

STEM CELL LABORATORY (STCL)



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Release Date: 26 Apr 2019

Expiration Date:

STCL-SOP-050 INFUSION FORM

ISBT 128 Barcode: _____

1 ☐ Yes

1 ☐ Yes

1 ☐ Yes

2 🗆 N0

2 🗆 N0

2 🗆 N0

Stem	Cell	Laboratory

 $Continue\ with\ question\ 7$

L. Date of infusion	//	(MONTH / DAY	/ YEAR)		
2. Start Time of infusion	:	End Time of infusion _	: HR: M	MIN (<u>24 HOU</u>	R CLOCK)
B. Were pre-infusion medication	ons administered with	in 2 hours of infusion?			
		4. Record Mo	edication:		
			Benadryl	1 ☐ Yes	2 🗆 N0
1 \[Yes \]	*		Hydrocortisone	1 ☐ Yes	2 🗆 N0
2 🔲 No			Methylprednisolone	1 ☐ Yes	2 □ N0
			Mannitol	1 ☐ Yes	2 □ N0
•			Other, specify	1 ☐ Yes	2 🗆 N0
Continue with question	5				
. Were emergency medication	ns administered durir	ng or within 2 hours of infusion	on?		
_		6. Record Me	edication:		
1 Tes			Benadryl	1 □ Yes	2 □ N0
2 🗆 🔻	2		Hydrocortisone	4 🗆 V	

		C	CAE v.5.0 Grading		
Toxicity	0	1 1	2	3	4
Infusion related reaction	none	□ Mild transient reaction; infusion interruption not indicated; intervention not indicated	□ Therapy or infusion interruption indicated but responds promptly to symptomatic treatment (e.g., antihistamines, NS AIDS, narcotics, IV fluids); prophylactic medications indicated for <=24 hrs.	□ Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae	☐ Life-threatening consequences; urgent intervention indicated
Sinus bradycardia	□ none	□ Asymptomatic, intervention not indicated	Symptomatic, intervention not indicated; change in medication initiated	□ Symptomatic, intervention indicated	☐ Life-threatening consequences; urgent intervention indicated
Sinus tachycardia	□ none	□ Asymptomatic, intervention not indicated	☐ Symptomatic; non-urgent medical intervention indicated	□ Urgent medical intervention indicated	
Fever (In the absence of Neutropenia, where neutropenia is defined ANC <1.0 x 10 ⁹ /L) (The temperature measurements listed are oral or tympanic)	□ none	□ 38.0 - 39.0 degrees C (100.4 - 102.2 degrees F)	□ >39.0 - 40.0 degrees C (102.3 - 104.0 degrees F)	□ >40.0 degrees C (>104.0 degrees F) for <=24 hrs.	□>40.0 degrees C (>104.0 degrees F) for >24 hrs.

STCL-SOP-050 Infusion Form Stem Cell Laboratory, DUMC Durham, NC

Fax **BOTH** sides of this form to Barbara Waters-Pick

(Fax # <u>919-684-1555</u>)

Methylprednisolone

Other, specify___

Mannitol

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Stem	Cell	Labora	atory
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ISBT 12	8 Barcode:	
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		CTC	CTCAE v5.0 Grading		
Toxicity	0	1	2	3	4
Hypotension	□ none	☐ Asymptomatic, intervention not indicated	 Non-urgent medical intervention indicated 	□ Medical intervention indicated; hospitalization indicated	☐ Life-threatening consequences and urge intervention indicated
For pediatric patients, sys.	tolic BP 65mmHg or less in	infants up to 1 year old and 70 m	mHg or less in children older than 1 yea	r of age, use two successive or three	measurements in 24 hours
Hypertension *Note: For pediatric patients, use age and sex appropriate normal values > 95th percentile ULN.	none	□ Adult: Systolic BP 120 - 139 mm Hg or diastolic BP 80 - 89 mm Hg; □ Pediatric: Systolic/diastolic BP >90th percentile but< 95th percentile; □ Adolescent: BP ≥120/80 even if < 95th percentile	□ Adult: Systolic BP 140 - 159 mm Hg or diastolic BP 90 - 99 mm Hg if previously WNL; change in baseline medical intervention indicated; recurrent or persistent (>=24 hrs.); symptomatic increase by >20 mm Hg (diastolic) or to >140/90 mm Hg; monotherapy indicated initiated; □ Pediatric and adolescent: Recurrent or persistent (>=24 hrs.) BP >ULN; monotherapy indicated; systolic and /or diastolic BP between the 95th percentile and 5 mmHg above the 99th percentile; □ Adolescent: Systolic between 130-139 or diastolic between 80-89 even if < 95th percentile	□ Adult: Systolic BP >=160 mm Hg or diastolic BP >=100 mm Hg; medical intervention indicated; more than one drug or more intensive therapy than previously used indicated; □ Pediatric and adolescent: Systolic and/or diastolic > 5 mmHg above the 99th percentile	□ Adult and Pediatric Life-threatening consequences (e.g., malignant hypertension transient or permanent neurologic deficit, hypertensive crisis); urg intervention indicated
Rigors, chills	□ none	☐ Mild sensation of cold; shivering; chattering of teeth	□ Moderate tremor of the entire body; narcotics indicated	☐ Severe or prolonged, not responsive to narcotics	
Nausea	□ none	Loss of appetite without alteration in eating habits	☐ Oral intake decreased without significant weight loss, dehydration or malnutrition	□ Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	
Vomiting	□ none	□ Intervention not indicated	☐ Outpatient IV hydration; medical intervention indicated	☐ Tube feeding, TPN, or hospitalization indicated	□ Life-threatening consequences
Dyspnea (shortness of breath)	□ none	☐ Shortness of breath with moderate exertion	☐ Shortness of breath with minimal exertion; limiting instrumental ADL	□ Shortness of breath at rest; limiting self-care ADL	☐ Life-threatening consequences; urge intervention indicate
Hypoxia	none		□ Decreased oxygen saturation with exercise (e.g., pulse oximeter <88%); intermittent supplemental oxygen	□ Decreased oxygen saturation at rest (e.g., pulse oximeter <88% or PaO2 <=55 mm Hg)	□ Life-threatening airwa compromise; urger intervention indicate (e.g., tracheotomy of intubation)
Hemoglobinuria	□ none	☐ Asymptomatic; clinical or diagnostic observations only; intervention not indicated			
mments:					
nature			Date		

STCL-SOP-050 Infusion Form Stem Cell Laboratory, DUMC Durham, NC

Signature Manifest

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All dates and times are in Eastern Time.

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Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		11 Apr 2019, 07:51:33 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
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Name/Signature	Title	Date	Meaning/Reason
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Quality

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Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		22 Apr 2019, 05:36:09 PM	Approved