**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):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_