



**EMORY HOSPITALS AND  
WINSHIP CANCER INSTITUTE  
PHYSICIAN'S ORDERS**

**Allergies/Sensitivities:** \_\_\_\_\_

NKA

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Protocol #: XXXXXX

Subject ID # \_\_\_\_\_

Informed Consent Signed  Yes  No

**INVESTIGATIONAL PROTOCOL:** **A Multicenter, Open-Label, Dose Escalation, Phase 1 Study of XXXXX in Adult Patients with Advanced Nonhematologic Malignancies**

Principle Investigator: John Kauh, MD      Research NP: Colleen Lewis      PIC# 17872 x8-5176  
 Research Coordinator: Rene Merriewether      PIC# 17027 x8-1802

**Cycle 1 ONLY**

Diagnosis: \_\_\_\_\_

1 Cycle = 28 Days

Cycle#: 1 Day 1: \_\_\_\_\_

Date and Time Order Written	Age	Measured Height (cm)	Measured Weight (kg)	BSA (m <sup>2</sup> )																				
		N/A		N/A																				
1	<b>Labs:</b> Administer drug(s) if: a. ANC: $\geq 1500/\text{mm}^3$ b. Plts $\geq 100,000/\text{mm}^3$ c. CrCL $\geq 50$ mL/min by C-G    d. TBili: $\leq 1.5X$ ULN e. AST and ALT: $\leq 2.5 \times$ ULN, 5 x ULN if due to disease																							
2	<b>CHEMOTHERAPY:</b> 1. XXXXX _____ mg (_____ mg/kg) IV daily on <b>Day 1 ONLY</b> (see below for infusion times) <b>****INVESTIGATIONAL DRUG SUPPLY****</b>  <b>At doses <math>\leq 20</math> mg/kg, XXXXX will be diluted with 0.9% NS and administered as an intravenous (IV) infusion in a total volume of 350 mL over 60 minutes.</b>  <b>At doses <math>&gt; 20</math> mg/kg, XXXXX will be diluted with 0.9% NS and administered as an IV infusion in a total volume of 700 mL over 120 minutes.</b>  <b>The prepared XXXXX/0.9% NS must be administered within 8 hrs of preparation using an infusion pump and 0.22 micron filter at the distal end of the infusion line.</b>  2. Flush line with 50 mL NS following completion of infusion  <table border="1"> <thead> <tr> <th></th> <th>Dose Level</th> <th>Dose (mg/kg/DAY)</th> <th>Dose (mg/kg/CYCLE)</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/></td> <td>1</td> <td>4 mg/kg/DAY</td> <td>4 mg/kg/CYCLE</td> </tr> <tr> <td><input type="checkbox"/></td> <td>2</td> <td>10 mg/kg/DAY</td> <td>10 mg/kg/CYCLE</td> </tr> <tr> <td><input type="checkbox"/></td> <td>3</td> <td>20 mg/kg/DAY</td> <td>20 mg/kg/CYCLE</td> </tr> <tr> <td><input type="checkbox"/></td> <td>4</td> <td>40 mg/kg/DAY</td> <td>40 mg/kg/CYCLE</td> </tr> </tbody> </table>  <b>Infusion Reactions:</b> For infusion related reactions, refer to <b>"Management of Infusion Related Reactions"</b> document					Dose Level	Dose (mg/kg/DAY)	Dose (mg/kg/CYCLE)	<input type="checkbox"/>	1	4 mg/kg/DAY	4 mg/kg/CYCLE	<input type="checkbox"/>	2	10 mg/kg/DAY	10 mg/kg/CYCLE	<input type="checkbox"/>	3	20 mg/kg/DAY	20 mg/kg/CYCLE	<input type="checkbox"/>	4	40 mg/kg/DAY	40 mg/kg/CYCLE
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Print  
Licensed Practitioner Name \_\_\_\_\_

Print Attending  
Physician Name \_\_\_\_\_

(Licensed Practitioner Signature/Contact #)

(Attending Physician Signature/Contact #)

Chemotherapy orders checked by:

Chemotherapy orders checked by:

(Signature)

(Signature)



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**Supportive Medications:**

1. **Acetaminophen** 650 mg PO Q4 hours PRN fever, myalgia
2. **Diphenhydramine** 25 mg IV Q4 hours PRN itching, hives
3. **Ondansetron** 8 mg IV x 1 PRN nausea/vomiting

3

**Monitoring:**

1. Place peripheral IV ON NON-INFUSION ARM for PK samples on day 1
2. ALL VITAL SIGNS AND EKGs ARE TO BE DONE IN SUPINE POSITION
3. Draw PK samples on days 1,2,4,8,15,22

**DAY 1**

Pre-Dose (\_\_\_\_:\_\_\_\_) VS BP \_\_\_\_\_ HR \_\_\_\_\_ T \_\_\_\_\_

**PK Sampling**

**PD Sampling**

12 Lead EKG

30 mins after start of infusion (\_\_\_\_:\_\_\_\_) VS BP \_\_\_\_\_ HR \_\_\_\_\_ T \_\_\_\_\_

5 min after end of infusion (\_\_\_\_:\_\_\_\_)

**PK Sampling**

25 min after end of infusion (\_\_\_\_:\_\_\_\_)

12 Lead EKG

30 min after end of infusion (\_\_\_\_:\_\_\_\_)

VS BP \_\_\_\_\_ HR \_\_\_\_\_ T \_\_\_\_\_

**PK Sampling**

**PD Sampling**

1 hour after end of infusion (\_\_\_\_:\_\_\_\_)

**PK Sampling**

2 hours after end of infusion (\_\_\_\_:\_\_\_\_)

VS BP \_\_\_\_\_ HR \_\_\_\_\_ T \_\_\_\_\_

**PK Sampling**

3 hours after end of infusion (\_\_\_\_:\_\_\_\_)

**PK Sampling**

5 hours after end of infusion (\_\_\_\_:\_\_\_\_)

**PK Sampling**

7 hours after end of infusion (\_\_\_\_:\_\_\_\_)

**PK Sampling**

**DAY 2**

VS BP \_\_\_\_\_ HR \_\_\_\_\_ T \_\_\_\_\_

12 Lead EKG

24 hours after end of infusion

(\_\_\_\_:\_\_\_\_)

**PK Sampling**

**PD Sampling**

Print  
Licensed Practitioner Name \_\_\_\_\_

Print Attending  
Physician Name \_\_\_\_\_

(Licensed Practitioner Signature/Contact #)

(Attending Physician Signature/Contact #)

Chemotherapy orders checked by:

Chemotherapy orders checked by:

(Signature)

RN

(Signature)

RN



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DAY 4 PK Sampling

DAY 8 PK Sampling

DAY 15 PK Sampling

DAY 22 PK Sampling

Print Licensed Practitioner Name \_\_\_\_\_ Print Attending Physician Name \_\_\_\_\_

(Licensed Practitioner Signature/Contact #) \_\_\_\_\_ (Attending Physician Signature/Contact #) \_\_\_\_\_

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Chemotherapy orders checked by: \_\_\_\_\_ RN \_\_\_\_\_

(Signature)

(Signature)