

IND Study # \_\_\_\_\_

# Physical Exam

Pg  of

Visit

Subject ID:        \*

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 # \_\_\_\_\_



Subject ID: I N D # # U A \* [ ][ ]

Visit Date: [ ][ ]

[ ][ ]

[ ][ ][ ][ ]

Day

Month

Year

Subject Initials: [ ][ ][ ]

Specimen Collection Date:

[ ][ ]

[ ][ ][ ]

[ ][ ][ ][ ][ ]

Day

Month

Year

WBC (K/ $\mu$ L)	[ ][ ] . [ ][ ]	<input type="checkbox"/>	<sup>√ if ND</sup>	Neutrophils (%)	[ ][ ] . [ ][ ]	<input type="checkbox"/>	<sup>√ if ND</sup>
Absolute Neutrophil Count	[ ][ ][ ][ ]	<input type="checkbox"/>		Total bilirubin (mg/dL)	[ ][ ] . [ ][ ]	<input type="checkbox"/>	
Platelets (K/ $\mu$ L)	[ ][ ][ ]	<input type="checkbox"/>		LDH (IU/L)	[ ][ ][ ][ ]	<input type="checkbox"/>	
RBC (M/ $\mu$ L)	[ ][ ] . [ ][ ]	<input type="checkbox"/>		Alk. phos. (IU/L)	[ ][ ][ ][ ]	<input type="checkbox"/>	
Hemoglobin (g/dL)	[ ][ ][ ] . [ ][ ]	<input type="checkbox"/>		SGOT/AST (IU/L)	[ ][ ][ ]	<input type="checkbox"/>	
BUN (mg/dL)	[ ][ ][ ]	<input type="checkbox"/>		SGPT/ALT (IU/L)	[ ][ ][ ]	<input type="checkbox"/>	
Creatinine (mg/dL)	[ ][ ][ ] . [ ][ ]	<input type="checkbox"/>		GGT (IU/L)	[ ][ ][ ]	<input type="checkbox"/>	
Sodium (mEq/L)	[ ][ ][ ]	<input type="checkbox"/>		PT (sec)	[ ][ ] . [ ][ ]	<input type="checkbox"/>	
Potassium (mEq/L)	[ ][ ] . [ ][ ]	<input type="checkbox"/>		PTT (sec)	[ ][ ] . [ ][ ]	<input type="checkbox"/>	
CO <sub>2</sub> (mEq/L)	[ ][ ][ ]	<input type="checkbox"/>		INR	[ ][ ][ ] . [ ][ ]	<input type="checkbox"/>	
Chloride (mEq/L)	[ ][ ][ ]	<input type="checkbox"/>					

Assay Collection

\_\_\_\_\_ [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year [ ][ ] H [ ][ ] H : [ ][ ] M [ ][ ] M [ ][ ]

\_\_\_\_\_ [ ][ ] Day [ ][ ][ ] Month [ ][ ][ ][ ] Year [ ][ ] H [ ][ ] H : [ ][ ] M [ ][ ] M [ ][ ]

Completed by: \_\_\_\_\_

On: [ ][ ] Day

[ ][ ][ ] Month

[ ][ ][ ][ ] Year

IND Study # \_\_\_\_\_

# Urine Analysis

Visit

Subject ID:        \*

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

**Subject ID:**        \*

**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

**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

IND Study # \_\_\_\_\_

### Drug Information

Pg  of

Visit

Subject ID:        \*

Visit Date:

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Month

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### Study Drug Dosing Information

IND Drug (15mg/kg)     mg

Lot No.

Infusion Time:

Start Time   :

Solution \_\_\_\_\_

90 ± Mins

Stop Time   :

Reaction:  Yes

60 ± Mins

No

30 ± Mins

### Vital Signs

✓ if Not Applicable

✓ if Not Done

Post Treatment Time:

:    
H H M M

Blood pressure

/

Pulse

/ minute

Temperature

.  °C  °F

Respirations

/ minute

Completed by: \_\_\_\_\_

On:

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Month

Year