Cycle 4	After Cycle 6	Post Treatment	Post Treatment
Date of Observation (m/d/y)						
Response: CR, PR, SD, PD	N/A					
SITES MEASURED						

SUBMIT ALL OF THE PRECEDING PAGES NOW.

Submit to the Data Management Center all completed data that has not been previously submitted.

Retain a copy of all forms submitted for your records and send the originals to:

CALGB Data Management Center
2200 W. Main St., Suite 340
Durham, NC 27705

Submit forms according to the schedule specified in the DATA SUBMISSION SECTION of the 9732 protocol, and listed at the beginning of the 9732 PROTOCOL TREATMENT FORMS book.

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045

TOXICITIES OBSERVED *12 MONTHS POST TREATMENT*

INSTRUCTIONS: Report all toxicities observed in the first 12 months post treatment. Complete all information in the upper right-hand box. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box. Retain a copy for your records and send original to CALGB DMC.

CALGB Form: C-524
CALGB Study No.: 9732
CALGB Patient ID.:_____
Amended Data?_____Yes

Patient's Name_____ Participating Group_____

8 **STAT USE ONLY**

Time Period Covered By This Form: From ☐☐ ☐☐ ☐☐☐☐ (m/d/y) To ☐☐ ☐☐ ☐☐☐☐ (m/d/y)

☐ Was an ADVERSE Drug Reaction Report filed based on an event reported below?

Coding Instructions: Use the CALGB Expanded Common Toxicity criteria to determine grade.
If no toxicity is reported for a specific category, code grade = 0

GRADE	Treatment Related (1=no, 2=yes, 3=unknown)	
		HEMATOLOGIC
☐	☐	WBC
☐	☐	Platelets
☐	☐	Hemoglobin
☐	☐	Granulocytes
☐	☐	Lymphocytes
☐	☐	Other, sp_____
		GASTROINTESTINAL
☐	☐	Nausea
☐	☐	Vomiting
☐	☐	Diarrhea
☐	☐	Stomatitis
☐	☐	Anorexia
☐	☐	Other, sp_____
		LIVER
☐	☐	Bilirubin
☐	☐	SGPT (AST)
☐	☐	Alk Phos
☐	☐	Other, sp_____
		KIDNEY
☐	☐	Creatinine
☐	☐	Other, sp_____

GRADE	Treatment Related (1=no, 2=yes. 3=unknown)	
		PULMONARY
☐	☐	Dyspnea
☐	☐	Other, sp_____
		HEART
☐	☐	Cardiac dysrhythmia
☐	☐	Cardiac ischemia
☐	☐	Other, sp_____
		NEUROLOGIC
☐	☐	Neuro sensory
☐	☐	Neuro motor
☐	☐	Neuro hearing
☐	☐	Other, sp_____
		ALLERGY
☐	☐	Allergic reaction
☐	☐	Other, sp_____
		FLU LIKE SYMPTOMS
☐	☐	Febrile neutropenia
☐	☐	Myalgia/Arthralgia
☐	☐	Other, sp_____
		MISCELLANEOUS
☐	☐	Specify_____
☐	☐	Specify_____

9732 REMARKS ADDENDA

CALGB Study No: 9732
CALGB Patient ID: _____
Amended Data? _____Yes

INSTRUCTIONS:. This form is to be used to detail patient history, physical findings and to describe adverse events or toxicities noted while the patient is on study. Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

Dates Covered: _____/_____/_____ to _____/_____/_____

RELAPSE: *12 MONTHS POST TREATMENT*

CALGB Form:	C-525
CALGB Study #:	9732
CALGB Patient ID:	_____
Amended Data ?	_____yes

INSTRUCTIONS: Assess any relapse noted during the first 12 months post treatment. Complete all information in the upper right-hand box. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient's Name: _____

TIME PERIOD COVERED BY THIS FORM:

From: ☐☐☐☐☐☐☐☐ **To:** ☐☐☐☐☐☐☐☐ **(m/d/y)** [8] **Stat Use Only**

☐ **Survival status**
1-Alive
2-Dead
3-Lost to follow-up

Date last known alive or date of death: ☐☐☐☐☐☐☐☐ **(m/d/y)**

[1] **Status of assigned Treatment:**
1-Therapy has been terminated permanently.
2-Therapy is being continued.

RESPONSE DATA

☐ **Best overall objective response to date:**
1-Complete response
2-Partial response
3-Regression (nonmeasurable disease)
4-Stable disease
5-Progression
6-Unevaluable

☐ **Current status of remission:**
1-Continues in remission
2-Relapsed after response or improvement
3-Died with no evidence of relapse

Date last known in remission:
☐☐☐☐☐☐☐☐ **(m/d/y)**

If any of the following have occurred during this report period, please give date(s):

Partial response/regression onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

Complete response onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First local-regional progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First distant disease progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

CNS metastases:
☐☐☐☐☐☐☐☐ **(m/d/y)**

[-1] **Total number of cycles of chemotherapy completed to date.**

PROGRESSION / RELAPSE DATA

If a progression/relapse has occurred, document the site of relapse and the method of assessment.

Sites Of Relapse
1-Not involved
2-Involved
3-Equivocal

Assessment Method
1-Clinical (palpation radiologic scan)
2-Pathologic 3-Autopsy

☐	Hilar Nodes	☐
☐	Mediastinal Nodes	☐
☐	Supraclavicular/Scalene Nodes	☐
☐	Primary Lung	☐
☐	Contralateral lung	☐
☐	Pleura	☐
☐	Liver	☐
☐	Adrenal(s)	☐
☐	Bone	☐
☐	Bone Marrow	☐
☐	Brain	☐
☐	Other Nodal, Specify_____	☐
☐	Other, Specify_____	☐

☐ **Was progression or relapse associated with initial site(s) of disease? (1=no, 2=yes)**

☐ **Did a new primary tumor develop? (1-no; 2-yes)**

If yes, date ☐☐☐☐☐☐☐☐ **(m/d/y)**

9732 MEASUREMENT FORM

CALGB Study No: 9732
CALGB Patient ID: _____
Amended Data? _____Yes

INSTRUCTIONS:. Document all tumor and lymph node measurements for the appropriate time-frame listed below. For MEASUREABLE DISEASE, record BIDIMENSIONAL measurements. For EVALUABLE DISEASE, record disease 'present' (initially), 'increase', 'unchanged', 'decrease' or 'absent' (subsequently). Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

	Baseline	After Cycle 2	After Cycle 4	After Cycle 6	Post Treatment	Post Treatment
Date of Observation (m/d/y)						
Response: CR, PR, SD, PD	N/A					
SITES MEASURED						

SUBMIT ALL OF THE PRECEDING PAGES NOW.

Submit to the Data Management Center all completed data that has not been previously submitted.

Retain a copy of all forms submitted for your records and send the originals to:

CALGB Data Management Center
2200 W. Main St., Suite 340
Durham, NC 27705

Submit forms according to the schedule specified in the DATA SUBMISSION SECTION of the 9732 protocol, and listed at the beginning of the 9732 PROTOCOL TREATMENT FORMS book.

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045

LONG-TERM FOLLOW-UP EVERY 6 MONTHS

Begin submitting the **C-400 Long-Term Follow-Up Form** (page 41), at 18 months after treatment has ended (or 6 months after the final **12 Month Post Treatment Response/Relapse Form** has been submitted). The C-400 needs to be submitted every 6 months for 3 years, then every year thereafter until relapse or death.

This form will need to be photocopied for submission on each occasion that follow-up is required.

In the event of relapse and /or death, submit the **Relapse Form For Long-Term Follow-up** (page 43) to document the date and site of relapse. Also include the **C-276 9732 Measurement Form** to document the relapse.

Submit the **Relapse Form For Long-Term Follow-Up** ***only in the event of a documented relapse and/or death during Long-Term Follow-up.***

If a second malignancy is discovered, submit the **C-215 Notice of second Malignancy Form.**

If the patient dies, submit the **C-113 Notification of Death Form**. If death is related to protocol treatment, follow the protocol guidelines for the reporting of Adverse Events (AERs).

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045

CALGB LONG-TERM FOLLOW-UP FORM

CALGB Form:	C-400
CALGB Study No.:	
CALGB Patient ID.:	_____
Amended data?:	_____ Yes

INSTRUCTIONS: This form covers a 6-month period for patients in long-term follow-up. This form is **first** filled out 18 months after the end of protocol treatment to cover the 6-month reporting period which extends from 12 to 18 months after the end of treatment. It may be filled out at an earlier time if specified in the protocol. It is submitted every 6 months thereafter until the patient's death.

Information in the upper right box must be completed for this form to be accepted. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight and circle all amended data. Retain a copy for your records and send original to CALGB Data Management Center.

Patient's Name _____ Participating Group _____

Patient Hospital Number _____ Participating Group Protocol No. _____

Main Member Institution/Adjunct _____ Participating Group Patient No. _____

THIS 6-MONTH REPORTING PERIOD COVERS

From ☐☐ ☐☐ ☐☐☐☐ (M D Y) To ☐☐ ☐☐ ☐☐☐☐ (M D Y)

PATIENT STATUS

☐ Survival Status
1. Alive
2. Dead (include Notification of Death Form if not previously submitted)
3. Lost to follow-up
4. Consent for follow-up withdrawn by patient (signed documentation provided to DMC)

☐☐ ☐☐ ☐☐☐☐ (M D Y) Date patient last known alive or date of death

CLINICAL STATUS

☐ Was patient examined by a physician during this reporting period? (1-No, 2-Yes)

☐☐ ☐☐ ☐☐☐☐ (M D Y) Last date patient examined by a physician during this reporting period

☐ Did relapse or progression occur during this reporting period?
1. No
2. Yes

☐ If relapse or progression occurred, have required data forms been submitted? (1-No, 2-Yes)
If forms not previously sent, please attach.

☐ If relapse occurred, have required samples been submitted? (1-No, 2-Yes)
If required and not previously submitted, send per protocol instructions.

CLINICAL STATUS (cont'd)

☐ Did the patient develop a new adverse event (toxicity) in this reporting period or did an existing adverse event (toxicity) continue or increase in severity?
1. No
2. Yes

☐ If yes, have required protocol-specific data forms been submitted? (1-No, 2-Yes)
(If data forms were not previously sent, please attach.)

☐ Has the patient developed a secondary malignancy during this reporting period?
1. No
2. Yes

☐ If yes, have Second Malignancy Form and other required data forms been submitted?
(1-No, 2-Yes) (If not previously sent, please attach.)
Also complete FDA form per protocol instructions.

NON-PROTOCOL TREATMENT GIVEN DURING THIS REPORTING PERIOD

☐ Has the patient received non-protocol therapy during this reporting period?
1. No
2. Yes

If yes, specify type of non-protocol treatment given _____

COMMENTS: _____

RELAPSE FORM FOR LONG-TERM FOLLOW-UP

CALGB Form:	C-525
CALGB Study #:	9732
CALGB Patient ID:	_____
Amended Data ?	_____yes

INSTRUCTIONS: Submit this form in the event of relapse while monitoring the patient on Long Term Follow-Up. Complete all information in the upper right-hand box. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable, or not done. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient's Name: _____

TIME PERIOD COVERED BY THIS FORM:

From: ☐☐☐☐☐☐☐☐ **To:** ☐☐☐☐☐☐☐☐ **(m/d/y)** [8] **Stat Use Only**

☐ **Survival status**
1-Alive
2-Dead
3-Lost to follow-up

Date last known alive or date of death: ☐☐☐☐☐☐☐☐ **(m/d/y)**

[1] **Status of assigned Treatment:**
1-Therapy has been terminated permanently.
2-Therapy is being continued.

RESPONSE DATA

☐ **Best overall objective response to date:**
1-Complete response
2-Partial response
3-Regression (nonmeasurable disease)
4-Stable disease
5-Progression
6-Unevaluable

☐ **Current status of remission:**
1-Continues in remission
2-Relapsed after response or improvement
3-Died with no evidence of relapse

Date last known in remission:
☐☐☐☐☐☐☐☐ **(m/d/y)**

If any of the following have occurred during this report period, please give date(s):

Partial response/regression onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

Complete response onset:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First local-regional progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

First distant disease progression/relapse:
☐☐☐☐☐☐☐☐ **(m/d/y)**

CNS metastases:
☐☐☐☐☐☐☐☐ **(m/d/y)**

[-1] **Total number of cycles of chemotherapy completed to date.**

PROGRESSION / RELAPSE DATA

If a progression/relapse has occurred, document the site of relapse and the method of assessment.

Sites Of Relapse
1-Not involved
2-Involved
3-Equivocal

Assessment Method
1-Clinical (palpation radiologic scan)
2-Pathologic 3-Autopsy

☐	Hilar Nodes	☐
☐	Mediastinal Nodes	☐
☐	Supraclavicular/Scalene Nodes	☐
☐	Primary Lung	☐
☐	Contralateral lung	☐
☐	Pleura	☐
☐	Liver	☐
☐	Adrenal(s)	☐
☐	Bone	☐
☐	Bone Marrow	☐
☐	Brain	☐
☐	Other Nodal, Specify_____	☐
☐	Other, Specify_____	☐

☐ **Was progression or relapse associated with initial site(s) of disease? (1=no, 2=yes)**

☐ **Did a new primary tumor develop? (1-no; 2-yes)**

If yes, date ☐☐☐☐☐☐☐☐ **(m/d/y)**

9732 MEASUREMENT FORM

CALGB Form:	C-276
CALGB Study No:	9732
CALGB Patient ID:	_____
Amended Data?	_____Yes

INSTRUCTIONS:. Document all tumor and lymph node measurements for the appropriate time-frame listed below. For MEASUREABLE DISEASE, record BIDIMENSIONAL measurements. For EVALUABLE DISEASE, record disease 'present' (initially), 'increase', 'unchanged', 'decrease' or 'absent' (subsequently). Complete all information in the upper right-hand box. Highlight all amended data and complete the amended data section in the upper right-hand box.

Patient' s Name _____

	Baseline	After Cycle 2	After Cycle 4	After Cycle 6	Post Treatment	Post Treatment
Date of Observation (m/d/y)						
Response: CR, PR, SD, PD	N/A					
SITES MEASURED						

CALGB: SECONDARY MALIGNANCY FORM

INSTRUCTIONS: Complete and submit this form as required by the protocol. Information in the upper right box must be completed for this form to be accepted. Do not leave any entries blank. Enter -1 to indicate that an answer is unknown, unobtainable, not applicable or not done. Retain a copy for your records and send ORIGINAL to the CALGB Data Management Center.

CALGB Form:	C-215
CALGB Study No.:	_____
CALGB Patient ID.:	_____
Amended Data?:	_____Yes

Patient's Name _____ Participating Group _____

Patient Hospital Number _____ Participating Group Protocol No. _____

Main Member Institution/Adjunct _____ Participating Group Patient No. _____

INSTRUCTIONS: Report any malignancy (1) of a new histologic type or (2) of a previous type which is judged to be a new primary. **DO NOT REPORT RECURRENCES ON THIS FORM**.

NOTE: If available, submit pathology report documenting the secondary malignancy along with this form. Refer to the protocol regarding sample submission instructions for secondary malignancies.

Type (site, histology) of secondary malignancy: _____

_____

Date of first pathologic diagnosis of secondary malignancy: ☐☐ ☐☐ ☐☐☐☐ (m/d/y)

☐ **Has FDA Form 3500 (MEDWATCH) or NCI/CTEP Secondary AML/MDS Form been sent to Central Office?** (1-no, 2-yes)

If yes, specify date sent: ☐☐ ☐☐ ☐☐☐☐ (m/d/y)

If no, specify reason not sent: _____

_____

NOTE: Investigators are required to report all secondary malignancies that occur during or following treatment on NCI sponsored protocols. Reporting is to be performed in the same manner as reporting Adverse Drug Reactions, including (within five (5) working days) completion of FDA Form 3500 (MEDWATCH) or NCI/CTEP Secondary AML/MDS Form.

COMMENTS

Completed By: _____ **Date Completed:** _____/_____/____
(Print or Type Name)

CALGB: NOTIFICATION OF DEATH

CALGB Form:	C-113
CALGB Study No:	_____
CALGB Patient ID:	_____
Amended data?	_____ Yes

Patient's Name _____ Participating Group _____

Patient Hospital Number _____ Participating Group Protocol No. _____

Main Member Institution/Adjunct _____ Participating Group Patient No. _____

INSTRUCTIONS: This form is to be submitted in the event of a patient's death due to any cause. It is to be submitted within four (4) weeks of death, along with copies of death certificate/autopsy report (if available). If appropriate, include other required CALGB forms if they have not already been submitted. If death has been reported via a monthly delinquency reminder list, this form must still be submitted if required by the protocol. This form is not applicable for most non-treatment studies, such as companions, psychiatric assessments, laboratory evaluations and cancer control studies.

Information in the upper right box must be completed for this form to be accepted. Do not leave any entries blank. Enter '-1' to indicate that an answer is unknown, unobtainable or not done. Highlight and circle all amended data and return to the CALGB Data Management Center.

Date of Death - The minimum requirements for entering a date of death into the database are month and year.

☐☐ ☐☐ ☐☐☐☐ Date of Death
M D Y

Cause of Death (specify): _____

_____

☐ 1 - Protocol treatment related(**Send AER to Central Office**)
2 - Protocol disease related
3 - Not related to protocol treatment or protocol disease

Comments:

Completed By: _____ **Date Completed:** _____/_____/_____
(Print or Type Name)

SUBMIT ALL OF THE PRECEDING PAGES NOW.

Submit to the Data Management Center all completed data that has not been previously submitted.

Retain a copy of all forms submitted for your records and send the originals to:

CALGB Data Management Center
2200 W. Main St., Suite 340
Durham, NC 27705

Submit forms according to the schedule specified in the DATA SUBMISSION SECTION of the 9732 protocol, and listed at the beginning of the 9732 PROTOCOL TREATMENT FORMS book.

If you have any questions or problems concerning the forms and/or data submission for 9732, please contact the Data Coordinator responsible for managing this study at:

CALGB Data Management Center
(919) 286-0045