STEM CELL LABORATORY (STCL)

DOCUMENT NUMBER: STCL-DIST-006 FRM2

DOCUMENT TITLE:

Adverse Event Reporting Form FRM2

DOCUMENT NOTES:

Document Information

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Control Information

Author: MSR68	**Owner:** WATER002
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Please complete the following Adverse Event Reporting form associated with the cellular therapy product infused. Sign, date, and fax the completed form to (919) 684-1555.

Donor Name *(if applicable)*:	Donor ID # *(if applicable)*:
Date / Time of Infusion: _____/_____/_____ _____:_____ **(AM/PM)** dd/ mmm/ yyyy hh:min *circle*	ISBT Barcode Assigned:
Recipient Name:	Recipient DOB:

Amount of Cellular Therapy Product infused (mL): _____

Start Time of Infusion: _____ **AM/PM** Stop Time of Infusion: _____**AM/PM**

Indicate if the thawed product was: ☐ washed ☐ not washed ☐ diluted prior to infusion ☐ not diluted

List any additives to unit(s):_____

Recipient Weight (kg): _____

Was therapy combined with other cellular therapy products: ☐Yes or ☐ No If yes, please explain: _____

_____

Please list GVHD prophylaxis and preparative Rx: _____

_____

You may check more than one event. If none, please check "none" from the list below. Please only record reactions that occurred within ***24 hours from the time of infusion***.

☐ Bacteremia	☐ Hypertension
☐ Sudden/Unexplained death	☐ Brachycardia
☐ Fever/Chills	☐ Transfusion Hemolytic Reaction
☐ Rash	☐ Other; _____
☐ Hematuria	_____
☐ Respiratory complications	☐ None

NOTE: IF AN ADVERSE EVENT HAS OCCURRED AND IS NOTED ABOVE, PLEASE INIDICATE ANY TREATMENT OR ACTIONS TAKEN TO RESOLVE THE ISSUES.

Authorized Signature/Title:

Print Authorized Name:

Print Name of infusing physician:

Transplant Facility Medical Review (*if applicable*):

NOTE: ***DUKE USE ONLY*** **-** *If an adverse event is documented above, signatures from the STCL Medical Center Medical Director (or designee) and Clinical Quality Program (CQP) are required below.*

STCL Medical Director Review:	Date:
Clinical Quality Program Review	Date:

Signature Manifest

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All dates and times are in Eastern Time.

STCL-DIST-006 FRM2 Adverse Event Reporting Form

Author

Name/Signature	Title	Date	Meaning/Reason
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Management

Name/Signature	Title	Date	Meaning/Reason
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Medical Director

Name/Signature	Title	Date	Meaning/Reason
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Quality

Name/Signature	Title	Date	Meaning/Reason
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Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	24 Apr 2025, 10:04:23 AM	Approved