**APPENDIX C** **AlloVir Chain of Custody Form REGION: US -Version 4.0**

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| Patient and Information |
| Patient ID: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Ex. Site#-Patient#) | Investigator Name: |  |

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| Shipment information: Shipment 1 (Dose 1 + 2 + 3) |
| Order ID: | *Listed on IRT Shipment Request:*  |
| Check Documentation Received: | [ ]  Azenta Pack-Out Slip[ ]  IRTShipment Request (Flexadvantage)[ ]  Certificate(s) of Conformance[ ]  Shipper return label[ ]  Safety Data Sheet (SDS)[ ]  Secondary label booklets (1 per vial)  | Were there intact zip ties present on the cryoshipper upon delivery?  | [ ]  Y [ ]  N |
| Were all contents listed on the IRT Shipment Request Form received? | [ ]  Y [ ]  N |
| Vial Removal from shipper: | \_\_\_ / \_\_\_\_\_ / \_\_\_\_\_DD MMM YYYY | \_\_\_\_\_\_\_HH:MM | Were there any temperature alarms in transit? | [ ]  Y [ ]  N |
| Was the transfer time out of Cryogenic conditions within the recommended 1 minute? | [ ]  Y [ ]  N | If No, Vial placement back in cryogenic conditions | \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_DD MMM YYYY HH:MM |
| **Icon  Description automatically generated** | If the contents were missing from the shipment or if a temperature alarm occurred during shipment, please follow the issue reporting instructions in section 12 the Cell Therapy Manual. |

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| Patient and Information |
| Patient ID: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Ex. Site#-Patient#) | Investigator Name: |  |

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| Shipment information: Shipment 2 (Dose 4 + 5 + 6 + 7) |
| Order ID:*Listed on IRT Shipment Request* |  |
| Check Documentation Received: | [ ]  Azenta Pack-Out Slip[ ]  IRTShipment Request (Flexadvantage)[ ]  Certificate(s) of Conformance[ ]  Shipper return label[ ]  Safety Data Sheet (SDS)[ ]  Secondary label booklets (1 per vial)  | Were there intact zip ties present on the cryoshipper upon delivery?  | [ ]  Y [ ]  N |
| Were all contents listed on the IRT Shipment Request Form received? | [ ]  Y [ ]  N |
| Were there any temperature alarms in transit? | [ ]  Y [ ]  N |
| Vial Removal from shipper: | \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_DD MMM YYYY HH:MM |
| Was the transfer time out of Cryogenic conditions within the recommended 1 minute? | [ ]  Y [ ]  N | If No, Vial placement back in cryogenic conditions | \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_DD MMM YYYY HH:MM |
| **Icon  Description automatically generated** | If the contents were missing from the shipment or if a temperature alarm occurred during shipment, please follow the issue reporting instructions in section 12 the Cell Therapy Manual. |

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| Patient and Information |
| Patient ID: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Ex. Site#-Patient#) | Investigator Name: |  |

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| **DOSE 1 (Secondary Label)** |
| Attach secondary label below (one for each vial that you prepare for infusion) |
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| Patient and Information |
| Patient ID: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Ex. Site#-Patient#) | Investigator Name: |  |

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| **DOSE 2 (Secondary Label)** |
| Attach secondary label below (one for each vial that you prepare for infusion) |
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| Patient and Information |
| Patient ID: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Ex. Site#-Patient#) | Investigator Name: |  |

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| **DOSE 3 (Secondary Label)** |
| Attach secondary label below (one for each vial that you prepare for infusion) |
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| Patient and Information |
| Patient ID: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Ex. Site#-Patient#) | Investigator Name: |  |

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| **DOSE 4 (Secondary Label)** |
| Attach secondary label below (one for each vial that you prepare for infusion) |
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| Patient and Information |
| Patient ID: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Ex. Site#-Patient#) | Investigator Name: |  |

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| **DOSE 5 (Secondary Label)** |
| Attach secondary label below (one for each vial that you prepare for infusion) |
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| Patient and Information |
| Patient ID: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Ex. Site#-Patient#) | Investigator Name: |  |

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| **DOSE 6 (Secondary Label)** |
| Attach secondary label below (one for each vial that you prepare for infusion) |
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| Patient and Information |
| Patient ID: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Ex. Site#-Patient#) | Investigator Name: |  |

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| **DOSE 7 (Secondary Label)** |
| Attach secondary label below (one for each vial that you prepare for infusion) |
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| Patient and Information |
| Patient ID: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Ex. Site#-Patient#) | Investigator Name: |  |

|  | Receipt | Dispensing | Destruction |
| --- | --- | --- | --- |
| **Vials** *(Lot Number; Vial Number)* | **Received in Good Condition** *(Mark N/A for vials not received)* | **Date Received***(dd-MON-yyyy)* | **Received and Unpacked By***(Initials)* | **Dispensed to Patient** | **Date Dispensed***(dd-MON-yyyy)* | **Dispensed By** *(Initials)* | **Date of Destruction***(dd-MON-yyyy )* | **Destroyed By***(Initials)* | **CRA Initials/Date***(Initials/ dd-MON-yyyy)* |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |

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| **Icon  Description automatically generated** | It is the responsibility of the site to ensure that the investigational product is stored in vapor phase liquid nitrogen (LN2) at ≤ -150°C upon receipt and removal from the shipper. |

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| Patient and Information |
| Patient ID: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Ex. Site#-Patient#) | Investigator Name: |  |

|  | Receipt | Dispensing | Destruction |
| --- | --- | --- | --- |
| **Vials** *(Lot Number; Vial Number)* | **Received in Good Condition** *(Mark N/A for vials not received)* | **Date Received***(dd-MON-yyyy)* | **Received and Unpacked By***(Initials)* | **Dispensed to Patient** | **Date Dispensed***(dd-MON-yyyy)* | **Dispensed By** *(Initials)* | **Date of Destruction***(dd-MON-yyyy )* | **Destroyed By***(Initials)* | **CRA Initials/Date***(Initials/ dd-MON-yyyy)* |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |
| 126 - \_ \_ - \_ \_ \_ \_ \_ ; \_ \_ \_ | [ ]  Yes [ ]  No [ ]  N/A |  |  | [ ]  Y [ ]  N |  |  |  |  |  |

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| **Icon  Description automatically generated** | It is the responsibility of the site to ensure that the investigational product is stored in vapor phase liquid nitrogen (LN2) at ≤ -150°C upon receipt and removal from the shipper. |