EXAMPLE OF VERIFICATION OF PRODUCT IDENTITY AT SAMPLE TRANSITION POINT

Disclaimer: This example is just one potential example of verifying and documenting the identify of a cellular therapy product and its intended patient when changes in custody occur. This particular example involves verification of product and recipient identity upon receipt at the infusion site from the contract manufacturing facility. The specific points in time and location of verification will depend on the number of times a product is distributed to a different entity and the types of identification allowed on each individual product label and trial. (Note that the use of the Donation Identification Number [DIN] is encouraged because it does not contain any protected health information, is specific to an individual product, and can be easily maintained throughout manufacturing.)

The general expectation is that the immune effector cell (IEC) program confirms the identity and recipient of each IEC product prior to infusion to ensure the correct individual receives the correct product. The manner and format of this process may vary for each organization and type of product. If this example is used, the program is responsible for updating it as new information becomes available.

VERIFICATION OF CELLULAR THERAPY PRODUCT AND INTENDED RECIPIENT

PRODUCT EXPECTED

DIN #	**Received From**: ☐ Apheresis Center XXX ☐ OTHER_____ **Off-Site Manufacturer** **Name**:_____

Patient Information:

Patient Name	Institution XXX MRN
Other Hospital/MRN	Protocol #
First Study ID # ☐ NA	Second Study ID # ☐ NA

Donor Information: ☐ NA for Autologous Products

Donor Name	Institution XXX MRN

The above documentation has been verified with source documentation
Verified by: **Date**

PRODUCT RECEIPT: Date: _____ Time: _____

Product ID #	Manufacturer Lot #	
ZIP TIE Numbers: ☐ NA	# of bags : ☐ NA	#of Vials ☐ NA

ZIP TIE or Tamper Resistant tape is intact? [ ] Yes [ ] No * [ ]NA	**Shipping conditions** ☐ LN2 (dryshipper) Expectation <-150°C
Product Type ☐ HPC (A) ☐ NC (WB) ☐ HPC (M) ☐ MALIG(TM) ☐ HPC (CB) ☐ INV PROD ☐ MNC(A) ☐ Other (specify: _____)	☐ Dry-Ice Expectation -90 to -65°C ☐ Refrigerated (Nanocool, Gel Pack) Expectation :1-10°C ☐ Ambient Expectation : 20-24°C Temp Reading of Monitoring Device: _____ °C Acceptable ☐ Y ☐ N* Temperature Device SN _____ ☐ NA * If unacceptable result for temperature or shipping conditions: contact the Sponsor.

Container Integrity OK?   [ ] Yes [ ] No, explain _____
Visual Inspection OK?   [ ] Yes [ ] No, explain _____

LABEL VERIFICATION

Copy/Photograph of product label and other associated labels and attach to this form. [ ] N/A [ ] Yes [ ] No

For all products	☐ Patient Name ☐ Institution XXX MRN ☐ Other MRN ☐ Unit # ☐ Product Name ☐ Product ABO / Rh ☐ Protocol # / Study ID # ☐ Manufacturer Lot #
Biohazard Tag(s)	☐ Auto Tie Tag #1 ☐ Auto Tie Tag #2 ☐ Auto Tie Tag #3
(☐ N/A)	☐ Allo Tie Tag #1 ☐ Allo Tie Tag #2 ☐ Allo Tie Tag #3 ☐ Pending Tie Tag #4

Comments: _____ * **[ ] Deviation Filed**

Product/Label Information verified by:		Date/Time
First Tech (at receipt)		
Second Tech		