

IND Study # _____

Eligibility Checklist

Pg of

Visit .

Subject ID: * Consent Date:
Day Month Year

Subject Initials:

Exclusion Criteria

Each criterion must be addressed and documented in the subject's medical record.

Y N NA

a. Disease-Specific Concerns

1. Subjects who have _____ will be excluded from this study due to the risk of worsening ulcers and healing difficulties

2. Stage _____ cancer

3. Inflammatory cancer

b. General Medical Concerns

1. Subjects with ECOG performance status 2, 3, and 4 are not eligible for this study

2. Allergy to any component of the treatment regimen

3. Refusal to use effective contraception while participating in this study

4. Inability to comply with study and/or follow-up procedures

5. Subjects with secondary malignancy other than superficial skin cancer (squamous cell carcinoma and basal cell carcinoma of the skin) should be excluded

c. Study Drug - Specific Concerns

1. Current, recent (within 4 weeks of the first infusion of this study), or planned participation in an experimental drug study

2. Blood pressure of > 150/100 mmHg. Essential hypertension well controlled with antihypertensive is not an exclusion criterion.

3. Unstable angina

4. New York Heart Association (NYHA) Grade II or greater congestive heart failure (see Appendix D)

5. History of myocardial infarction within 6 months

6. History of stroke within 6 months

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Y N NA

- 7. Clinically significant peripheral vascular disease
- 8. Evidence of bleeding diathesis or coagulopathy
- 9. Presence of central nervous system or brain metastases
- 10. Major surgical procedure, open biopsy, or significant traumatic injury within 28 days prior to Day 0, anticipation of need for major surgical procedure during the course of the study
- 11. Minor surgical procedures such as fine needle aspirations or core biopsies within 7 days prior to Day 0
- 12. Pregnant (positive pregnancy test) or breast feeding
- 13. Urine protein: creatinine ratio ≥ 1.0 at screening
- 14. History of abdominal fistula, gastrointestinal perforation, or intra-abdominal abscess within 6 months prior to Day 0
- 15. Serious, non-healing wound, ulcer, or bone fracture

Subject meets all eligibility criteria

If the subject did not meet all eligibility criteria, was a waiver granted by the medical monitor

Signature of Principal Investigator

Date:
Day Month Year

Completed by

Date:
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IND Study # _____

Radiology

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Visit 0 . 0

Subject ID: I N D # # U A * Consent Date:
Day Month Year

Subject Initials:

	Day	Month	Year	Normal	Local/ Regional	Metastatic	√ if ND
Chest X-ray	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CT Brain and/or	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MRI Brain	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CT Chest and/or	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MRI Chest	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CT Abdomen and/or	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MRI Abdomen	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bone Scan	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PET CT	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Completed by: _____

On:
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EKG

Pg of

Visit .

Subject ID: * Consent Date:
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Subject Initials:

Date of ECG:
Day Month Year

Overall interpretation: Normal
 Clinically insignificant abnormality
 Clinically significant abnormality (*specify*)

- 1 _____
- 2 _____
- 3 _____
- 4 _____
- 5 _____
- 6 _____

Completed by: _____

On:
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Ancillary Exams

Pg of

Visit .

Subject ID: * Consent Date:
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Date of Mammogram:
Day Month Year

Normal

Abnormal

Birad: 0 1 2 3 4 5 6

Date of MUGA:
Day Month Year

LVEF %

Completed by: _____

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Physical Exam

Pg of

Visit .

Subject ID: *

Consent 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: _____

On: Day

Month

Year

Subject ID: I N D # # U A * Consent Date:
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Target Lesion Measurement

Tumor laterality (√ one) Left Right

Site		Horizontal	x	Vertical	Product (cm)
<input type="text"/> <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/>	.	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<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"/>	<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"/>	<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

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

Site	Palpable?	Non-palpable?	Measurable?	Horizontal	x	Vertical	Product (cm)
<input type="text"/> <input type="text"/> <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

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Vital Signs

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Visit 0 . 0

Subject ID: I N D # # U A * Consent Date:
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Exam Date:
Day Month Year

Height: . cm In

Weight: . kg lbs

Blood Pressure: /

Pulse: / minute

Temperature: . °C °F

Respirations: / minute

Performance Status: 0 1 2

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Day Month Year

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Urine Analysis

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Subject ID: I N D # # U A * Consent Date:
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Subject Initials:

Specimen Collection Date:
Day Month Year

UPC

√ if
ND

Protein (mg/dL)

Creatinine (mg/dL) .

Protein / Creatinine ratio .

Urine Pregnancy Test

Date of Urine Pregnancy Test: or √ if NA
Day Month Year

Completed by: _____

On:
Day Month Year