Poseida Therapeutics, Inc.

(A Member of the Roche Group)

Cellular Therapy Lab and P-CD19CD20-ALLO1 Administration Manual

Protocol Number

P-CD19CD20-ALLO1-001

Roche/Genentech Study ID: XO45648

Version 3: 11Mar2026

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1. INTRODUCTION

This manual describes Poseida Therapeutics, Inc., a member of the Roche Group investigational product P-CD19CD20-ALLO1 shipment, tracking, storage, and administration for the study entitled: Open-Label, Multicenter, Phase 1 Study to Assess the Safety of P-CD19CD20-ALLO1 in Subjects with Selected Relapsed/Refractory B cell Malignancies.

Forms described in this document and samples attached as appendices include:

- **P-CD19CD20-ALLO1-001 Dose Infusion Authorization Form (**Appendix 1) – This form will be completed and provided by Poseida. The form requires principal investigator (PI) review and approval before dose administration.
- **P- CD19CD20-ALLO1-001 Dose Administration Form (**Appendix 2) – This form is to be completed by the site staff preparing and administering the dose.
- **P- CD19CD20-ALLO1-001 Investigational Product Destruction Form (**Appendix 3) – This form should be completed in the event P- CD19CD20-ALLO1 requires destruction on-site.
- **Allogeneic Product Shipment and Receipt Record (previously named Chain of Custody Form) (**Appendix 8) **–** This form will be completed for each shipment of Investigational Product (IP) shipped to and received at a site.

2. PERSONNEL

Sponsor – Poseida Therapeutics, Inc. (A member of the Roche Group)

Name	Title	Email	Phone
Simon Heidegger, MD	Medical Monitor	heidegger.simon@gene.com	+1 650-534-7409
Lan Hoang	Clinical Program Director	hoang.lan@gene.com	+1 818-203-5459
Preety Grewal	Sr. Clinical Trial Leader	grewal.preety@gene.com	+1 619-876-8523
Olesya Srur	Sr. CGT Logistics & Distribution Manager	CGT_PTCB_Logistics-d@gene.com	+1 858-926-7360
Kayla Shaw	Sr. CGT Logistics & Distribution Specialist	CGT_PTCB_Logistics-d@gene.com	+1 858-926-7360

3. PRODUCT DESCRIPTION - P-CD19CD20-ALLO1

P-CD19CD20-ALLO1 is comprised of allogeneic CAR-T cells that target both CD19 and CD20 and have been genetically modified using an electroporation-based, non-viral (DNA transposon) gene delivery system called the piggyBac® (PB) DNA modification system and the Cas-CLOVER™ gene editing system. The primary attributes of P-CD19CD20-ALLO1 are conferred by the genes introduced in the PB transposon, including anti-CD19 and anti-CD20 targeting

variable human heavy-chain domains (VH)-based CAR (VCAR) gene, a dihydrofolate reductase (DHFR) selection mutant protein (mutein) gene, and an inducible caspase-9 (iCasp9)-based safety switch gene, and the genes ablated using the Cas-CLOVER™ gene editing system: the T cell receptor beta chain (TRBC) and beta-2-microglobulin (B2M) genes.

There are 2 CAR expression cassettes, one is composed of an extracellular CD19-binding VH protein fused to a CD8α spacer, a CD8α transmembrane domain, an intracellular 4-1BB signaling domain and a CD3ζ signaling domain. The second CAR expression cassette is composed of an extracellular CD20-binding VH protein fused to a CD8α spacer, a CD8α transmembrane domain, an intracellular 4-1BB signaling domain and a CD3ζ signaling domain.

4. FORMULATION

P-CD19CD20-ALLO1 drug product consists of cells formulated in a sterile, cryopreservation medium containing 50% (v/v) PLASMA-LYTE A and 50% (v/v) CryoStor® CS10.

5. HOW SUPPLIED

P-CD19CD20-ALLO1 is manufactured by Poseida under current Good Manufacturing Practices (cGMP) conditions. P-CD19CD20-ALLO1 is an off-the-shelf product with release testing performed and a Certificate of Analysis (COA) generated for each lot. P- CD19CD20-ALLO1 is supplied frozen at ≤ -130°C in either a 20 mL "AT-Closed Vial®" or in 250 mL cryogenic freezing cryobags at a target concentration of 8 x 10^6 cells per mL. Each vial contains approximately 20 mL of P-CD19CD20-ALLO1 and the product cryobag label states a net fill volume of 30 mL, however, there might be an additional overfill up to 2 mL to account for any dead volume during the filling process. P- CD19CD20-ALLO1 (vials or cryobags) is shipped to the clinical site in a vapor phase liquid nitrogen cryogenic shipping system (transport dewar) at ≤ -130°C. The cryobags are encased in an aluminum cassette.

Figure 1 is an example of vial labeling and Figure 2 is an example of the cryobag labeling of P-CD19CD20-ALLO1.

Figure 1: Example Vial Label

Vol: 20 mL Vial: XXX[1] DIN #: XXXXXXXXXXXXX[2]
Store at ≤ -130°C

See Infusion Authorization Form for Dose

P-CD19CD20-ALLO1 Conc. 8 x 10^6 cells/mL

Part #: XX.XXX[3] Lot #: XXXXX[4]
DOM: DDMMMYYYY[5]

Manufactured by Poseida Therapeutics
Protocol #: P-CD19CD20-ALLO1-001
Caution: New Drug--Limited by Federal (or United States) law to investigational use

EVALUATED FOR INFECTIOUS SUBSTANCES

Figure 2: Example Cryobag Label

Vol: 30 mL
Store at: ≤-130°C in LN2 vapor phase
Refer to dosing documentation
P-CD19CD20-ALLO1
Part #: 80.038[3]
Target Conc.: 8×10^6 cells/mL
Lot #: XXXXX[4]
Manufactured by Poseida Therapeutics
DOM: DDMMMYYYY[5]
Caution: New Drug--Limited by Federal (or United States) law to investigational use

Footnotes for Figure 1 and Figure 2:

- [1]Vial XXX: Vial number starting with 001
- [2]DIN: Donation Identification Number, 13-digit identifier (facility ID number, year and sequence number) eye readable text below the barcode, do not include the flag and check character
- [3]Part#: Variable field, unique identifier assigned by Poseida
- [4]Lot#: Variable field, unique identifier assigned by Poseida
- [5]DOM: Date of Manufacture defined as the date of final drug product formulation

Supplies

Sites will supply the latex free, non-filtered blood product compatible infusion set with a 3-way stopcock as appropriate for the dose and volume, and normal saline.

For subjects dosed using vials, Poseida will supply the AT-Adapt, needle-less collection device for AT-Closed Vial that should be used to extract cells from the AT-Closed Vial.

To minimize variability, the BD alaris pump infusion set (manufacturer number 2426-0007), or the McKesson administration set (manufacturer number SF3258-10H) is recommended, though equivalent sets may be utilized if this is not available.

6. P-CD19CD20-ALLO1 SHIPMENT AND RECEIPT

Receipt of Transport Dewar

P-CD19CD20-ALLO1 (vials or cryobags) will be supplied in an appropriately sized vapor phase liquid nitrogen cryogenic shipping system (transport dewar) at ≤ -130°C prior to or on the start date of conditioning chemotherapy. The product will be shipped in either a Cryoport or DV10 transport Dewar. Please see Appendix 4 or Appendix 6, as applicable, for instructions on transport Dewar receipt/unloading/return.

Please see Appendix 5 or Appendix 7, as applicable, for instructions on transport Dewar temperature information.

Condition Verification

Inspect the dewar for external damage such as large dents. Verify no major frost or condensation on the outside of the unit, which could indicate either a complete or partial loss of vacuum and potential damage to the vial(s) or cryobag(s). If frost/condensation found, please contact CGT_PTCB_Logistics-d@gene.com, the Poseida Clinical Trial Manager (CTM), and your CRA immediately.

Check the temperature log to ensure no significant temperature changes occurred during transportation. When removing the vial(s) or cryobag(s) from the transport dewar, inspect the vial or cryobag contents and appearance. If the product experienced a temperature excursion or is not in good condition (such as cracks or any abnormalities), immediately contact CGT_PTCB_Logistics-d@gene.com, the Poseida CTM, and your ICON CRA immediately.

When possible, please photograph damage or other abnormalities and provide the images to Poseida.

Receipt/Unloading Documentation:

1. Complete Section 4 of the accompanying Allogeneic Product Shipment and Receipt Record (previously named Chain of Custody) form in Appendix 8.
2. **Verify** the items are in good condition, all documentation was received, and primary identifiers match the documentation.

- **Sign & Date** to confirm your inspection.
- **Scan and return** the form to the email indicated on the form.

3. On the day of the receipt, transfer P-CD19CD20-ALLO1 into a vapor phase liquid nitrogen freezer or equivalent that steadily maintains the temperature of ≤ -130°C.

4. A Dose Infusion Authorization (DIA) Form (Appendix 1) will be provided by Poseida typically within a few days of subject enrollment. Once the DIA is received, please confirm you received sufficient product to administer the calculated dose. If the label(s) on the cryobag(s) received for a subject's infusion indicates the total volume is less than the prescribed dose of P-CD19CD20-ALLO1 (+/- 10%), contact Poseida to determine the next step. The product may be held in storage to combine with a subsequent shipment if it has been maintained at ≤ -130°C without thawing.

7. STORAGE

Vials and cryobags containing P-CD19CD20-ALLO1 cells should be stored at the site in blood bank/cell processing center conditions in a monitored ≤ -130°C vapor phase cryogenic freezer or equivalent until the subject is ready for infusion.

8. STABILITY

It is strongly recommended that P-CD19CD20-ALLO1 cells be administered immediately after thaw. However, it is intended that P-CD19CD20-ALLO1 cells will be infused within 30 minutes (up to 1 hour) of thawing. Please contact your ICON CRA or CTM or Poseida to confirm stability outside of these conditions.

9. PHASE AND COHORT DOSE ADMINISTRATION

This is a Phase 1 open label study. P-CD19CD20-ALLO1 will be administered intravenously as a single dose. Dose levels will be tested by cohort in the 3+3 escalation design described in Section 3.1 of the protocol. You will receive the confirmed cohort assignment on the signed DIA Form (Appendix 1) on or before the start of conditioning chemotherapy.

Per agreement with the FDA, dosing limits will be determined based on TCR+ cells in the cell product, which will not exceed 7.0 x 10^4 TCR+ cells/kg. The TCR+ assay specifications and results will be reflected on the product lot Certificate of Analysis (CofA) for new P-CD19CD20-ALLO1 product lots. Infusion of P-CD19CD20-ALLO1 lots released prior to 15Jan2026 will adhere to the administration of ≤7 x 10^4 CD3+ T cells/kg limit, whereas infusion of P-CD19CD20-ALLO1 lots released on/after 15Jan2026 will adhere to the administration of ≤7.0 x 10^4 TCR+ cells/kg limit. This will be reflected on the DIA forms for each patient along with the respective product lot to be administered.

10. ADMINISTRATION, HANDLING AND DISPOSAL

P-CD19CD20-ALLO1 contains allogeneic human T cells from healthy donors; site staff should utilize universal precautions to prevent transmission of blood borne infections as outlined by the Center for Disease Control and Prevention(http://www.cdc.gov/niosh/topics/bbp/universal.html). Procedures for handling live human cells should be followed per the local institutional policy and process.

Aseptic technique must be followed for all steps involving products for administration to immunocompromised patients.

P-CD19CD20-ALLO1 is administered on Day 0 (per clinical study protocol), two days after the last dose of conditioning chemotherapy.

After a subject is enrolled, an approved P-CD19CD20-ALLO1 DIA Form (Appendix 1) will be sent to the investigative site providing the assigned arm, dose and the total volume of P-CD19CD20-ALLO1 cells to be administered. Confirm that the product, quantity of product and COA received matches the information on the DIA form. You should have enough vials or cryobags to provide at minimum the required total volume for infusion as outlined on the DIA form. If the label(s) on the cryobag(s) received for a subject's infusion indicates the total volume is less than the prescribed dose of P-CD19CD20-ALLO1 (+/- 10%), contact Poseida to determine the next step.

During administration and processing, record all requested information on the P-CD19CD20-ALLO1 Administration Form in Appendix 2.

10.1a General Thawing Instructions for Vials and Cryobags

Record the time removed from the freezer on the P-CD19CD20-ALLO1 Administration Form Appendix 2.

Prior to each infusion, the vials or cryobags containing P-CD19CD20-ALLO1 required for that infusion may be transferred at ≤ -130ºC to the point-of-care and thawed, or thawed and aliquoted into appropriate volumes dictated by the DIA Form in a pharmacy, cell processing lab, or other appropriate facility and transported to the point-of-care at room temperature for immediate infusion. Thawing at the point-of-care is the preferred method. Contact Sponsor if other transport conditions are needed.

10.1b Thawing Instructions for Vials

Whether single or multiple vials are required for the infusion, it is intended that P-CD19CD20-ALLO1 cells be infused within 1 hour of thawing. Vials should be thawed using a water bath at 36° to 38°C, with the vial(s) placed inside a sterile cryobag in case of a leak and to prevent contamination of the vial(s). In case multiple vials are required to be thawed, no more than 2 vials should be thawed simultaneously within one water bath.

Record the water bath temperature on the P-CD19CD20ALLO1 Administration Form Appendix 2**.**

The vials will be submerged in the water bath and gently swirled continuously until the cells have been fully thawed. There must be no frozen clumps left in the vial(s). Vial thaw time will depend on the size and type of water bath used but will generally take 10-20 minutes. If thawing is taking longer than 20 minutes, contact Sponsor to discuss methods for thaw time reduction. If your site experiences longer thaw times with two vials thawed simultaneously, it may be preferable to thaw one vial at a time; please contact Poseida with any questions. If a vial appears to be damaged, leaking or otherwise compromised, do not proceed with the infusion and contact Poseida immediately for guidance.

In case of unforeseen circumstances, thawed vials may be stored at 2° to 8°C for up to 4 hours.

DO NOT maintain the cells outside of 2° to 8°C once thawed.

Record thaw start and end time on P-CD19CD20-ALLO1 Administration Form Appendix 2.

10.1c Thawing Instructions for Cryobags

Each cryobag may be contained in a sealed overwrap pouch. Keeping the protective overwrap pouch on (if provided), the cells should be thawed in the cryobag(s) immediately prior to starting the infusion using a water bath at 36° to 38°C. The cryobag and overwrap pouch are to be placed inside a secondary, sterile cryobag in case of a leak and to prevent contamination of the **second** cryobag. Cells are to be infused immediately upon thawing. If immediate infusion is not possible, thawed cells may be maintained at room temperature for up to 30 min (up to 1 hour) prior to infusion. If multiple cryobags are required for infusion, the first cryobag should be thawed and infused (including saline flush) prior to thawing the second cryobag, and so on.

Record the water bath temperature on the P-CD19CD20-ALLO1 Administration Form Appendix 2.

The thawing process is expected to take approximately 3 to 4 minutes per cryobag. Each cryobag should be fully submerged and gently massaged for 3 minutes. After 3 minutes of full submersion and gentle massage, check for any remaining ice crystals in the cryobag and if needed, place the cryobag back into the water bath for one additional minute and continue gentle massage, recheck the cryobag and, if ice remains, repeat for one more minute before proceeding. Repeat until ice crystals have thawed. There must be no frozen ice crystals left in the cryobag(s). If a cryobag appears to be damaged, leaking or otherwise compromised, do not proceed with the infusion, and contact Poseida immediately for guidance.

In case of unforeseen circumstances, when thawed cells cannot be infused immediately, ideally infuse within 30 min, but thawed cells may be stored at room temperature for up to **1 hour**. Contact Sponsor if cells cannot be infused within 1 hour of thawing.

Record thaw start and end time on P-CD19CD20-ALLO1 Administration Form Appendix 2.

10.2a Preparation of Vials

Prior to each infusion, the vials required for that infusion may be transferred at ≤ -130ºC and thawed, aliquoted into appropriate volumes dictated by the DIA Form in a pharmacy, cell processing lab or other appropriate facility.

Thawed P-CD19CD20-ALLO1 may be transported (in a secondary container such as infusion cryobag or syringe) to the bedside at 2° to 8°C (contact Poseida if other transport conditions or temperatures are needed).

Thawed cell suspension should be removed from AT vials gently by using the provided AT Adapt needle-less device (https://www.aseptictech.com/products/adapttm) and connecting the appropriate syringe to the luer lock tip:

- Gather AT-Closed Vial, syringe and AT-Adapt device
- Remove the flip top

- Remove the protective cover from the AT-Adapt device

- Firmly press the AT-Adapt device on to the AT-Closed Vial to pierce the stopper.

- Lift the AT-Adapt device until the lower tab touches the cap bead

- Remove the protective cover of the luer connection. Attach a syringe to the vial using the luer lock on the AT-Adapt device and withdraw product.
- Video of how to use the AT-ADAPT™ device for the AT-Closed Vial®:

https://www.youtube.com/watch?v=pbwgZVqV2Yk

If the total volume from the number of vials provided exceeds the assigned dose for the subject, draw up and administer only the volume of product corresponding to the assigned dose. If a sufficient number of vials have not been provided for a volume of the product corresponding to the assigned dose for the subject, contact Poseida to determine the next step. The product may be held in storage to combine with a subsequent shipment if it has been maintained at ≤ -130ºC without thawing. Or, upon approval from Poseida, the product may be administered immediately, however the dose for that subject will be recorded as the dose received, not the prescribed or cohort assigned dose, and all data from that subject analyzed accordingly.

10.2b Preparation of Cryobags

The P-CD19CD20-ALLO1 cells will be provided in cryobags at a target concentration of 8 x 10^6 cells/mL (or as otherwise identified on the product label).

Depending on the institution and the volume to be infused, P-CD19CD20-ALLO1 may be administered IV by infusion pump, gravity, or syringe.

A single or multiple cryobag(s) will be supplied containing at least the prescribed dose. The prescribed volume to be administered is located on the DIA Form Appendix 1.

Whether single or multiple cryobag(s) are required for the infusion, it is intended that cells be infused immediately after thawing (thawed cells may be stored at room temperature for up to 1 hour). If multiple cryobags are required, each cryobag should be thawed separately and infused immediately prior to thawing the next cryobag.

For infusion volumes <20 mL, the recommended infusion method is via syringe.

Administration of whole/full cryobag(s) is recommended to be performed by infusion pump or gravity. If a partial cryobag is required for infusion, the required volume should be aliquoted either by removing the appropriate volume from a cryobag such that the total volume of all cryobags to be administered is equal to the prescribed volume, or by drawing a sufficient volume into a syringe for administration from the syringe.

If the label on the cryobag(s) received for a subject's infusion indicates the volume is more than the prescribed dose of P-CD19CD20-ALLO1 (+/- 10%), only a volume of the product corresponding to the assigned dose should be administered.

If the label(s) on the cryobag(s) received for a subject's infusion indicates the total volume is less than the prescribed dose of P-CD19CD20-ALLO1 (+/- 10%), contact Poseida to determine the

next step. The product may be held in storage to combine with a subsequent shipment if it has been maintained at ≤ -130ºC without thawing. Or, upon approval from Poseida, the product may be administered immediately, however the dose for that subject will be recorded as the dose administered, not the prescribed or cohort assigned dose, and all data from that subject will be analyzed accordingly.

10.3 Infusion (Same Instructions for Vials and Cryobags)

Emergency medical equipment (e.g., emergency trolley) should be available during the infusion in case the subject has an allergic response, or severe hypotensive crisis, or any other reaction to the infusion. An intensive care unit should be within a reasonable distance of the investigational drug administration location.

The cells should be administered via an intravenous infusion at a flow rate of approximately 1 to 20 mL per minute through an 18-gauge, latex free, non-filtered Y-type blood product compatible set with a 3-way stopcock as appropriate for the dose and volume.

The duration of the infusion should be approximately 1 to 20 minutes per cryobag, based on the volume. The preferred route of administration is via PICC line, central line, mid-line, or large bore peripheral IV. Use of a port-a-cath is not recommended.

P-CD19CD20-ALLO1 will be administered intravenously by infusion pump, gravity or syringe via non-filtered tubing as follows:

- To minimize variability, the BD alaris pump infusion set (manufacturer number 2426-0007) or the McKesson administration set (manufacturer number SF3258-10H) is recommended, but other equivalent sets may be used if this is unavailable. Please contact Poseida with any sourcing issues or questions.
- For infusion volumes > 20 mL, it is preferred that administration be via infusion pump or gravity. Syringes may be used in exceptional circumstances for volumes ≥20 mL with Medical Monitor approval.
- For infusion volumes ≤20 mL, it is recommended to use an appropriately sized syringe. See Table 1:

Table 1:Recommended Small Volume Syringes based on Dose Volume

Dose Volume	Recommended Syringe Size
>10 mL to < 20 mL	20 mL syringe
>5 mL to ≤ 10 mL	10 mL syringe
>1 mL to ≤ 5 mL	5 mL syringe
>0.5 mL to ≤ 1 mL	1 mL syringe
≤ 0.5 mL	0.5 mL syringe

- Flush venous line with normal saline (no heparin) to keep open.
- Spike P-CD19CD20-ALLO1 product cryobag with non-filtered tubing set with flow regulator (but no clamps) or attach syringe containing P-CD19CD20-ALLO1 cells if delivering via syringe push/pump.
- Prime line carefully to avoid allowing any cells to flow out before connecting to patient venous access. Record the P-CD19CD20-ALLO1 infusion start time on the P-CD19CD20-ALLO1 Administration Form Appendix 2.
- The thawed product should be infused over approximately 1 to 20 minutes per cryobag as appropriate for the volume.
- The cryobag or syringe should be gently agitated during P-CD19CD20-ALLO1 infusion to prevent cell clumping.
- If the entire contents of the cryobag or syringe are infused by gravity, a slow push may be used if necessary.
- Repeat process if multiple cryobags or syringes are necessary to provide the prescribed dose.
- If the entire contents of a cryobag or syringe have been administered, if possible, back flush the cryobag or syringe with normal saline and infuse it while maintaining a closed tubing system to minimize the number of cells unintentionally retained in the cryobag or syringe.
- After the entire dose is infused, the tubing should be flushed at the same infusion rate with at least 20 mL normal saline (no heparin) to ensure all P-CD19CD20-ALLO1 is delivered.
- Record the P-CD19CD20-ALLO1 infusion completion time and the volume delivered on the P-CD19CD20-ALLO1 Administration Form Appendix 2.

Please contact your ICON CRA and CTM or Poseida prior to enrolling subjects if institutional standards are different from those listed above.

10.4 Disposal of Vial(s) and Cryobag(s)

The vial or cryobag label(s) should be copied or photographed for ICON CRA review prior to disposal if institutional SOPs/guidelines allow. Destroy any unused cells according to institutional SOPs/guidelines. Empty vials and cryobags and/or remaining cells should be disposed of per institutional biosafety guidelines and documented in the Investigational Product Destruction Form (Appendix 3). In the event of unused or damaged product/packaging, Poseida should be contacted immediately to determine disposition.

11. QUESTIONS AND CONCERNS

Please contact your ICON CRA and CTM or Poseida prior to enrolling patients if institutional standards are different from those listed above.

Non-emergency study related questions or concerns should be directed to your assigned ICON CRA. Please copy both the ICON and Poseida Clinical Trial Manager.

Questions that are critical or time sensitive may be directed to:

Medical Monitor
Simon Heidegger, MD
Medical Director - Oncology Early Development
+1 650-534-7409
heidegger.simon@gene.com

APPENDIX 1. P-CD19CD20-ALLO1 DOSE INFUSION AUTHORIZATION FORM

Protocol P-CD19CD20-ALLO1-001

P-CD19CD20-ALLO1 Dose Infusion Authorization Form

Subject ID: _____ Product Lot Number: _____

Subject Weight (kg) at Screening: _____ Date of Manufacture: _____

Poseida will perform the calculations below to determine the maximum allowable infusion dose (MAID) required for P-CD19CD20-ALLO1 and provide the completed form to the site.

		Result	Unit
A'	% CAR Expression (results from CofA)		%
B'	Select one of the following: ☐ % TCR+ (results from CofA)[1] ☐ % Residual CD3+ (results from CofA)		%
C'	Maximum allowable CD3+ or TCR+ cells/kg (FDA guidance)	70,000	cells/kg
MAID	Max. Allowable Infusion Dose *(Record result as NNN.NNNN x 10^6)* $\left(\frac{C'XA'}{B'}\right)$		cells/kg

[1] If result of TCR+ assay is < LOQ, the LOQ (0.4%) will be used in this calculation.

Study Arm: _____

Cohort Number: _____ Cohort Dose (A): _____ x 10^6 cells/kg

If Cohort Dose (A) _____ > MAID _____ : **Do not proceed**

If Cohort Dose (A) _____ ≤ MAID _____ : Proceed to table below

Poseida will perform the calculations below to determine the infusion dose required for P-CD19CD20-ALLO1 and provide the completed form to the site.

The investigative site will infuse the Total Volume for Infusion per Line G below.

A completed form, with all signatures, must be received prior to infusing the product into a subject.

		Result	Units
A	Dose in P-CD19CD20-ALLO1 cells/kg (Cohort Dose)		cells/kg
B	Subject Weight (kg)		Kg
C	Total P-CD19CD20-ALLO1 cells required *(Record result as NNN.NNNN x 10^6)* _____ X _____ **A** **B**		cells

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P-CD19CD20-ALLO1 Dose Infusion Authorization Form

D	% CAR Expression (results from CofA)		%
E	Total Cells Required for Infusion [(C÷D) x 100%] *(Record result as NNN.NNNN x 10^6)* _____ ÷ _____ x 100 **C** **D**		cells
F	Viable Cell Concentration (from CofA)		cells/mL
G	Total Volume for Infusion (mL) *(Record results as N.N)* _____ ÷ _____ **E** **F**		mL

Form Prepared by: _____ (Print Name) _____ (Signature) _____ (Date)

Sponsor Medical Monitor Approval: _____ (Print Name) _____ (Signature) _____ (Date)

Sponsor Quality Assurance Approval: _____ (Print Name) _____ (Signature) _____ (Date)

Investigative site personnel should review the calculations presented in the table above.

Dose Preparation/Infusion Personnel Approval: _____ (Signature) _____ (Date)

Investigator Approval: _____ (Signature) _____ (Date)

The completed form should be filed at the site with the subject's source documentation.

APPENDIX 2. P-CD19CD20-ALLO1 ADMINISTRATION FORM

P-CD19CD20-ALLO1-001 PREPARATION AND ADMINISTRATION FORM

Principal Investigator: _____ Subject ID: _____ Date of Administration: _____
(DDMMMYYYY)

Were any of the vials or cryobags damaged during preparation/administration? ☐ Yes ☐ No
If any vials or cryobags are damaged, please contact CGT_PTCB_Logistics-d@gene.com immediately.

Preparation and Administration Reminders:
- *P-CD19CD20-ALLO1 cells should be infused immediately upon thawing if possible.*

P-CD19CD20-ALLO1-001 Preparation

Vial # (Enter N/A for Cryobags)	Lot #	Time Removed from Freezer	Freezer Temp	Water Bath Temp	Thaw		Refrigeration ☐ N/A – product not placed in fridge			Volume Administered	Verified by 2 independent individuals that vial/cryobag label information matches the DIA form	
					Start Time	Stop Time	Start Time	Stop Time	Fridge Temp			
--	--	hh:mm (24 hr)	°C	°C	hh:mm (24 hr)	hh:mm (24 hr)	hh:mm (24 hr)	hh:mm (24 hr)	°C	mL	Initial	Initial

P-CD19CD20-ALLO1-001 PREPARATION AND ADMINISTRATION FORM

***PARTIAL CRYOBAG: If a partial cryobag is returned and a volume of product is to be removed from a cryobag (in Cell Therapy Lab or at point-of-care via dispensing pump), record the volume details below:**

Volume Withdrawn from Cryobag (mL): _____ **Volume Remaining in Cryobag (mL):** _____

How Administered *(partial bag)*: ☐ infusion pump ☐ gravity ☐ syringe

Preparation Personnel			
Printed Name	**Title**	**Signature**	**Date**

P-CD19CD20-ALLO1-001 PREPARATION AND ADMINISTRATION FORM

P-CD19CD20-ALLO1-001 Administration

Infusion Start Time hh:mm (24 hr)	Infusion Stop Time (after cells administered) hh:mm (24 hr)	Infusion Stop Time (after saline flush) hh:mm (24 hr)	Volume Administered (mL)

Check to confirm a filter was not used	☐ no filter used
What method was used for infusion (full bags):	☐ Gravity ☐ Slow Push ☐ Infusion pump
What flow rate was used for the infusion?	
Infusion Set Manufacturer:	
Infusion Set Product Name:	
Infusion Set Serial/Item Number:	
Needle Gauge:	
If any issues were experienced infusing the product, please list below and contact CGT_PTCB_Logistics-d@gene.com and your CRA immediately:	

P-CD19CD20-ALLO1-001 PREPARATION AND ADMINISTRATION FORM

Infusion Personnel			
Printed Name	**Title**	**Signature**	**Date**

APPENDIX 3. INVESTIGATIONAL PRODUCT DESTRUCTION FORM

P-CD19CD20-ALLO1-001 DESTRUCTION FORM

(For Any Used/Empty Vials or Cryobags as well as Unused Product)

Principal Investigator Name:		Site Number:		Subject ID:	

Investigational Product Number	Part Number	Lot Number	Date of Manufacture	Vial Number (Enter N/A for Cryobag lots)
P-CD19CD20-ALLO1				
P-CD19CD20-ALLO1				
P-CD19CD20-ALLO1				
P-CD19CD20-ALLO1				
P-CD19CD20-ALLO1				
P-CD19CD20-ALLO1				
Name and Address of Pharmacy or other designated organization performing destruction:				**Date of Destruction:** _____ Date *(dd-mmm-yyyy)*
This is to certify that all material has been destroyed in accordance with local regulations.				
Company/Pharmacy Representative:	_____ Signature	_____ Print Name	_____ Title	_____ Date *(dd-mmm-yyyy)*

Appendix 4. Transport Dewar Instruction – Receipt / Unloading Of Cryoport Hv3

CRYOPORT EXPRESS® CRYOGENIC HV3 SHIPPING SYSTEM

Shipment Unloading Instructions

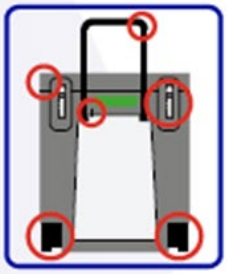
Cryoport Systems

NEED HELP? CONTACT CRYOPORT SYSTEMS' CLIENT CARE AT (949) 470-2305 OR EMAIL CS@CRYOPORT.COM

Step 1

Wear the appropriate Personal Protective Equipment (PPE) when handling cryogenic shipments.

Step 2



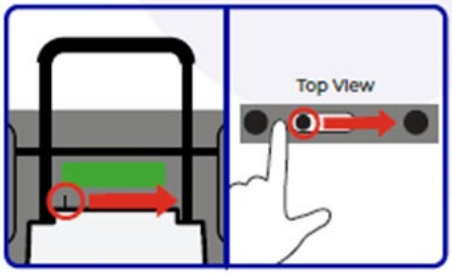
Once the shipping system arrives, check the enclosure and hardware for any damage that may have happened during transit.

NOTE: If you see any damage, please call Cryoport Systems' Client Care at (949) 470-2305.

Step 3

To lift the metal handle, see Step 4. Once the handle is up, hold it, place your foot at the bottom of the metal panel, tilt the shipper back, and use the integrated wheels to move it to the desired location.

Step 4



To unlock the metal handle, use one hand to slide the lever to the right and the other to lift or lower the handle.

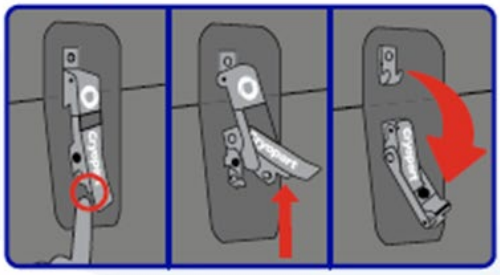
NOTE: If the metal handle is bent or broken, use the nested handles on the sides to move the shipping system.

Step 5

Use scissors to remove zip ties from both steel latches.

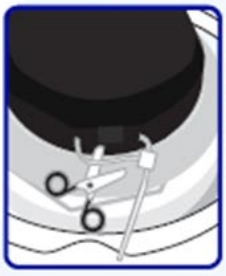
NOTE: If a serialized zip tie is present, record the serialized number on all necessary documentation.

Step 6



To unlock the latches, push the button located behind the latch handle and lift. To disconnect the top, pull the latch away from the hooks.

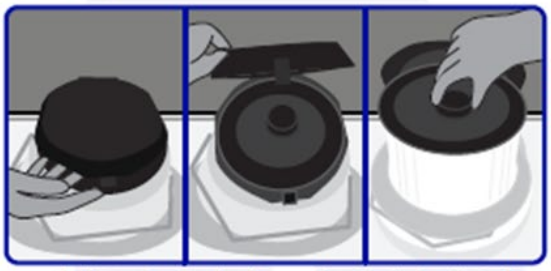
Step 7



To access the dewar, open the lid and cut off the zip tie on the hinged cap with scissors.

NOTE: If a serialized zip tie is present, record the serialized number on all necessary documentation.

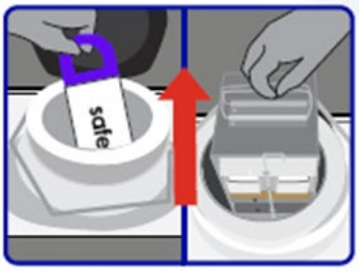
Step 8



NOTE: If the dewar does not emit vapor after the plug is removed, please call Cryoport Systems' Client Care at (949) 470-2305.

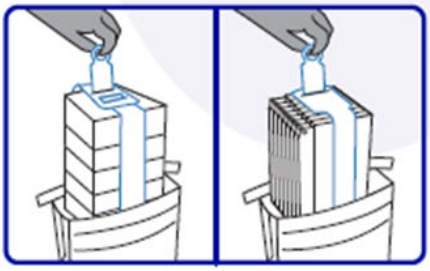
Open the hinged cap and pull up on the circular handle in the center to remove the vapor plug. Set the vapor plug aside, with fleece lining facing up.

Step 9



Slowly lift the packaged commodity out of the dewar by pulling upwards. Remove all secondary packaging.

Step 10 *For Safepak® XL ONLY*



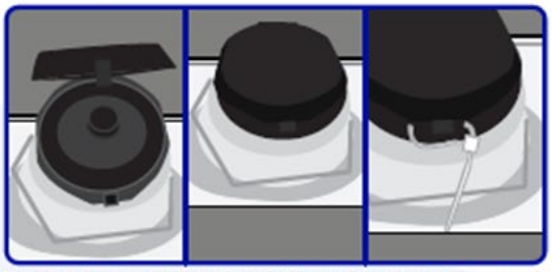
Cut open the top of the Safepak® XL and remove the payload.

Step 11

Place any returnable accessories back into the empty dewar.

NOTE: Please do not place single-use accessories or trash in the empty dewar.

Step 12



Reinsert the vapor plug. Close the hinged cap and secure it with a zip tie.

NOTE: If a serialized zip tie is present, record the serialized number on all necessary documentation.

Step 13

Locate the clear Leg 3 travel pouch in the document compartment. Remove the EMPTY label and place it over the classification label on the metal panel.

Step 14 *For BioServices Shipments ONLY*

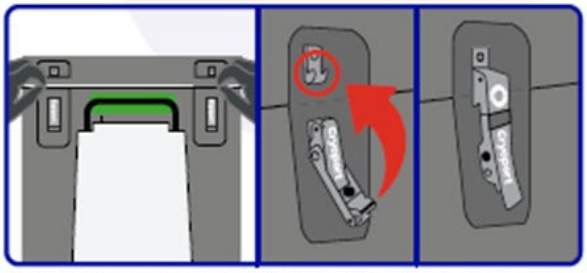
Place the other two (2) EMPTY labels over the BioServices labels on the enclosure and metal panel.

Step 15 *For International Shipments ONLY*

Remove the commercial invoices located in the shipping pouch. Then sign and date.

Return all shipping documents behind the Air Waybill, including any permits, forms, licenses, etc.

Step 16



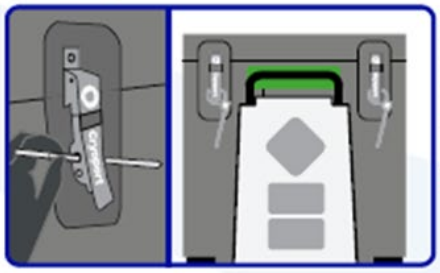
Close the lid and align it with the base. After aligning the enclosure, lift the latch handles and connect them to the hooks. Then, pull the latch handle down towards the enclosure until you hear a click to secure the latch. Complete this step for both latches.

Step 17

Pack the necessary documents into the Leg 3 envelope, with the air waybill on top. Then seal the envelope, remove the sticker backing, and place it on the enclosure's lid placard.

NOTE: Documents will include the air waybill and the QA certification (if necessary).

Step 18



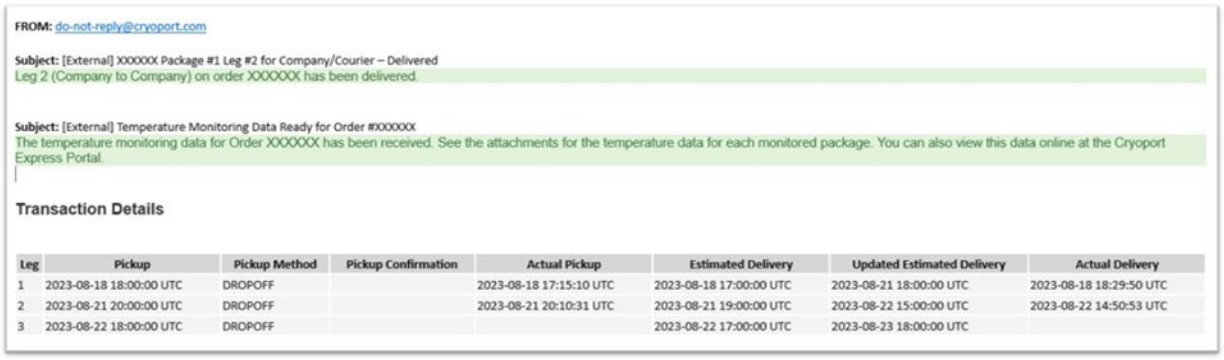
Insert the zip tie from left to right through each metal latch hole, wrap it around each latch, tighten it, and secure the lid.

NOTE: If a serialized zip tie is present, record the serialized number on all necessary documentation.

Step 19

Place the shipping system on flat ground. See Step 4 to lift the metal handle with your hands, then place your foot at the bottom of the metal panel, tilt the shipper back, and use the integrated wheels to move it to the desired location.

Appendix 5. Transport Dewar Instruction – Temperature Information For Cryoport



FROM: do-not-reply@cryoport.com

Subject: [External] XXXXXX Package #1 Leg #2 for Company/Courier – Delivered
Leg 2 (Company to Company) on order XXXXXX has been delivered.

Subject: [External] Temperature Monitoring Data Ready for Order #XXXXXX
The temperature monitoring data for Order XXXXXX has been received. See the attachments for the temperature data for each monitored package. You can also view this data online at the Cryoport Express Portal.

Transaction Details

Leg	Pickup	Pickup Method	Pickup Confirmation	Actual Pickup	Estimated Delivery	Updated Estimated Delivery	Actual Delivery
1	2023-08-18 18:00:00 UTC	DROPOFF		2023-08-18 17:15:10 UTC	2023-08-18 17:00:00 UTC	2023-08-21 18:00:00 UTC	2023-08-18 18:29:50 UTC
2	2023-08-21 20:00:00 UTC	DROPOFF		2023-08-21 20:10:31 UTC	2023-08-21 19:00:00 UTC	2023-08-22 15:00:00 UTC	2023-08-22 14:50:53 UTC
3	2023-08-22 18:00:00 UTC	DROPOFF			2023-08-22 17:00:00 UTC	2023-08-23 18:00:00 UTC	

Internal Temperature report may be obtained by selecting any Live View Link provided in an email.

Appendix 6. Transport Dewar Instruction – Receipt / Unloading Of Dv10

Receiving Dv10 Transport Dewar (Soft Case Exterior)

Section A: Receiving Shipper

Step A1	Retract Handle Push The Handle Button And Push The Top Of The Handle Down Until Fully Retracted. Retracting The Handle Will Ensure Unencumbered Access To The Shipper. 
Step A2	Remove Security Seal (If Applicable) If Using A Security Seal To Prevent The Opening Of The Shipper Lid, Cut And Remove It  Open Shipper Case Lid Once The Security Seal Has Been Removed, Pull Both Zippers Away From Each Other Until The Lid Can Be Opened.

Section B: Unloading Samples

Step B1	<u>Remove Smart Cap From Shipper</u> Carefully Cut And Remove The Security Seal That Attaches The Smart Cap To The Security Loop Around The Dewar Neck. Pull Up With Both Hands To Slide The Smart Cap Out Of The Dewar Neck. Please Note, Proper Placement Of The Dv10 Smart Cap When Not Seated In The Dewar Body Is Probe Side Up. Serious Damage To The Probe May Occur If Placed Otherwise 
Step B2	<u>Remove Extractor From Dv10 Core</u> (If Applicable) Grabbing The Handles Of The General Extractor Wearing Appropriate Protective Equipment, Pull Up Firmly To Remove From The Dv10 Shipper. Unpack And Store Payload According To The Manufacturer's Instructions.

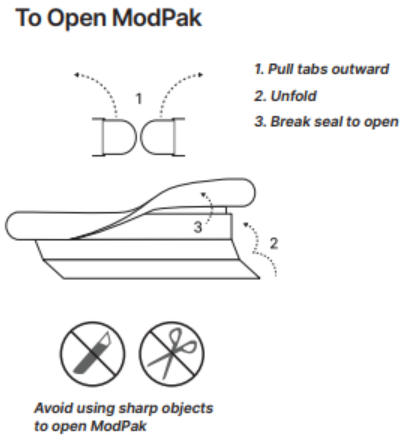
<table>
<tr>
<td></td>
<td>


Place Any Returnable Accessories Back Into The Shipper.
After Lowering The General Extractor Into Dv10 Core, Confirm That The Handle Is Lying Flush With The Top Of The Extractor To Mitigate Damage To The Dv10 Smartcap.

Or

<u>Remove Modpak From Dv10 Core</u> (If Applicable)
Grabbing The Handles Of The Modpak Wearing Appropriate Protective Equipment, Pull Up Firmly To Remove From The Dv10 Shipper.

Unpack And Store Payload According To The Manufacturer’s Instructions.



</td>
</tr>
<tr>
<td>Step B3</td>
<td>
<u>Place Smart Cap Back On Dv10</u>
Firmly Set Smart Cap Into The Neck Of The Dewar To Prevent Damage To The Unit.

<u>Zip Up Lid & Close Outer Box.</u>
Prepare The Dv10 For Return Shipment By Closing The Shipper Outer Pack Lid With The Zipper Closures.
</td>
</tr>
</table>

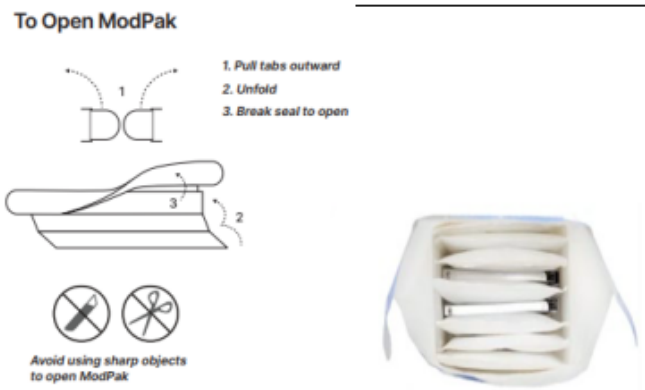
Receiving Dv10 Transport Dewar (Hard Case Exterior)

Section A: Receiving shipper

Step A1	RETRACT HANDLE Push the handle button and push the top of the handle down until fully retracted. Retracting the handle will ensure unencumbered access to the shipper.  
Step A2	REMOVE SECURITY SEAL (if applicable) If using a security seal to prevent the opening of the shipper hatch lid, cut and remove it. OPEN SHIPPER HATCH LID Once the security seal has been removed, turn the security latch counterclockwise. The latch will release, and the top hatch can be opened.    ACCESS DOCUMENT STORAGE You may find documents on the side of the dewar or secured from the hook and loop surface on the interior of the cover. Other documents may be placed in the hard case's exterior document pouch.  

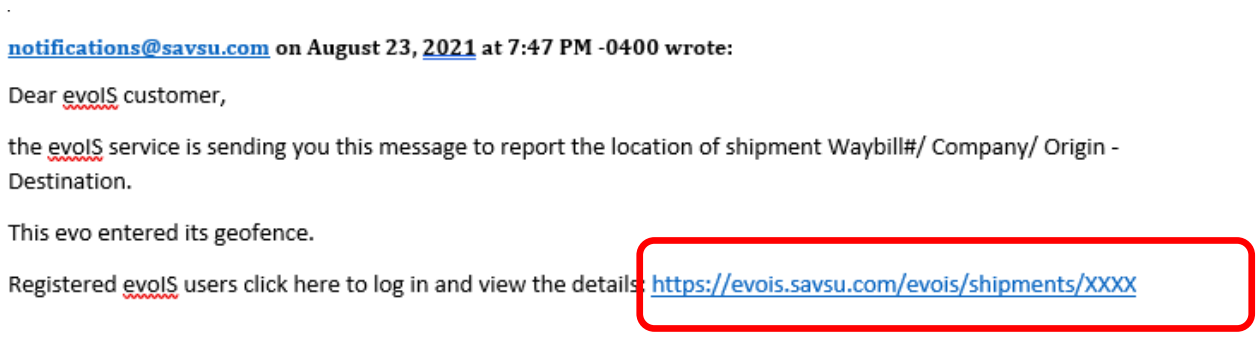
Section B: Unloading Samples

Step B1	REMOVE SMART CAP FROM SHIPPER Using a pair of scissors or wire cutters, carefully cut and remove the security seal that attaches the Smart Cap to the security loop around the dewar neck, if applicable.  Pull up with both hands to slide the Smart Cap out of the dewar neck. **PLEASE NOTE, proper placement of the DV10 Smart Cap when not seated in the dewar body is PROBE SIDE UP. Serious damage to the probe may occur if placed otherwise.** 
Step B2	REMOVE THE PACK-OUT SYSTEM (MODPAK) FROM DV10 CORE Grabbing the handles of the ModPak, wearing appropriate protective equipment, pull up firmly to remove from the DV10 shipper.   Unpack and store payload according to the Sponsor's instructions.

	
Step B3	PLACE SMART CAP BACK ON DV10 Firmly set Smart Cap into the neck of the Dewar to prevent damage to the unit.  CLOSE THE HATCH LID Prepare the DV10 for return shipment by closing the shipper's outer hatch lid  MOVING AND HANDLING If you need to move the case, place the retractable handle in the short-locked position by extending the handle all the way up and then lowering it back to the locked position. To avoid damage, keep the handle in a retracted position when it is not in use.

Appendix 7. Transport Dewar Instruction – Temperature Information For Dv10

Internal Temperature May Be Obtained Through The E-Mail That Was Provided During Transport / Delivery.



notifications@savsu.com on August 23, 2021 at 7:47 PM -0400 wrote:

Dear evoIS customer,

the evoIS service is sending you this message to report the location of shipment Waybill#/ Company/ Origin - Destination.

This evo entered its geofence.

Registered evoIS users click here to log in and view the details: https://evois.savsu.com/evois/shipments/XXXX

Evois Non-Registered Users Could Be Provided With External Link For Monitoring.

Appendix 8. Allogeneic Product Shipment And Receipt Record

PART 1. Shipment Record			
Section 1. Logistics to complete clinical site identification.			
Protocol:		**Principal Investigator:** First Name Last Name	
Site ID:		**Expected Product Receipt Date:** DD / MMM / YYYY	
Completed By:	**Print:**	**Sign:**	**Date:**
Section 2. Logistics to complete shipment information.			
Shipment Courier:		**Courier Bill of Lading #:**	
Product:	**Product Packaging:** ☐ Vial ☐ Bag	**Number of Units to be Shipped:**	**Lot/Batch Number:**
Ship From (Name and Address): ☐ Manufacturing Site ☐ Storage Depot ☐ Other		**Ship To (Name and Address):** ☐ Clinical Site ☐ Storage Depot ☐ Other	
Institution Name: **Address:** **City/State/Zip code/Country:** **Contact:** **Tel/E-mail:**		**Institution Name:** **Address:** **City/State/Zip code/Country:** **Delivery Contact:** **Tel/E-mail:**	
Completed By:	**Print:**	**Sign:**	**Date:**
Section 3. Shipper to complete final product manufacturing and pack-out information. ****Contact Logistics for any issues or concerns before shipment arrives.****			
Number of Units Packed:	**Part #:**		**Lot/Batch #:**
Unit(s) ID #: ☐ N/A (not on label)	**Mfg Date:** DD / MMM /YYYY		**Shelf life verified:** ☐Yes ☐N/A (Mock)
Pack-Out Date: DD / MMM /YYYY	**Pack-Out Time** : 24-hour clock		**Time Zone:** ☐Pacific ☐Mountain ☐Central ☐Eastern ☐Other:
LN_2 Shipper #:	**Data Logger Serial #:**		**Serialized Tag #:**
Completed By:	**Print:**	**Sign:**	**Date:**
Verified By:	**Print:**	**Sign:**	**Date:**

PART 2. Receipt Record		
Section 4. Receiving site to complete final product receipt information upon delivery to Pharmacy or Designated Facility.		
Has the LN_2 shipper arrived in good condition?		☐Yes ☐No
Date of Receipt of LN2 shipper: _____ DD / MMM /YYYY	Time of Receipt: ____ : ____ 24-hour clock	Time Zone: ☐Pacific ☐Mountain ☐Central ☐Eastern ☐Other: ____
Record shipper temperature at arrival _____°C	Serialized Tag #: _____	
After reviewing the temperature log, has the LN2 shipper maintained the required temperature range during transport?		☐Yes ☐No
Number of Units Received: _____	Lot/Batch #: _____	Unit(s) ID#: _____ ☐ N/A (not on label)
After inspection, is the drug product received in good condition?		☐Yes ☐No
Has the transfer of drug product into the vapor phase nitrogen freezer occurred?		☐Yes ☐No
Date of Transfer into vapor phase nitrogen freezer: _____ DD / MMM /YYYY	Time of transfer ____ : ____ 24-hour clock	Time Zone: ☐Pacific ☐Mountain ☐Central ☐Eastern ☐Other: ____
If the answer is "No" to any of the questions in Section 4, please list the issues below and contact CRO (assigned CRA) and Sponsor immediately.		
Completed By:	Print Name: Sign:	Date:

Please scan and return completed form to Logistics at logistics@poseida.com upon receipt.