**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 inspection. Equivalent documentation is acceptable if all information below is included.

**Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Position:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

| **Topic** | **Yes** | **No** | **N/A** | **Comment** |
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| ***Specific training and competency in each of the following:*** |
| B3.3.4.1 Indications for autologous and allogeneic immune effector cellular therapy. |   |   |   |   |
| B3.3.4.2 Selection of suitable recipients and appropriate preparative regimens. |   |   |   |   |
| B3.3.4.3 Donor selection, evaluation, and management.  |   |   |   |   |
| B3.3.4.4 Donor and recipient informed consent. |   |   |   |   |
| B3.3.4.5 Administration of preparative regimens.  |   |   |   |   |
| B3.3.4.6 Monitoring and management of cytokine release syndrome.  |   |   |   |   |
| B3.3.4.7 Administration of cellular therapy products, including immune effector cells, genetically modified cells, and other cellular therapies.  |  |  |  |  |
| B3.3.4.8 Management of complications related to the administration of cellular therapy products.  |   |   |   |   |
| B3.3.4.9 Management of neutropenic fever. |  |  |  |  |
| B3.3.4.10 Diagnosis and management of pulmonary complications. |  |  |  |  |
| B3.3.4.11 Diagnosis and management of fungal disease.  |  |  |  |  |
| B3.3.4.12 Diagnosis and management of sinusoidal obstruction syndrome and other causes of hepatic dysfunction.  |  |  |  |  |
| B3.3.4.13 Management of thrombocytopenia and bleeding, including recognition of disseminated intravascular coagulation.  |  |  |  |  |
| B3.3.4.14 Monitoring and management of mucositis. |  |  |  |  |
| B3.3.4.15 Monitoring and management of gastrointestinal complications.  |  |  |  |  |
| B3.3.4.16 Monitoring and management of pain. |   |   |   |   |
| B3.3.4.17 Monitoring and management of neurologic toxicity, including immune effector cell associated neurotoxicity syndrome (ICANS). |  |  |  |  |
| B3.3.4.18 Monitoring and management of cardiac dysfunction. |  |  |  |  |
| B3.3.4.19 Monitoring and management of renal dysfunction.  |  |  |  |  |
| B3.3.4.20 Monitoring and management of anaphylaxis. |  |  |  |  |
| B3.3.4.21 Monitoring and management of infectious processes, including immunodeficiencies and opportunistic infections. |  |  |  |  |
| B3.3.4.22 Diagnosis and management of dermatologic complications.  |  |  |  |  |
| B3.3.4.23 Evaluation of post-treatment cellular therapy outcomes. |   |   |   |   |
| B3.3.4.24 Monitoring and management of tumor lysis syndrome. |  |  |  |  |
| B3.3.4.25 Monitoring and management of macrophage activation syndrome / hemophagocytic lymphohistiocytosis.  |  |  |  |  |
| B3.3.4.26 Evaluation of late effects of cellular therapy. |   |   |   |   |
| B3.3.4.27 Documentation and reporting for patients on investigational protocols. |   |   |   |   |
| B3.3.4.28 Reporting responsibilities for adverse events according to Applicable Law. |  |  |  |  |
| B3.3.4.29 Palliative and end of life care.  |  |  |  |  |
| B3.3.4.30 Age-specific donor and recipient care.  |  |  |  |  |
| ***Specific clinical training and competency in each of the following for allogeneic cellular therapy:*** |
| B3.3.5.1 Identification, evaluation, and selection of cell source, including use of donor registries.  |   |   |   |   |
| B3.3.5.2 Donor eligibility determination.  |   |   |   |   |
| B3.3.5.3 Methodology and implications of HLA typing. |   |   |   |   |
| B3.3.5.4 Methodology and implications of testing for chimerism. |  |  |  |  |
| B3.3.5.5 Management of patients receiving ABO incompatible cellular therapy products.  |   |   |   |   |
| B3.3.5.6 Diagnosis and management of acute and chronic Graft versus Host Disease. |  |  |  |  |
| ***Knowledgeable in the following procedures:*** |
| B3.3.6.1 Cellular therapy product collection procedures. |   |   |   |   |
| B3.3.6.2 Cellular therapy product processing. |   |   |   |   |
| B3.3.6.3 Cellular therapy product cryopreservation. |   |   |   |   |
| B3.3.6.4 Cellular therapy product administration. |   |   |   |   |
| B3.3.6.5 Extracorporeal photopheresis for GVHD. |  |  |  |  |
| B3.3.6.6 Therapeutic apheresis.  |  |  |  |  |

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

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