DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

DOCUMENT NUMBER: APBMT-COMM-047

DOCUMENT TITLE:
Immune Effector Cells Standards Training and Competency Checklist

DOCUMENT NOTES:

Document Information

Revision: 01	**Vault:** APBMT-Common-rel
Status: Release	**Document Type:** APBMT

Date Information

Creation Date: 13 Jan 2025	**Release Date:** 07 Feb 2025
Effective Date: 07 Feb 2025	**Expiration Date:**

Control Information

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Previous Number: None	**Change Number:** APBMT-CCR-258

FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY

Immune Effector Cells Standards Training and Competency Form

This form is provided as a tool for documenting training and competency required of Clinical Program Directors, attending physicians, physicians-in-training, and advanced practice providers/professionals (as applicable). Confirmation that training was provided and competency was assessed during the current accreditation cycle in each of the following areas must be provided to FACT prior to an on-site inspection. Equivalent documentation is acceptable so long as all information below is included.

Name: _____

Position: _____

Topic	Yes	No	N/A	Comment
Specific training and competency in each of the following:				
B3.3.2.1 Indications for cellular therapy.				
B3.3.2.2 Selection of suitable recipients and appropriate treatments.				
B3.3.2.3 Donor selection, evaluation, and management (when applicable).				
B3.3.2.4 Donor and recipient informed consent (when applicable).				
B3.3.2.5 Cellular therapy product administration and patient management.				
B3.3.2.6 Adverse events associated with cellular therapy.				
B3.3.2.7 Management of anticipated complications of cellular therapy, including, but not limited to, cytokine release syndrome, tumor lysis syndrome, macrophage activation syndrome, graft versus host disease, cardiac dysfunction, respiratory distress, neurologic toxicity, renal and hepatic failure, disseminated intravascular coagulation, anaphylaxis, neutropenic fever, infectious and noninfectious processes, mucositis, and nausea and vomiting.				
B3.3.2.8 Monitoring and management of pain.				
B3.3.2.9 Evaluation of post-treatment cellular therapy outcomes.				
B3.3.2.10 Evaluation of late effects of cellular therapy.				
B3.3.2.11 Documentation and reporting for patients on investigational protocols.				
Specific clinical training and competency in each of the following for allogeneic cellular therapy:				
B3.3.3.1 Identification, evaluation, and selection of cell source, including use of donor registries.				
B3.3.3.2 Donor eligibility determination.				
B3.3.3.3 Methodology and implications of human leukocyte antigen (HLA) typing.				
B3.3.3.4 Management of patients receiving ABO incompatible cellular therapy products.				

Knowledgeable in the following procedures:				
B3.3.4.1 Cellular therapy product collection.				
B3.3.4.2 Cellular therapy product processing.				
B3.3.4.3 Cellular therapy product cryopreservation.				
B3.3.4.4 Cellular therapy product administration.				

Reviewer Signature and Date (must be signed by someone other than personnel being assessed):

_____ _____

Signature Manifest

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All dates and times are in Eastern Time.

APBMT-COMM-047 Immune Effector Cells Standards Training and Competency Checklist

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Document Release

Name/Signature	Title	Date	Meaning/Reason
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