DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Adverse Event Form FRM1

DOCUMENT NOTES:

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APBMT-COMM-030 FRM1 Adverse Event Form
APBMT Program

Duke University Medical Center
Durham, NC 27710

FOR NMDP DONORS ONLY

Donor GRID: _____

Recipient NMDP ID: _____-_____-_____

If the NMDP donor adverse event is considered serious (death, life threatening, hospitalization, or significant incapacity/disability) report the event to NMDP using Form 701(Donor Adverse Event Form) by FAX or submit electronically on FormsNet3.

Donor ID

Date ☐☐ ☐☐ ☐☐
M D Y

Type of Procedure (circle): Apheresis Harvest ECP

Type of Donor (circle): Autologous Allogeneic (Related) Allogeneic (NMDP)

Record the highest grade of adverse event during the procedure.			CTCAE v5.0 Grading	
ADVERSE EVENTS	**1**	**2**	**3**	**4**
FEVER	□ 38.0 – 39.0 °C (100.4 – 102. °F)	□ > 39.0 - 40.0 °C (102.3 - 104.0 °F)	□ > 40.0 °C (> 104.0 °F) for <= 24 h	□ > 40.0 °C (> 104.0 °F) for > 24 h
CHILLS	□ Mild sensation of cold; shivering; chattering of teeth	□ Moderate tremor of the entire body; narcotics indicated	□ Severe or prolonged, not responsive to narcotics	-------
NAUSEA	□ 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	□ Intervention not indicated	□ Outpatient IV hydration; medical intervention indicated	□ Tube feeding, TPN, or hospitalization indicated	□ Life-threatening consequences urgent intervention indicated
SINUS BRADYCARDIA	□ Asymptomatic, intervention not indicated	□ Symptomatic, intervention not indicated; change in medication initiated	□ Symptomatic, intervention indicated	□ Life-threatening consequences; urgent intervention indicated
SINUS TACHYCARDIA	□ Asymptomatic, intervention not indicated	□ Symptomatic; non-urgent medical intervention indicated	□ Urgent medical intervention indicated	-------
DYSPNEA	□ 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; urgent intervention indicated
HYPOXIA	-------	□ 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)	□ Lie-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)

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HYPOTENSION	□ Asymptomatic, intervention not indicated	□ Non-urgent medical intervention indicated	□ Medical intervention indicated; hospitalization indicated	□ Life-threatening consequences urgent intervention indicated
HYPERTENSION	□ **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 □ **Pediatric** 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 mm Hg above the 99th percentile	□ **Adult and Pediatric:** Life-threatening consequences (e.g., malignant hypertension, transient or permanent neurologic deficit, hypertensive crisis); urgent intervention indicated
VASOVAGEL REACTION	-------	-------	□ Present	□ Life-threatening consequences; urgent intervention indicated
ALLERGIC REACTION	□ Systemic intervention not indicated	□ Oral intervention indicated	□ Bronchospasm; hospitalization indicated for clinical sequelae; intravenous intervention indicated	□ Life-threatening consequences; urgent intervention indicated
ANAPHYLAXIS	-------	-------	□ Symptomatic bronchospasm, with or without urticaria; parenteral intervention indicated; allergy-related edema/angioedema; hypotension	□ Life-threatening consequences; urgent intervention indicated

Comments:_____

Signature _____ Date_____

At completion of the form, FAX to 919-385-9527. For questions, please contact Apheresis Coordinator.

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Instructions for Completing the Adverse Events Record

Donor ID	Record donor's medical record number. (Patient label acceptable.)
Donor GRID and Recipient NMDP ID	Record donor GRID and NMDP recipient ID numbers, (if applicable)
Date	Record date of the procedure.
Type of Procedure	Circle type of procedure.
Type of Donor	Circle type of donor.

Record highest grade of adverse event during procedure.	• Review the adverse event list. • If the apheresis patient experiences any of the graded Adverse Events listed, check the appropriate box. • Record types of treatment given, if applicable in the electronic medical record.
Comments	Record any additional comments related to the adverse event, if applicable.
Signature/Date	The care provider/designee will sign and date the form.
Fax	Fax completed form to the appropriate area within 24 hours

Signature Manifest

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Title: Adverse Event Form FRM1

All dates and times are in Eastern Time.

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Author

Name/Signature	Title	Date	Meaning/Reason
Sally McCollum (MOORE171)		03 Jul 2019, 08:25:15 AM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		03 Jul 2019, 08:31:19 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		03 Jul 2019, 08:33:50 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)		03 Jul 2019, 10:13:58 AM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		09 Jul 2019, 02:33:43 PM	Approved