**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. |