

IND Study # _____

Physical Exam

Pg of

Visit

Subject ID: I N D # # U A *

Visit Date:

Day

Month

Year

Subject Initials:

	WNL	ABN	√ if ND	Comment if Abnormal
General	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Chest Wall	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Pulmonary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Extremities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Lymphatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
Psych	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____

Completed by: _____

Date:

Day

Month

Year

IRB # _____

IND Study # _____

Tumor Assessment (COR)

Pg of

Visit

Subject ID: I N D # # U A *

Visit Date: Day Month Year

Subject Initials:

Check here if tumor assessment was not performed

Target Lesion Measurement

Tumor laterality (check one) Left Right

Site		Horizontal		Vertical	Product (cm)
<input type="text"/>		<input type="text"/>	.	<input type="text"/>	.
<input type="text"/>		<input type="text"/>	x	<input type="text"/>	.
<input type="text"/>		<input type="text"/>	.	<input type="text"/>	.
<input type="text"/>	<input type="checkbox"/>	√ if Not Applicable		<input type="text"/>	.
		<input type="text"/>	.	<input type="text"/>	.
		<input type="text"/>	x	<input type="text"/>	.
		<input type="text"/>	.	<input type="text"/>	.
		Product of all target lesions			<input type="text"/>
			.	<input type="text"/>	.

Site codes: UOQ=Upper Outer Quadrant, LOQ=Lower Outer Quadrant, UIQ=Upper Inner Quadrant, LIQ=Lower Inner Quadrant, CEN=Centrally Located

Regional Nodes/Axilla

Does the subject have involvement of the regional nodes/axilla? Yes – complete below No

Site	Palpable?	Non-palpable?	Measurable?	Horizontal		Vertical	Product (cm)
<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	.	<input type="text"/>	.
			→	<input type="text"/>	.	<input type="text"/>	.
				<input type="text"/>	.	<input type="text"/>	.
				Product of all target lesions			<input type="text"/>
					.	<input type="text"/>	.

Site codes: RAX=Right Axilla, LAX=Left Axilla, RSC=Right Supraclavicular, LSC=Left Supraclavicular

Completed by: _____

On: Day Month Year

IND Study # _____

Vital Signs

Pg of

Visit

Subject ID: I N D # # U A *

Visit Date:
Day

Month

Year

Subject Initials:

Check here if vital signs were not performed

Date of this exam:
Day Month Year

Height: . cm in

Weight: . kg lbs

Blood Pressure: /

Pulse: / minute

Temperature: . °C °F

Respirations: / minute

Performance Status: 0 1 2

\checkmark if Not Applicable

\checkmark if Not Done

Post Treatment Time: :
H H M M

Blood pressure: /

Pulse: / minute

Temperature: . °C °F

Respirations: / minute

Completed by: _____

On:
Day

Month

Year

IND Study # _____

Laboratory

Pg of

Visit

Subject ID: I N D # # U A *

Visit Date:
Day Month Year

Subject Initials:

Specimen Collection Date:
Day Month Year

WBC (K/ μ L)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/>	^{√ if} ND	Neutrophils (%)	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	^{√ if} ND
Absolute Neutrophil Count	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>		Total bilirubin (mg/dL)	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	
Platelets (K/ μ L)	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>		LDH (IU/L)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	
RBC (M/ μ L)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/>		Alk. phos. (IU/L)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	
Hemoglobin (g/dL)	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>		SGOT/AST (IU/L)	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	
BUN (mg/dL)	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>		SGPT/ALT (IU/L)	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	
Creatinine (mg/dL)	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>		GGT (IU/L)	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	
Sodium (mEq/L)	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>		PT (sec)	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	
Potassium (mEq/L)	<input type="text"/> . <input type="text"/>	<input type="text"/>		PTT (sec)	<input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	
CO ₂ (mEq/L)	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>		INR	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/>	<input type="text"/>	
Chloride (mEq/L)	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>					

Assay Collection

_____ :

_____ :

Completed by: _____

On:
Day Month Year

IND Study # _____

Urine Analysis

Pg of

Visit

Subject ID: I N D # # U A *

Visit Date:

Day

Month

Year

Subject Initials:

Specimen Collection Date:

Day

Month

Year

UPC

√ if
ND

Protein (mg/dL)

Creatinine (mg/dL)

Protein / Creatinine ratio

Completed by: _____

On:

Day

Month

Year

IRB # _____

IND Study # _____

Drug Information

Pg of

Visit

Subject ID: I N D # # U A *

Visit Date:

Day

Month

Year

Subject Initials:

Study Drug Dosing Information

IND Drug (15mg/kg) mg

Day

Month

Year

Lot No.

Infusion Time:

Start Time :

Solution _____

90 ± Mins

Stop Time :

Reaction: Yes

60 ± Mins

No

30 ± Mins

Docetaxel (75mg/m²) mg

Day

Month

Year

Cyclophosphamide mg

Completed by: _____

On:

Day

Month

Year

IRB # _____

IND Study # _____

Drug Information

Pg of

Visit

Subject ID:

I	N	D	#	#	U	A
---	---	---	---	---	---	---

 *

Visit Date:
Day

Month

Year

Subject Initials:

Study Drug Dosing Information

Doxorubicin (60mg/m²)

mg

Day

Month

Year

Completed by: _____

On:
Day

Month

Year

IRB # _____

IND Study # _____

Ancillary Exams

Pg of

Visit

Subject ID: I N D # # U A * Visit Date:

Day

Month

Year

Subject Initials:

\checkmark if Not Applicable

\checkmark if Not Done

Date of Mammogram

Day

Month

Year

Normal

Abnormal

Birad: 0 1 2 3 4 5 6

\checkmark if Not Applicable

\checkmark if Not Done

Date of MUGA:

Day

Month

Year

LVEF %

Completed by: _____

On:
Day

Month

Year

IRB # _____

IND Study # _____

Pathologic Response

Pg of

Visit

Subject ID: I N D # # U A *

Visit Date:

Day

Month

Year

Subject Initials:

Miller and Payne classification

- Grade 1
Some alteration to individual malignant cells but no reduction in overall number
- Grade 2
Minor loss of invasive tumor cells but overall cellularity still high
- Grade 3
Moderate reduction in tumor cells up to an estimated 90% loss
- Grade 4
Marked disappearance of invasive tumor cells such that only small clusters of widely dispersed cells detected
- Grade 5 (pCR of the primary tumor)
No invasive cells identifiable in sections from the site of the previous tumor

ALN N/A

- A
True ALN negative
- B
ALN positive, no therapeutic response
- C
ALN positive, evidence of partial pathological response
- D
ALN previously positive but converted to node negative after NC

Completed by: _____

On:

Day

Month

Year

IRB # _____

IND Study # _____

Hormonal/XRT

Pg of

Visit

Subject ID: *

Visit Date:
Day

Month

Year

Subject Initials:

Hormonal

Was treatment with hormonal therapy indicated in this subject? Yes No

If yes, record all treatments (tamoxifen or anastrozole **only**) including doses, dates and indications on the Concurrent Medication pages

Radiation

Was treatment with radiation indicated in this subject? Yes No

Radiation Start Date:
Day Month Year

Radiation Stop Date:
Day Month Year

Was treatment with radiation completed? Yes No

Total cGy administered:

Completed by: _____

On:
Day

Month

Year