BCMA CAR-T Cell Therapy Product Procedures Manual (CTPPM) Training for NA (North America)

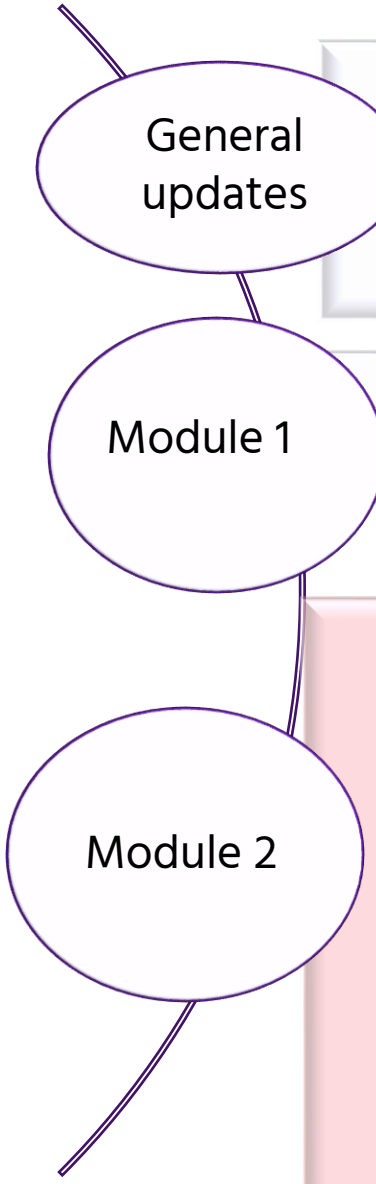
Material Version: 6.0

Based on CTPPM V6.0, 25-FEB-2025

Region: NA-North America

Johnson&Johnson

Summary of changes from v5.0 to v6.0



- Clarifications CTPPM training requirements
- Important note for the local teams related to the use of the correct version of the COC/I Forms
- Removal of COC/COI regional form prefix

- Clarification that the study coordinator is typically responsible for the CQUENCE Subject Slot Management and to share the IRT Screening Notification with the Collection Staff

- Updated with the new COC/COI Form wording and visuals including the new IDM related questions
- Clarification of the Collection Staff responsibility to share the apheresis bag label information with the Study Coordinator
- Note added that accent marks are not allowed for DIN/Apheresis ID/SEC-DIS
- Applicable for EEA: Note added that if the SEC-DIS number is created by the cell lab, the SEC-DIS should be entered in IRT (not only the DIN)
- Clarification added to strip the tubing and return to original shape prior to sealing
- Based upon current practice the note was removed related to leaving 1 sampling bulb attached when sending the collection to CPC, not applicable anymore
- Clarifications related to special situations added
- Note related to subject middle name removed. The IP Label will only include First and Last Name of the subject. Middle name or initial even when included on IRT or collection label will not be used for the final product

Summary of changes from v5.0 to v6.0

Module 3

- Shipper picture updated
- Updated visual of the APH-TRN Form reflecting the question related to the apheresis transfer.
Removal of COC/COI regional form prefix and screenshot of the APH-TRN Form updated

Module 4

- Overview of the on-site cryopreservation steps was removed
- Instructions added related to the temperature check prior to packing the cells into LN2 shipper

Module 5

- Clarification added that the study coordinator is typically responsible to share information entered in IRT with the shipping staff prior to packaging/shipping.

Summary of changes from v5.0 to v6.0

Module 6

- Info added related to the link issued by the courier via email enabling the site to review the temperature data for the IP shipment
- Study Coordinator responsibility added to share the IP Lot# entered in IRT by manufacturer with the Cell Lab
- Certificate of Compliance or CAR-T Final Release Form was replaced by CAR-T Final Release Documentation.
- TIB wording updated, QR code instructions removed.
- Instructions added to always consult the full temperature report (ex: EVO IS Temperature report) via a link received by the courier.
- Instructions and a visual included on how to review the LN2 Shipper Temperature Report.
- Instructions updated on how to report a transit and on-site storage TOR

Clarifications related to Transport of Thawed IP added

Module 7

NA

Module 8

- Removal of COC/COI regional form prefix and addition of form versions
- Removal of 2 study/region specific memo's *(For UK: Donor screening requirements for apheresis material to be cryopreserved by Anthony Nolan, Cryopreservation Center (UK CPC); CLARIFICATION for J&J Innovative Medicine Cell Therapy Product Procedures Manual (CTPPM) Section 6.7 'Problems and Special Situations': Temperature Out of Range (TOR) Events)*

Summary of changes - COC/COI Forms

- The following content changes were done:
  - **APH-TRN (TV-eFRM-10456)**
    - Question 7 format changed to answer YES
    - Section 2 was updated to include the release by and received by wording
    - Reduced the number of times the site staff has to initials/date
  - **SHIP_APH (TV-eFRM-10455)**
    - Reduced the number of times the site staff has to initials/date
  - **REC (TV-eFRM-10449)**
    - Content changes
- COC/COI forms have been updated to delete the prefix related to the region

CTPPM v5.0

CoC/CoI Form Number	Form Description	Form Name
TV-eFRM-10456	Apheresis Chain of Custody/Chain of Identity Form	NA_APH-TRN
TV-eFRM-10455	Site Shipment Form for Chain of Custody/Chain of Identity	NA_SHIP_APH
TV-eFRM-10449	IP Shipment Receipt Checklist or Site	NA_REC

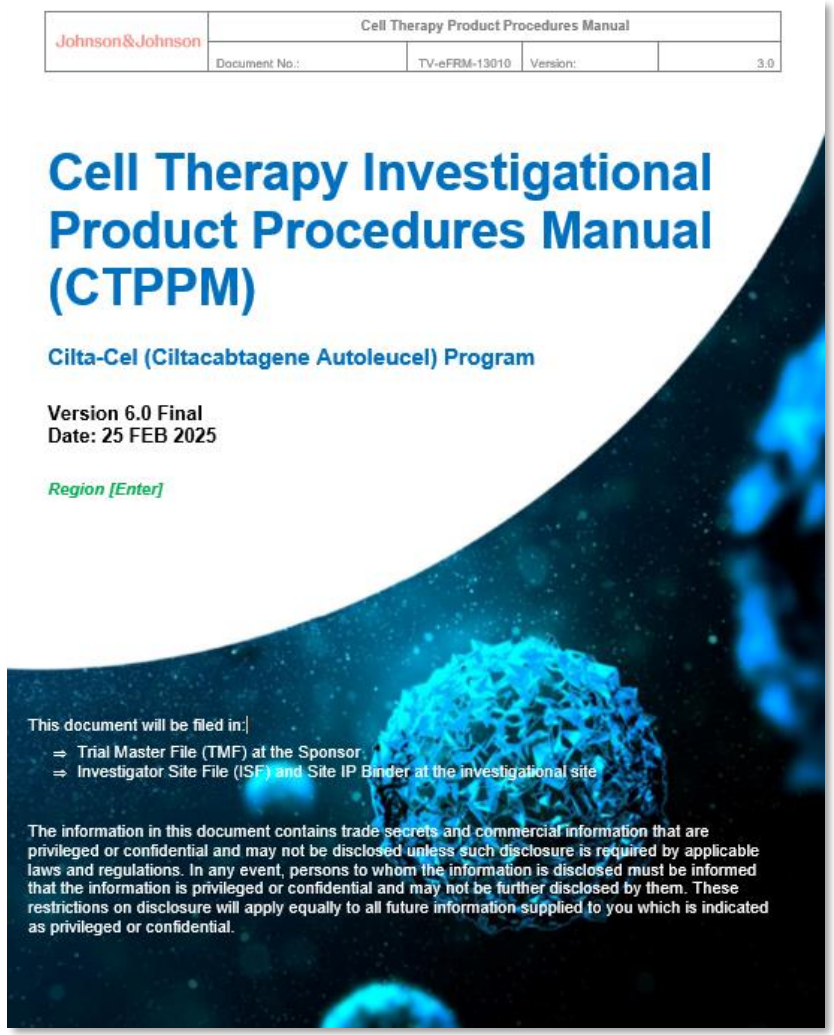
CTPPM v6.0

CoC/CoI Form Number	Form Description	Form Name
TV-eFRM-10456	Apheresis Chain of Custody/Chain of Identity Form	**APH-TRN**
TV-eFRM-10455	Site Shipment Form for Chain of Custody/Chain of Identity	**SHIP_APH**
TV-eFRM-10449	IP Shipment Receipt Checklist or Site	**REC**

Modules

Cell Therapy Product Procedures Manual (CTPPM) provides instructions to investigational site personnel on the Sponsor's requirements and Instructions for the following:

Module	Overview
1 - Pre-collection	Provides details on the manufacturing slot approval process
2 - Apheresis & Cell Management	Covers all cell collection and labelling activities
3 - Cell Transfer (Applicable when packing is completed at cell lab)	Includes cell collection transfer to clinical site cell lab/shipment facility
4 - Cryopreservation Procedure	Includes the process for sites that will perform the on-site cryopreservation process
5 - Packing and Shipment	Provides instructions for packing and shipping apheresis material to the Central Cryopreservation Centre
6 - Receipt and Storage of Investigational Product (IP)	Includes receipt, handling & storage of IP Problems and Special Situations e.g. TOR events, Quarantine, Damaged/Lost IP and Product Quality Complaints
7 - Returns and Destruction	Includes process of IP return and destruction
8 - CoC/CoI Maps & Forms	Includes all chain of custody and chain of identity maps, forms and summary of documents. Study/Region specific attachments.



Instructions for Site Staff: CTPPM Training Requirements

All site staff should complete the relevant CTPPM training needed in order to effectively carry out their role in the study. Please see table below to determine which modules/slides are required for your role/delegated task and should be the primary focus of your CTPPM training.

Role/delegated task* in this study (as applicable)	Focused sections/slides required for your role/delegated task
Site staff delegated to Tasks: • **Manage Slot Reservation Process**	Module 1: Pre-Collection
Site staff delegated to Tasks: • **Manage Apheresis and Cell Collection**	Module 2: Apheresis and Cell Management Module 3: Cell Transfer (if applicable)
Site staff delegated to Tasks: • **Packaging, labelling and/or Shipping of Apheresis Product**	Module 5: Packaging and Shipment
Site staff delegated to Tasks: • **Manage Cell Therapy Investigational Product Receipt, Storage, Temperature Monitoring, Return, On-Site IP Destruction**	Module 6: Receipt and Storage of IP Module 7: Return and On-Site IP Destruction
Site staff delegated to Tasks: • **Manage Chain of Custody/Chain of Identity**	Module 8: COC/COI Maps and Forms
Site staff delegated to Tasks: • **Manage the On-Site Cryopreservation**	Module 4: Cryopreservation Procedure
Other Support Staff or Study Specific Tasks	As assigned by PI

** Exact delegation log tasks may vary for your study.*

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Expectations

Training

- This presentation contains ***selected highlights***, please ensure relevant site staff read and understand the latest version of the **entire CTPPM**.
- Instructions provided in CTPPM must be followed precisely.
- Any **deviations must be documented and reported** to the Site Manager.

Records

- Records shall be stored securely so that they can be accurately, completely, and consistently accessed in a timely manner.
- In compliance with the record retention period and terms outlined in agreements with Sponsor / Manufacturer.
- In compliance with regulatory requirements

CTPPM Scope

- **Cellular product: From Slot Reservation until IP Receipt & Storage**
- ***Exclusions:***
  - Refer to JNJ-68284528 IP Preparation and Administration Instructions (**IPPI**) for Dispensing, preparation, administration
  - **Comparator** drugs

COC/COI Overview

Chain of Identity (COI)

- For autologous cells: COI ensures collection of apheresis material used in investigational product (IP) manufacturing is administered back to the same subject.
- **Throughout the COI process for each subject, J&J will track 2 unique identifying elements at each step**

1 **Donation Identification Number/ID No. (DIN)/ Single European Code (SEC-DIS)/ Apheresis ID** assigned to the product at point of collection by the investigational site

2 **Subject Number** assigned to the subject by the investigational site via IRT*

Chain of Custody (COC)

- COC is the permanent data capture that identifies the staff who handles the cell product from the start of cell collection through to product administration.

Managed by J&J Clinical Supply Chain (CSC)

coordinated using a paper-based system

*IRT= Interactive Response Technology

Before getting started

Materials required onsite:

- COC/COI Forms
- Wire cutter
- Bulk Label supplies binder

System accesses:

- IRT
- MBOX
- CQUENCE
- Additional study specific requirement

Module 1: Pre-Collection

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Subject Slot Management - Study Coordinator

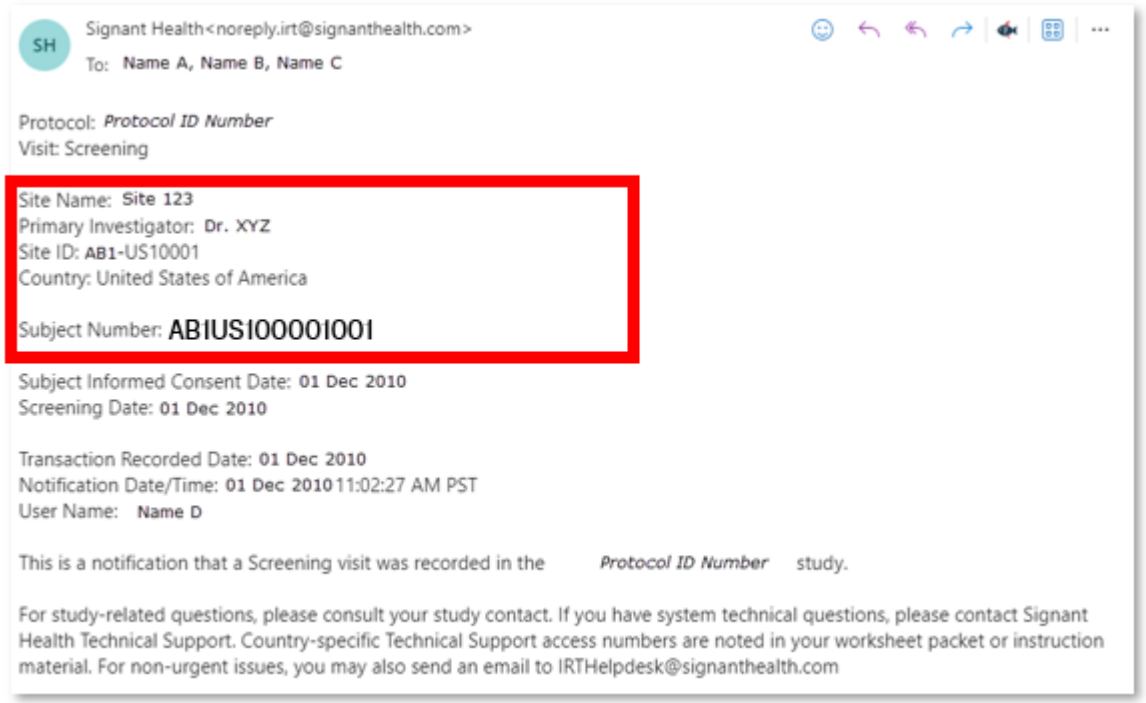
- **Sponsor approval of slot is required for each potential patient prior to consenting**
- CQUENCE is the web-based subject management system used to track and view the Subject Treatment Journey of a Clinical Trial subject, from slot assignment to investigational product infusion.
- CQUENCE is important to the CTPPM process for:
  - **Booking Slots**
  - **Managing Apheresis Dates**
  - **Booking IP on Site Dates**
  - **Providing an overview of the complete CAR-T patient journey**
- Specific steps that need to be completed via CQUENCE are mentioned throughout the CTPPM

If apheresis date is re-scheduled after slot approval, please notify Central Scheduling (Central.Scheduling@ITS.JNJ.com)

Responsibility #1: The Study Coordinator shares the IRT Screening Notification with the Collection Staff

- The Study Coordinator must share the IRT Screening Notification with the collection staff prior to the collection
- Why? The collection staff needs the study specific information indicated on the IRT Screening Notification for COC/I form completion

Example of an IRT Screening Notification Email (Signant Health)



Signant Health<noreply.irt@signanthealth.com>
To: Name A, Name B, Name C

Protocol: *Protocol ID Number*
Visit: Screening

Site Name: Site 123
Primary Investigator: Dr. XYZ
Site ID: AB1-US10001
Country: United States of America

Subject Number: AB1US10000I001

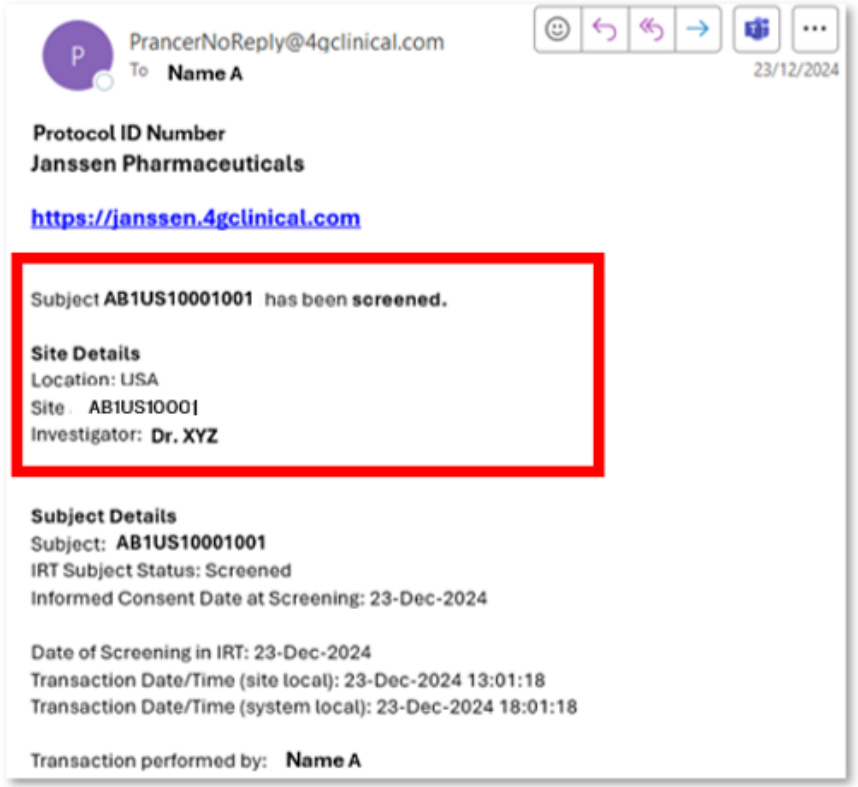
Subject Informed Consent Date: 01 Dec 2010
Screening Date: 01 Dec 2010

Transaction Recorded Date: 01 Dec 2010
Notification Date/Time: 01 Dec 2010 11:02:27 AM PST
User Name: Name D

This is a notification that a Screening visit was recorded in the *Protocol ID Number* study.

For study-related questions, please consult your study contact. If you have system technical questions, please contact Signant Health Technical Support. Country-specific Technical Support access numbers are noted in your worksheet packet or instruction material. For non-urgent issues, you may also send an email to IRTHelpdesk@signanthealth.com

Example of an IRT Screening Notification Email (4G)



PrancerNoReply@4qclinical.com
To Name A
23/12/2024

Protocol ID Number
Janssen Pharmaceuticals

https://janssen.4gclinical.com

Subject **AB1US10001001** has been **screened.**

Site Details
Location: USA
Site AB1US10001
Investigator: **Dr. XYZ**

Subject Details
Subject: **AB1US10001001**
IRT Subject Status: Screened
Informed Consent Date at Screening: 23-Dec-2024

Date of Screening in IRT: 23-Dec-2024
Transaction Date/Time (site local): 23-Dec-2024 13:01:18
Transaction Date/Time (system local): 23-Dec-2024 18:01:18

Transaction performed by: **Name A**

Module 2: Apheresis & Cell Management

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Infectious Disease Marker (IDM) Results

Manufacturing requires that the clinical site confirms they followed local rules and regulations regarding IDM testing:

- For regions where IDM testing **is a requirement** by local rules and regulations, confirm testing was performed by checking **YES**
- For regions where IDM testing **is not a requirement**, confirm that the site followed local rules and regulations regarding IDM testing by checking **YES**

Mark the question in the COC/I form as follow:

APH_TRN Form

7. The site confirms they followed local rules and regulations regarding IDM testing	Yes ☑

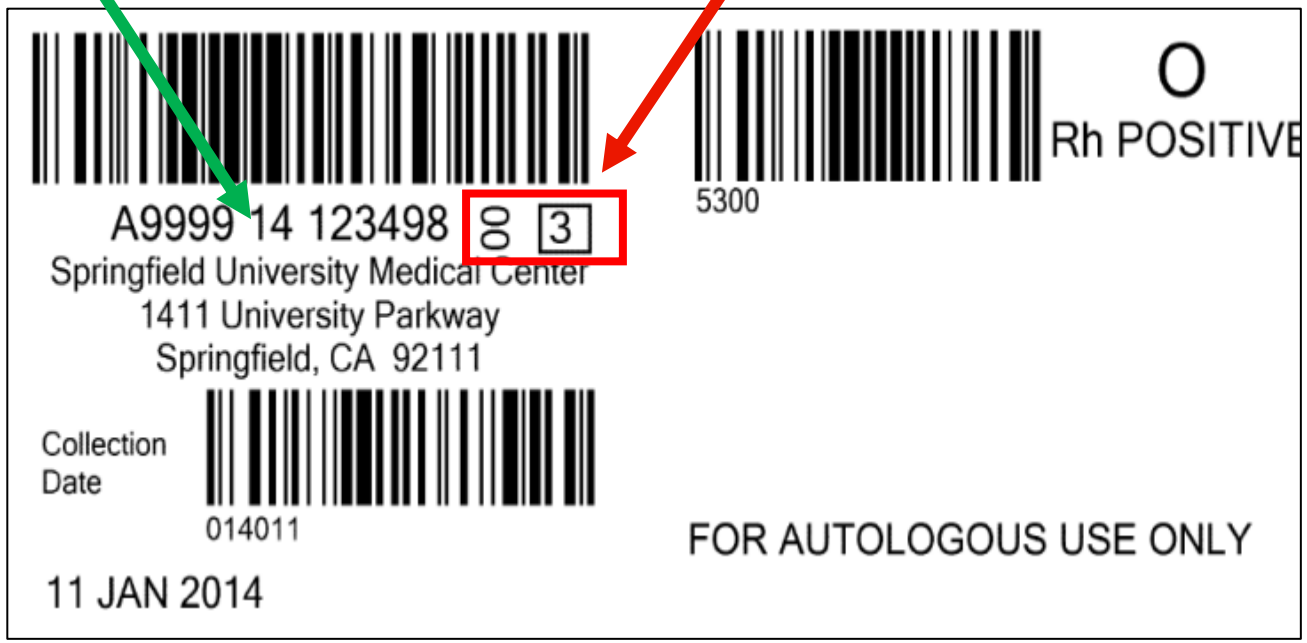
IDM testing results, if performed, **MUST** be kept by the clinical site and be readily available if requested by J&J during an inspection/audit. The records are kept as per Quality Agreement Terms.

Responsibility #2: Collection staff shares the Apheresis Site Bag Label information with the Study Coordinator

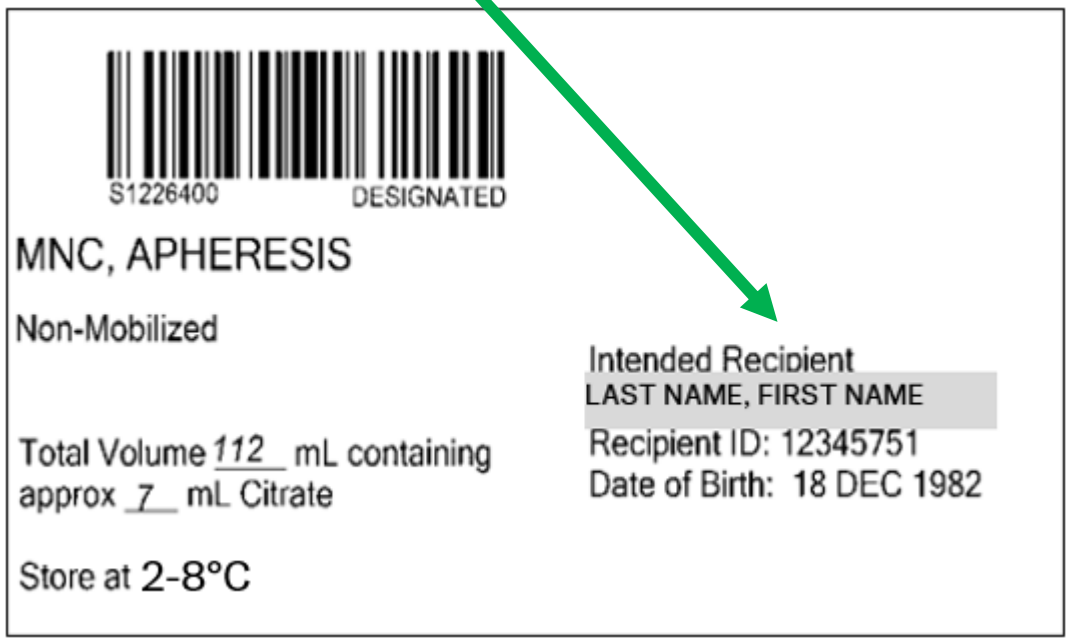
- **Collection staff** must share the Apheresis Site Bag Label Information (see pictures below) with the **Study Coordinator** as soon as it is available on the day of collection
- Why? This information from the Apheresis Site Bag Label **must match** the information entered on the IRT system.

Unique Identifier **Do NOT Include the Flag Characters**

NOTE: Accent marks are not allowed. (e.g., Ř, Í, Á, Š)



Subject's Name and DOB



Critical steps: IRT system

IRT Transactions

- **On the day of Apheresis collection** - the following information must be entered on the IRT system as soon as the information is available **(preferably in the morning)**:
  - Subject's full name
  - DIN or SEC-DIS or Apheresis ID (to match the collection label)
    Note that accent marks are not allowed (e.g., Ř, Í, Á, Š)
  - Patient's weight

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Site Apheresis bag Label: Minimum requirements

- **Type of collection**: MNC, Apheresis
- **Subject Full Name** (incl. middle name or initial as documented in medical records)
- **Date of Birth**
- **Unique identifier** for apheresis collection (DIN or Apheresis ID or SEC-DIS, as applicable per region)
- **Date and time** of apheresis end of collection (incl. time zone)
- **Volume of apheresis** collection
- **Volume of anti-coagulant** in the collection bag
- **Storage temperature**: 2-8°C
- **Warnings** as per local regulations
- If expiration is documented on label → **32 hours** from end of collection time as per JNJ stability requirement

Apheresis Collection Label Example

Example of Site Apheresis bag label

Ensure that any required **warnings** are applied per local standards & regulations

Expiry: 32hrs from end of collection

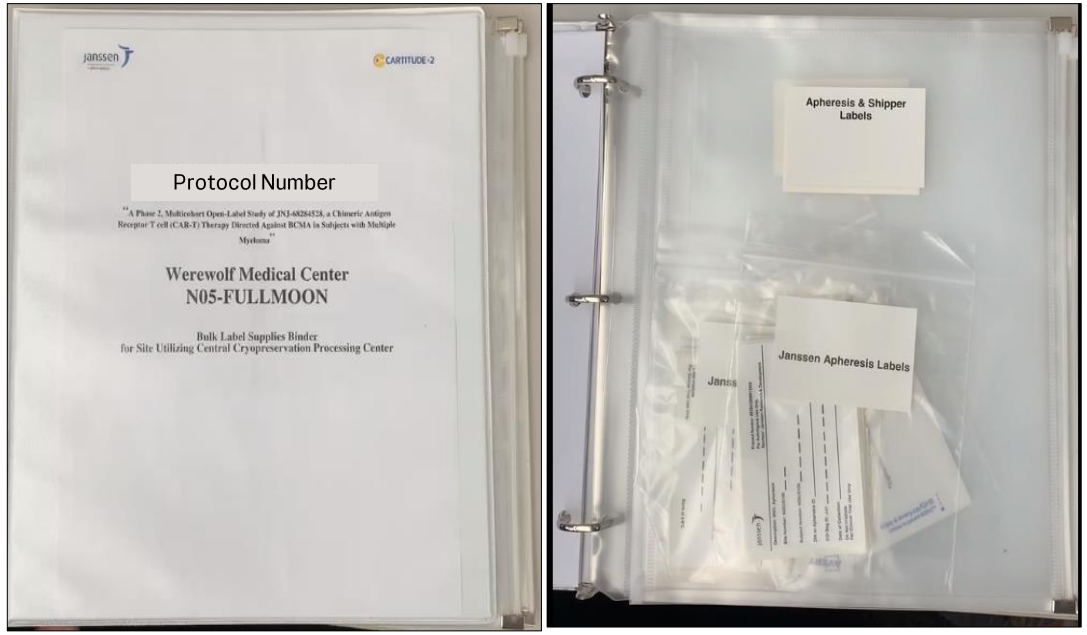
Storage temperature 2-8^{0}C

Example of Sponsor Apheresis Label

Sponsor provided Labels

Bulk Label Supplies Binder contains:

- Sponsor Apheresis Label
- Shipper Label
- Self-laminating cards
- Zip ties (to attach laminating card to apheresis bag)



Resupply lead time = 3 weeks

Labels containing study specific identifiers should be used ***in conjunction with clinical site generated labels.***

Sponsor Labels

Sponsor Apheresis Label:

janssen

Protocol Number: 68284528MMY3004
For Autologous Use Only
Sponsor: Janssen Research & Development

Description: MNC, Apheresis

Site Number: V47 _ _ _ _ _ _ _

Subject Number: V47 _ _ _ _ _ _ _ _ _ _

DIN or Apheresis ID: _____

Date of Collection: _____

Do Not Irradiate
For Clinical Trial Use Only

Store at 2-8°C

Sites should complete the following information on the Sponsor Apheresis label:

- Site IRT Number
- Subject IRT Number
- DIN or Apheresis ID
- Date of collection

Note: If there is a COI Bag ID / COI – Mark as 'N/A' and strikethrough the COI and COI Bag ID fields on the labels, then initial and date)

Attach to apheresis collection bag with self-laminating card & hang tie

Shipper Label:

janssen

SHIPPER LABEL

Protocol Number: 68284528MMY3004
For Autologous Use Only
Sponsor: Janssen Research & Development

Description: MNC, Apheresis

Site Number: V47 _ _ _ _ _ _ _

Subject Number: V47 _ _ _ _ _ _ _ _ _ _

DIN or Apheresis ID: _____

Do Not Irradiate
For Clinical Trial Use Only

Store at 2-8°C

Sites should complete the following information on the Shipper label:

- Site IRT Number
- Subject IRT Number
- DIN or Apheresis ID

Place the shipper label on outer packaging of CREDO CUBE (see Module 5)

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Cell Collection

- **Required for apheresis collection:**
  - MNC, Apheresis collection target is **9 x 10^9 Total white blood cells (WBCs) aka Total Nucleated Cells (TNC),** containing a high % of MNC.
    - Acceptable range: 6 to 12 x 10^9 Total WBCs.
    - Approximately 9-12 L of whole blood should be processed.
  - Strip the tubing and return to original shape prior to sealing.
  - Leave a **minimum of 15 cm (6 inches)** of tubing when sealing off the apheresis bag from the collection kit. Use the **three welds** technique.
  - The apheresis material must be transferred and placed into a 2-8^{0}C shipper **within 60 minutes** of the collection end time.
  - NOTE: Plasma addition is not required.

- **Recommended guidelines for end-of-apheresis collection:**
  - **Perform a WBC count at the midpoint** of the collection to ensure the target cell number 9 x 10^9 Total WBCs (TNC) is reached, to minimize patient apheresis collection time (if applicable).

Special Situations

Discovery of Positive IDM post-apheresis

- If a positive/reactive IDM result is discovered post donation:
  - The clinical staff is responsible for communication of this result with **J&J per quality agreement terms**.
  - Also, inform the SM.

Multiple collections on the same day

- If unexpected issues on the day of collection lead to the apheresis collection being stopped & a new collection being initiated on the same day:
  - J&J approval to send both apheresis material collection bags is required.
  - **Contact J&J for support (Central.Scheduling@ITS.JNJ.com) and SM.**
  - Each apheresis collection will have its own unique identifier (DIN / Apheresis ID / SEC-DIS).
  - Each apheresis collection will have its own transaction in IRT and own COC/I Form.

Repeat apheresis

- If the minimum total WBCs is not collected on the first attempt:
  - The sponsor **may request** a second collection.
  - Product bags from multiple collections will not be combined.
  - Each apheresis collection should be performed with the goal of achieving 9 x 10^9 Total WBC target.

Critical steps: IRT system

IRT Data

- **Subject name must match** the name on the collection label

Note: Investigational Product (IP) Label may only include First and Last Name of the subject. Middle name or initial even when included on IRT or collection label may not be used for the final product.

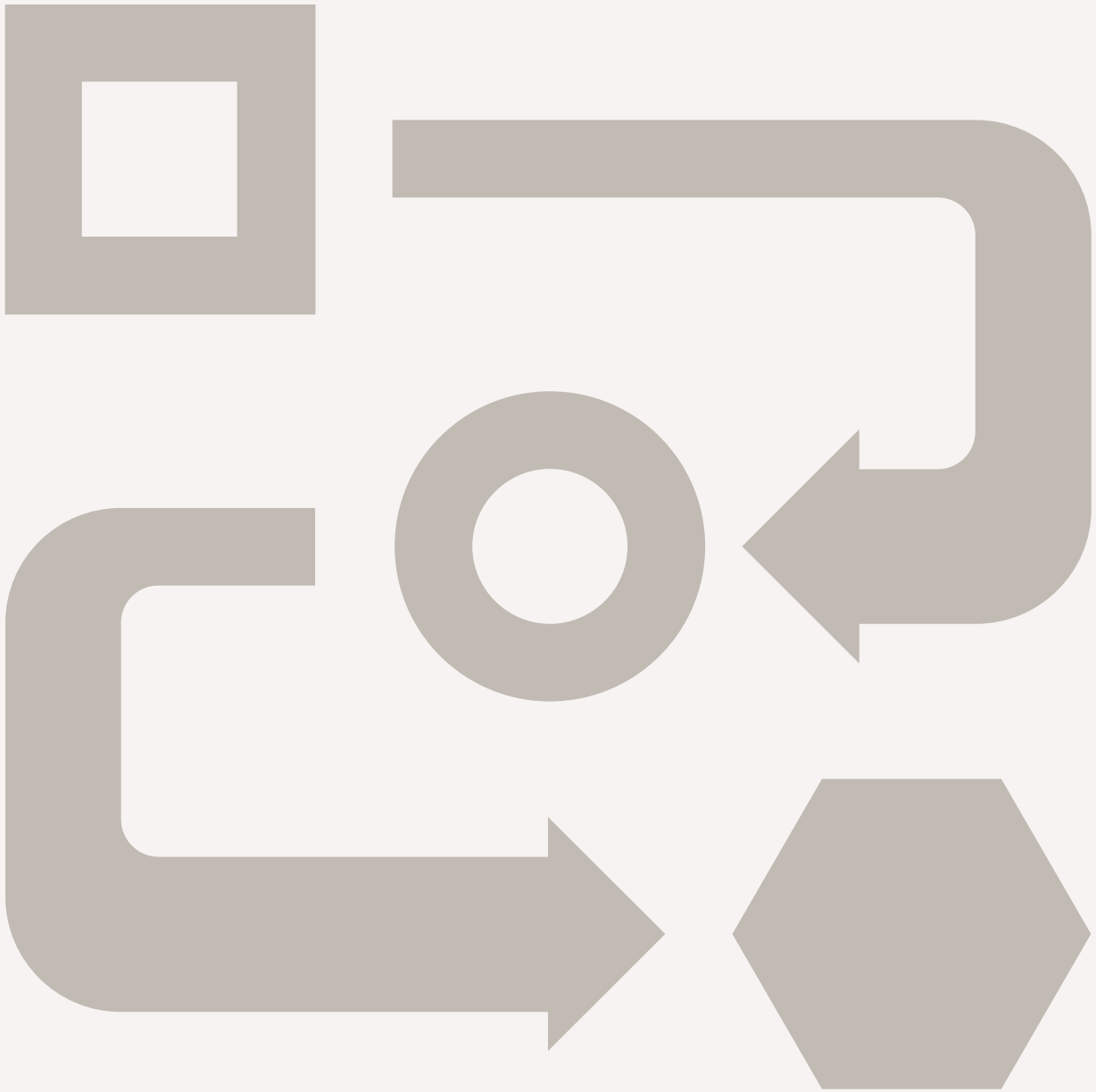
- **Subject Weight**
  - MUST be consistent with source data on day of apheresis
  - MUST be weight (in kg) on day of the apheresis
  - Should be rounded to **one (1) decimal point (ex. 85.0kg)**
- **Data** must be **double checked** for accuracy matching source document.

If you identify an error in any of the COC/COI (Name, DOB, SEC-DIS/DIN/apheresis ID) or weight information entered in IRT – please notify your CSOM and SM immediately

Refer to: Interactive Response Technology (IRT) System Site User Instruction Manual

Module 3: Cell Transfer

(only applicable to sites who perform transfer of apheresis material from collection location to be packed at a different location)



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Module 3: Transfer of apheresis material to Cell Processing Lab

- This module applies to sites that transfer the collected apheresis material to the site's cell processing lab or to another facility for subsequent packing and shipment to the cryopreservation center.
- Apheresis material must be:
  - Transferred and placed into the 2-8°C Credo Cube within one hour (60 minutes) of the end of collection time.
  - If more time is required, store the apheresis product in a monitored refrigerator or intermediary transport at 2-8^{0}C until the time of shipment occurs.
  - Chain of Custody transfer will be documented in **APH-TRN** COC/COI form

Section 2: Transfer of Apheresis Material

1. Confirm if a transfer of the apheresis material is needed. Yes ☐ N/A ☐

If yes, enter Date and Time (24h clock) collection staff released custody of apheresis material to the cell Laboratory or shipping facility:

D D - M M M - Y Y Y Y Time: _____ Time Zone: _____

Released By:	Name (printed):	Signature: D D - M M M - Y Y Y Y
Received By:	Name (printed):	Signature: D D - M M M - Y Y Y Y

If transfer to another location is not required, check N/A on this section

Module 4: Cryopreservation

(only applicable to sites who perform on-site cryopreservation)

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Sponsor Labels

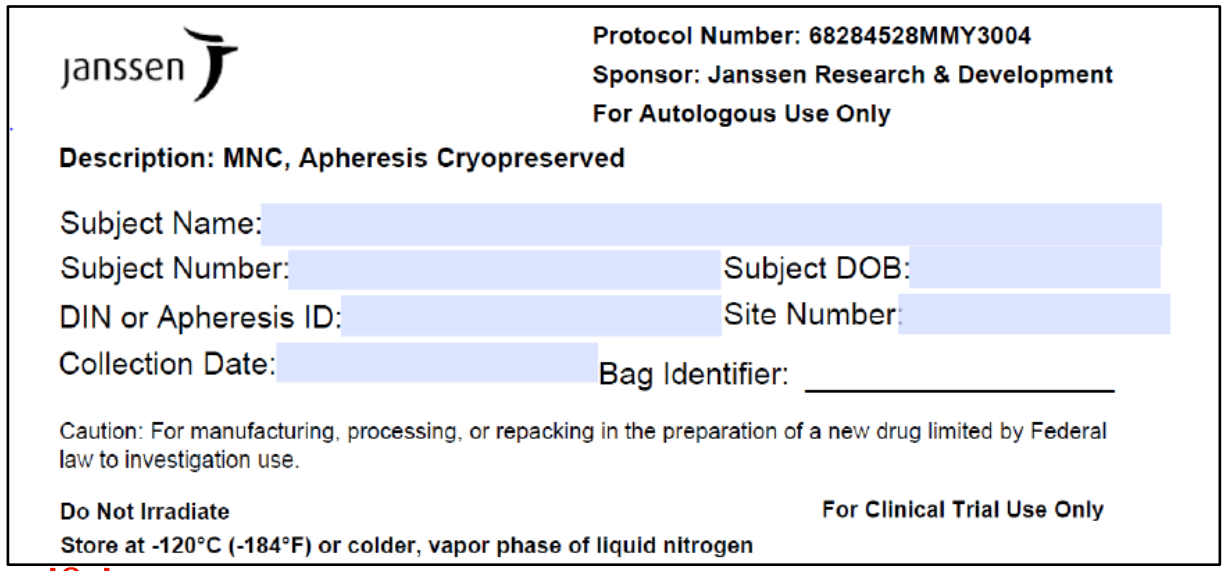
Sites that have completed **on-site cryopreservation** tech transfer of the J&J method.
Please refer to the batch record for details on the onsite cryopreservation process

The following labels will accompany the apheresis material to the cell lab:

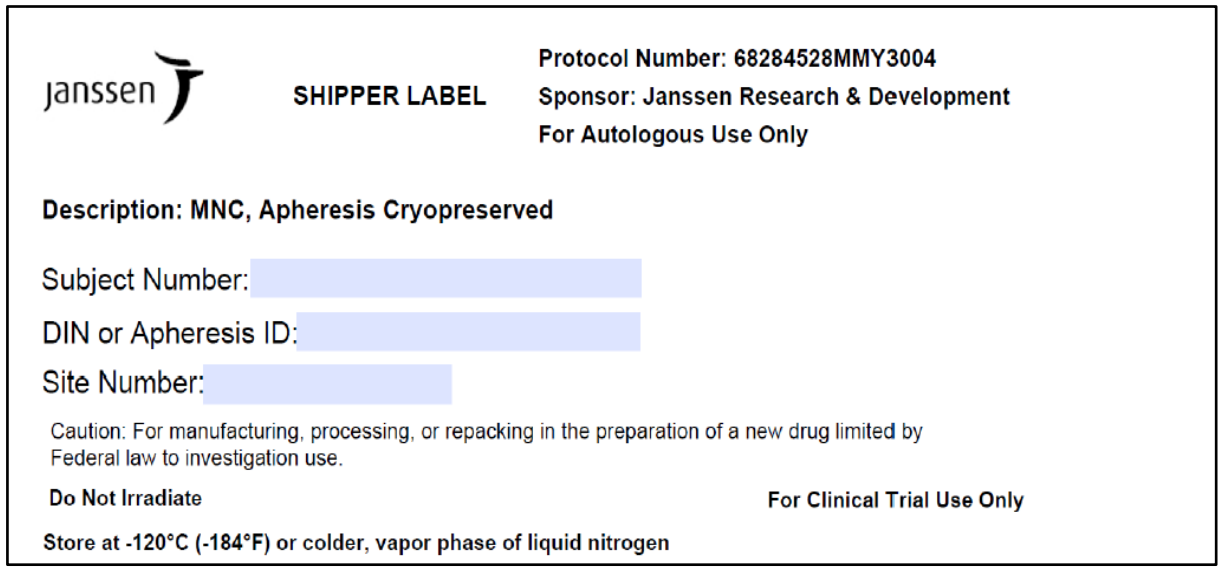
- One (1) sponsor apheresis label attached to the apheresis material bag
- One (1) site apheresis bag label affixed to the apheresis bag

The labels below will be created by the cell lab using the sponsor-approved label templates

Example of Cryo Bag and Cassette Label



Example of Shipper & Batch Record Label



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Packing of cryopreserved apheresis material

- In frozen state, the cryopreserved material bag is brittle
- It is very important to handle the cassette and cryopreserved material bag with care to avoid damage
- Pack the cryopreserved apheresis material bag into the cassette, ensuring that the **ports are orientated towards the top of the cassette with the locking hinge**.

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Packing of cryopreserved apheresis material into LN2 Shipper

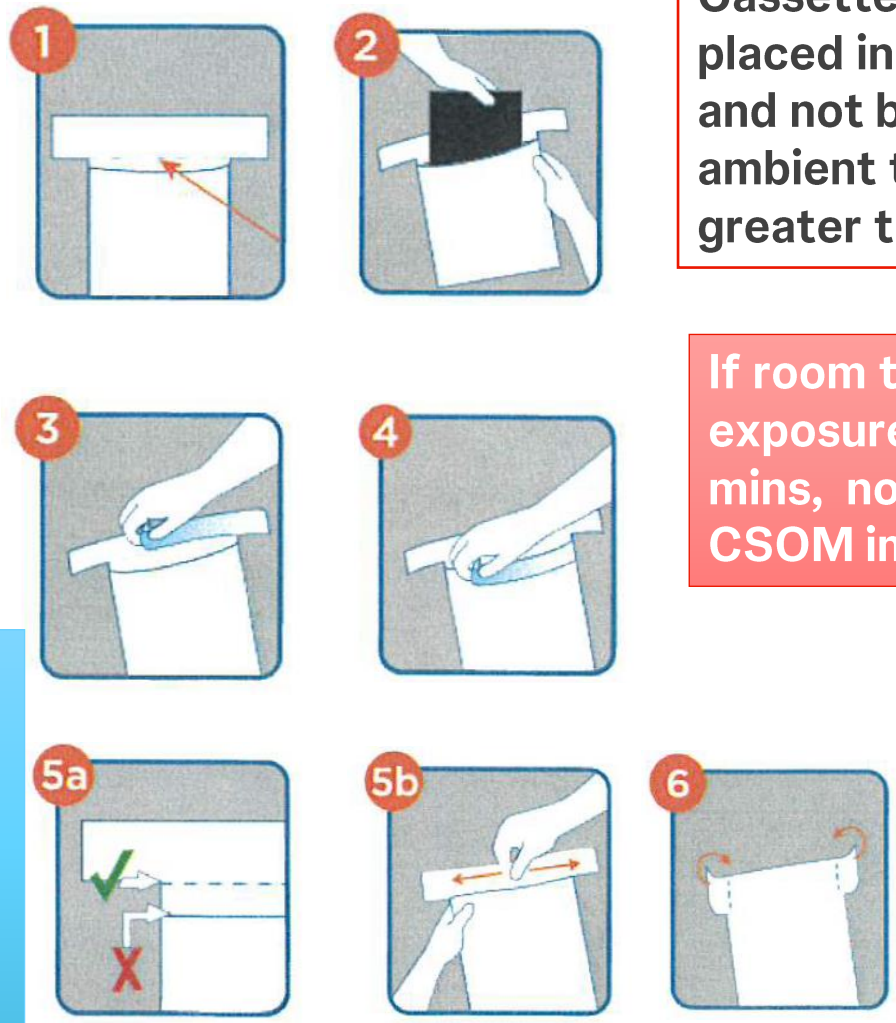
If using the 1-piece packing solution **Cryogenic Containment Pouch:**

- Pre-fold over the scored line shown with an arrow.
- The pre-fold may fold over the adhesive seal cover.
- Insert the cassette with the locking hinge toward the top and push completely down past the adhesive seal into the Cryogenic Containment Pouch.
- Ensure the cassette is not behind the adhesive seal.

Peel off adhesive strip cover on top flap.

Peel off adhesive strip cover on the on the envelope pouch.

- Seal the Cryogenic Containment Pouch.
- Ensure to fold flap along pre-folded scored line. Start sealing from centre of pre-fold and work out to the sides. Seal must not have any wrinkles or gaps.
- Fold tabs around seal with pressure.
- Tabs must be sealed as close as possible to the envelope.



Cassette(s) should be placed in cryoshipper and not be exposed to ambient temperature greater than 3 minutes.

If room temperature exposure > 3 mins, notify CSOM immediately

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Packing of cryopreserved apheresis material into LN2 shipper cont.

1. Place sealed cryogenic containment envelope pouch with frozen bag/cassette into the cassette rack as shown in figure 1.
   - Ensure proper orientation so the locking hinge of the cassette is at the top of the rack.

2. Use the foam dunnage provided in the shipper kit pouch as shown in figure 2.

3. Place one piece of the foam dunnage on top of the envelope within the cassette rack as shown in figure 3.

1.

2.

3.

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LN2 Shipper - Receipt and Packing

1. Verify that the EVO-IS ID number (last 4 digits) on the AWB matches the EVO-IS ID number on the LN2 shipper lid.

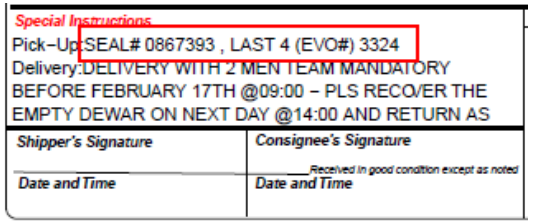
2. Verify the temperature inside the LN2 shipper:

   To obtain the current shipper temperature condition, press the temperature indicator button (TIB).

   - **A steady white** light indicates the last payload temperature recorded by the system is within range.
   - If **no light** is present:

     a) Use the public link shared by courier to review the shipping temperature graph.
   - **A flashing light** indicates temperature out of range (TOR). Proceed to contact J&J immediately. Do not use the LN2 shipper.

1



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Module 5: Packing & Shipment

(only applicable to sites shipping apheresis to CPC)

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Communication Plan with Site, Courier & Sponsor

The apheresis material shipment procedure involves 2 steps:

1. Delivery of the empty CREDO CUBE shipper to the site (for packing of apheresis material)

2. Pick-up for shipment of the apheresis material from clinical site to the Cryopreservation Center (CPC)

IMPORTANT! Notify your CSOM Central.Scheduling@ITS.JNJ.com right away and copy your SM if the packed shipper will not be ready for pick-up by the courier by agreed time. Should the pick-up time be delayed, alternate plans may need to be implemented based on flight or ground transportation constraints.

Review of Packing Materials

USA

- ✓ A CREDO CUBE shipper
- ✓ A labelled cryopreservation kit pouch kept inside the credo cube
- ✓ A labelled clinical site kit pouch which includes:
  - •A Non activated temperature monitoring device (TempTale Ultra)
  - •A polybag
  - •An absorbent pad
  - •AWB for shipment to CPC

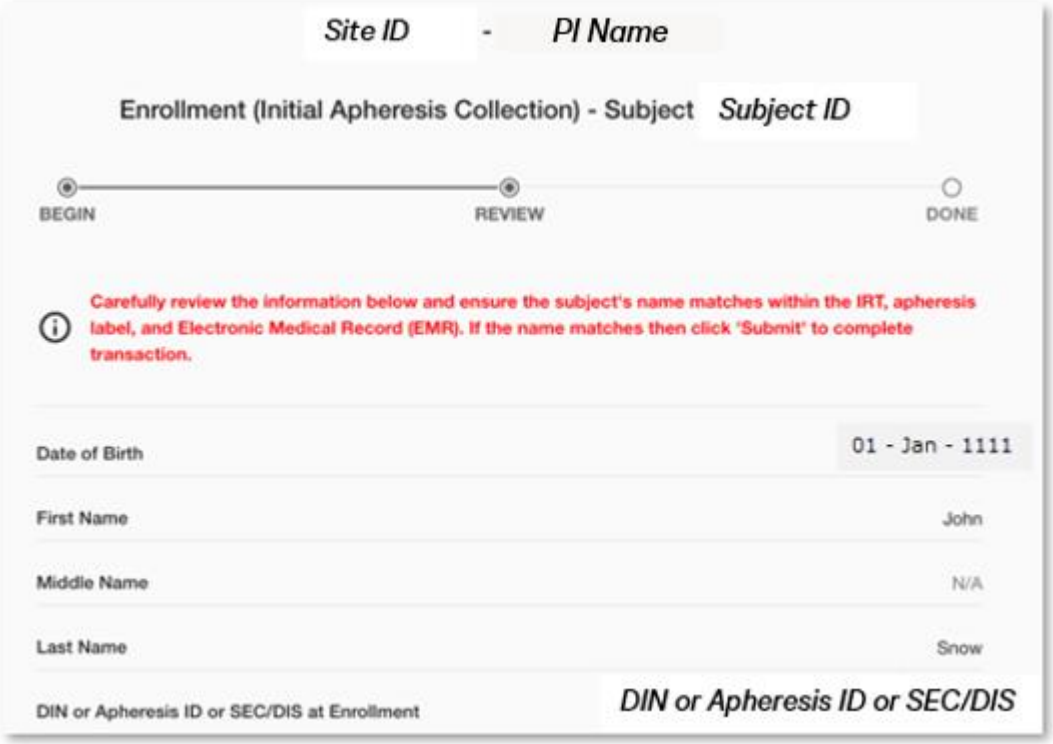
CANADA

- ✓ A CREDO CUBE shipper
- ✓ Large Polythene Bag containing:
  - •PolyBag
  - •Absorbent pad
  - •Non-activated temperature monitoring device (TempTale Ultra)
  - • The courier will bring an **AWB** containing the **subject number** for shipment to the cryopreservation center.

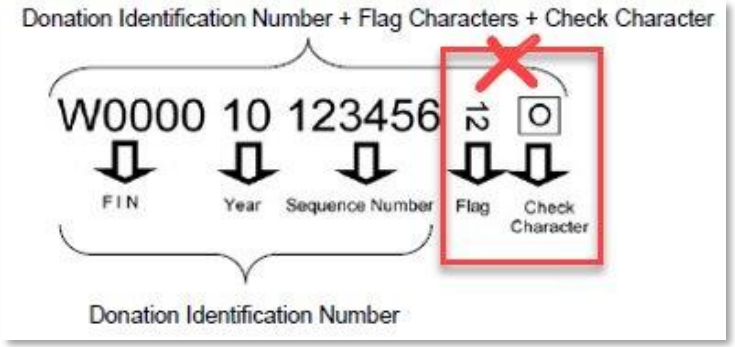
The courier will bring an **AWB** containing the **subject number** for shipment to the cryopreservation center.

Responsibility #3: The Study Coordinator shares information entered in IRT with Shipping Staff prior to Packing/Shipping

- The Study Coordinator must take a screen shot of the information entered in IRT and share it with the Packing/Shipping staff (see example below)
- Why? The information entered in the IRT system must match Apheresis Site Bag Label and COC/I form information
- Important Note: Do not add Flaggs to the unique identifier (see picture below)



Unique Identifier for apheresis collection as applicable to your region/country/site.
NOTE: Accent marks are not allowed. (e.g., Ř, Í, Á, Š)



Courier Pick Up

(Applicable for NA except for Canada)

- The sponsor will arrange for a courier to pick up apheresis material on the day of apheresis collection
- Courier will issue an automated pre-alert/order confirmation to the site once the order has been placed by the sponsor Including Subject Number and reference the AWB (which will be included in the shipment)
- The CREDO CUBE shipper container will be pre-conditioned at 2-8 ºC
- Shipper will arrive in the morning (9-11am local time)
- Courier will pick-up the shipper on the same day after pack-out at 2pm local time

Site is responsible for entire packing – procedure highlights:

IMPORTANT: Notify your CSOM Central.Scheduling@ITS.JNJ.com & copy your SM if there are any delays in packing as this will impact delivery to the CPC

J&J

Courier Pick Up
(Applicable for Canada)

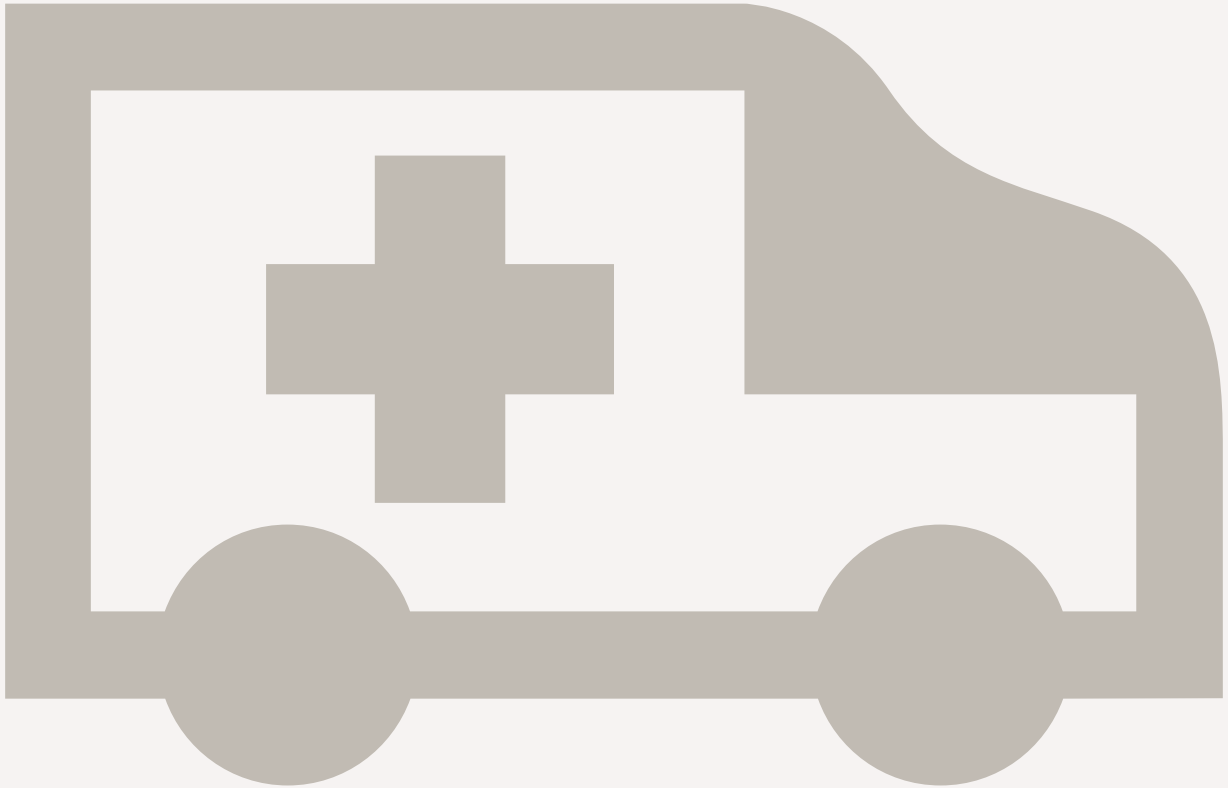
- The sponsor will arrange for a courier to pick up apheresis material on the day of apheresis collection
- **World Courier** will email order confirmation to the site once the order has been placed by the sponsor Including Subject Number and reference the AWB (which will be included in the shipment)
- As pre-agreed, the courier can deliver shipper in the morning and return for pick-up on the same day after packing (at the agreed pick-up time).
- The CREDO CUBE shipper container will be pre-conditioned at 2-8 °C

Site is responsible for entire packing – procedure highlights:

IMPORTANT: Notify your CSOM Central.Scheduling@ITS.JNJ.com & copy your SM if there are any delays in packing as this will impact delivery to the CPC

J&J

Module 6: Receipt & Storage of IP



J&J

Communication Plan with Site, Courier & Sponsor

Initiate

Once the IP has been released from Manufacturing Quality, the sponsor will arrange delivery. IP Delivery date will be confirmed with the site by CSOM/SM.

Delivery Notification

The courier will send one geo-fence notification to the clinical site contact(s) on the day of delivery, when the shipment is within a 5-miles radius of the clinical site.

A link will also be provided that will enable the site to review the temperature data for the IP shipment

IP shipper Arrival

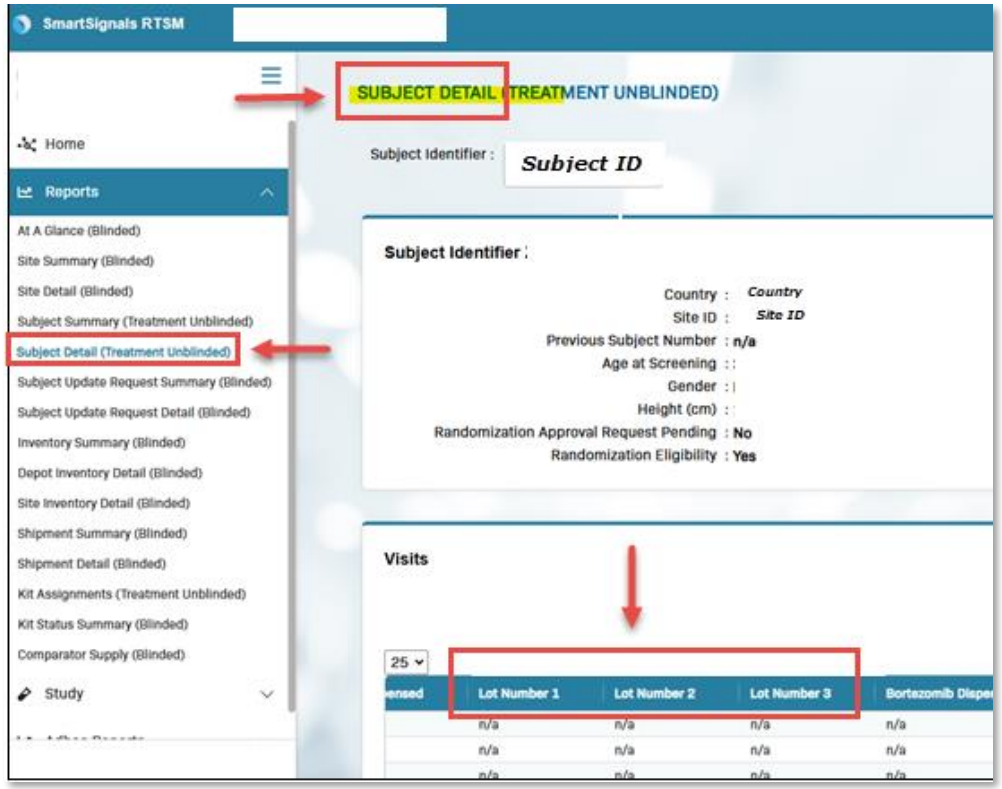
The shipper will arrive at the site at the agreed local time and location for the receipt.

J&J

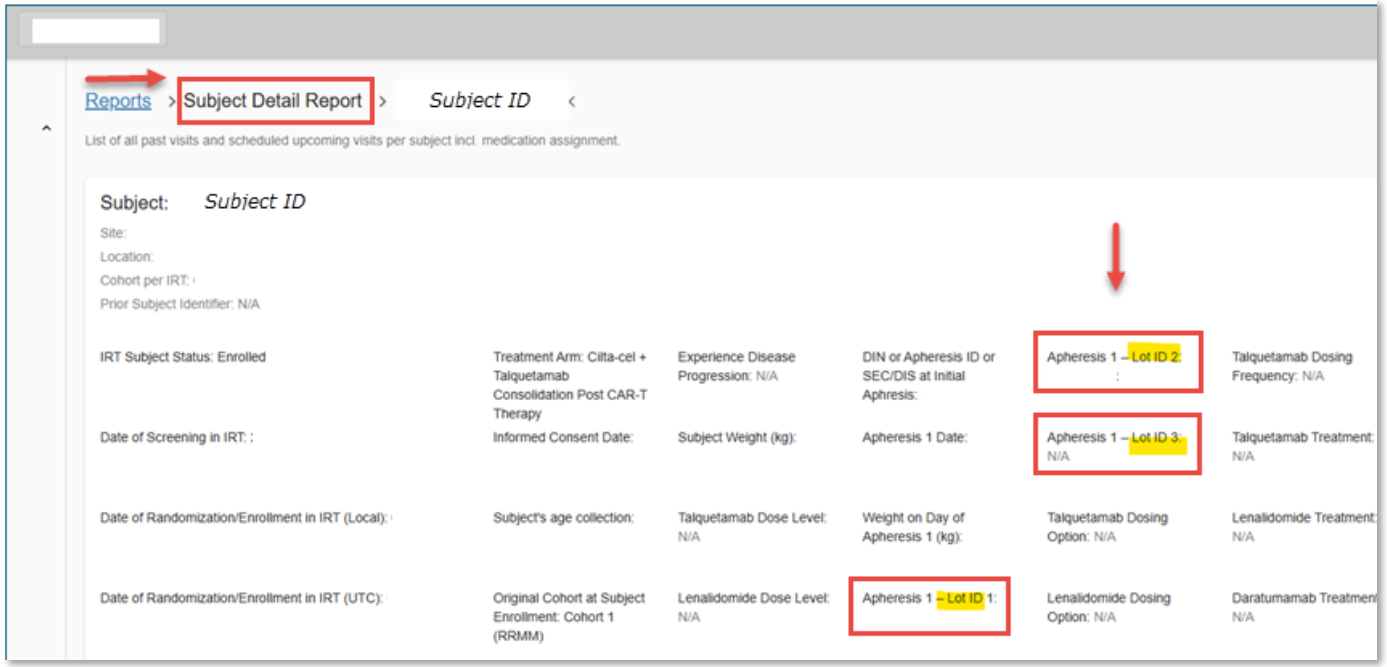
Responsibility #4: The Study Coordinator shares IP Lot# entered in IRT by manufacturer with the Cell Lab

- The Study Coordinator must take a screen shot of the information entered in IRT by manufacturing and share with Cell Lab prior to Investigational Product (IP) arrival.
- Why? The Lot# entered in the IRT system must match Lot # from the Cassette and IP Label

Example IRT 'Subject Detail Report' incl IP Lot # (Signant Health)



Example IRT 'Subject Detail Report' incl IP Lot # (4G)



IP Requirements Highlights

- During on-site storage and during any internal transportation, IP must not be separated from the cassette
  - The packaging is designed to protect the drug from breakage and damage therefore the IP should not be removed

- JNJ-68284528 (ciltacabtagene autoleucel) must be kept frozen at ≤-120 °C vapor phase of liquid nitrogen.
  - Temperature conditions during on-site storage and any internal transportation between sites of IP must be monitored and recorded

- IP cassette(s)/bag(s) should not be exposed to ambient temperature greater than 3 minutes.
  - Each time, one IP cassette is removed from vapour phase of LN2, start the timer for the IP bag transfer to the LN2 tank or Cryoshipper & monitor that IP room temperature exposure remains ≤ 3 min.

Refer to the IP Label, CTPPM and IPPI for comprehensive information.

Receipt of IP

- Prior to receipt of IP the site will need to inform CSOM/SM on the dates for lymphodepletion.
- The site coordinator shares IRT notification containing IP information with Cell Lab
- CAR-T Final Release Documentation will accompany the IP
- A shipper label will accompany the product, keep this label in the subject's chart to be used if IP return to manufacturing is needed.
- Alert your CSOM/SM to any issue with delivery of the IP
- A link to the IP shipping temperature report is provided via email by the courier

LN2 Shipper - Receipt and Packing

1. Verify that the EVO-IS ID number (last 4 digits) on the AWB matches the EVO-IS ID number on the LN2 shipper lid.

2. Verify the temperature inside the LN2 shipper:

   To obtain the current shipper temperature condition, press the temperature indicator button (TIB).

   - **A steady white** light indicates the last payload temperature recorded by the system is within range.
   - If **no light** is present:

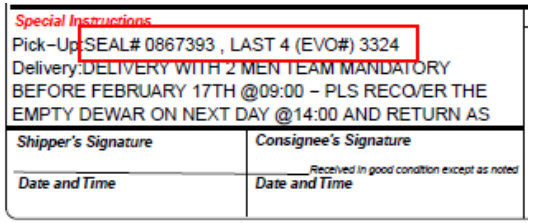
     a) Proceed to transfer the IP to on-site storage. Use the public link shared by courier to review the shipping temperature graph.

   - **A flashing light** indicates temperature out of range (TOR). Proceed to transfer product to on-site storage under quarantine storage conditions and contact J&J immediately.

3. Complete relevant IP receipt form section 1 (**REC**)

Always consult the full temperature report using the link provided by the courier via email to determine if a TOR took place.

1



2

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Unpacking and storage of IP

1. Using a wire cutter, cut and discard the tamper evident seal wire on the cassette rack

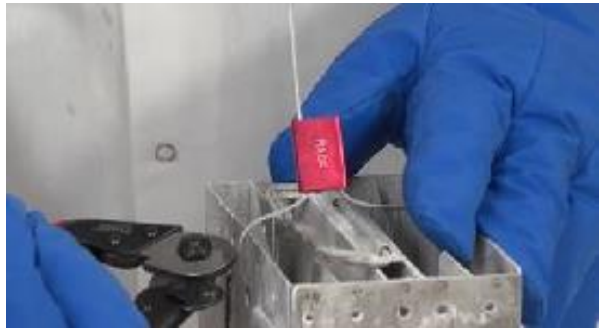
2. Remove dunnage prior to removing cassette from rack. The foam dunnage will be located on top of the envelope within the cassette rack

3. Remove the cassette from the rack

4. Cut open the pouch and remove the cassette

IP cassette(s) should be placed in LN_2 tank and not be exposed to ambient temperature greater than 3 minutes.
If 3 mins are exceeded, notify your CSOM/Site Manager immediately.

1



2

3

4

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Unpacking multiple cassettes/bags of IP from one shipper

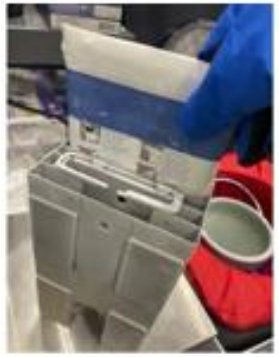
Each IP must be removed one at a time, and the rack with the remaining IP bag must be immediately returned to the shipper and the shipper lid secured.

Follow Module 6 from CTPPM Steps 6.4.4 to 6.4.6.

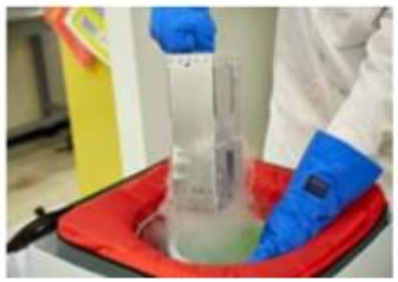
1. Remove the **first IP cassette/bag** from the rack slots.
   - ➢ Start the timer for the first IP bag.
2. Immediately, **re-insert** the rack containing the remaining IP bag(s) into the shipper and **secure the smartcap lid** on the DV10 shipper
3. Cut open the pouch and remove cassette
4. Proceed with the checks for the first IP cassette/bag
5. Repeat steps above with each individual remaining IP cassette/bag.
   - ➢ Each time an IP bag is removed , start the timer for that specific bag.

Remember: Each cassette must not be exposed to ambient temperature longer than 3 minutes

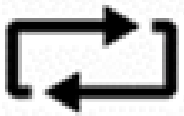
1



2

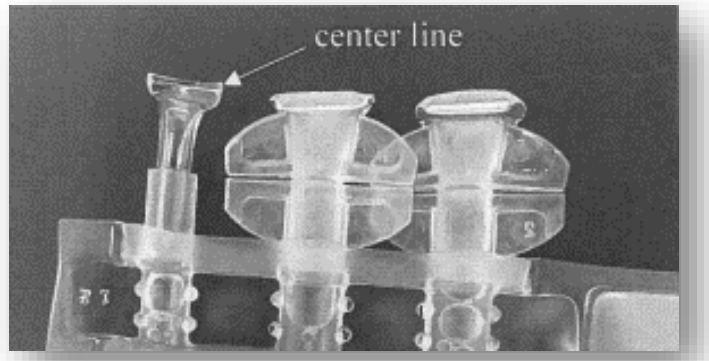


3



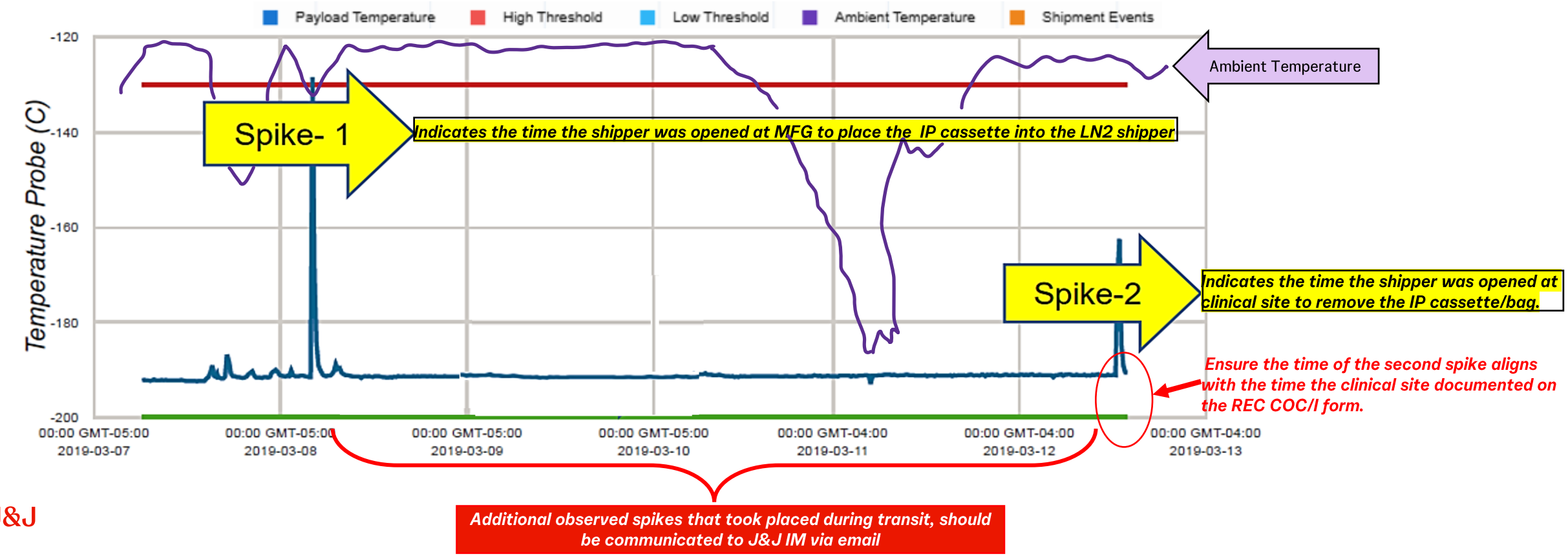
Product Inspection

- **Prior to placing cassettes in LN2 storage, each cassette needs to be checked AND opened to also inspect each IP bag. These checks include cassettes/IP bags integrity & labels accuracy.** (Step 6.4.5)
- When the cassette containing the IP bag is removed from vapor phase LN_2, and is in the frozen state
  - IP bag is brittle
  - It is very important to handle the cassette and IP bag with care to avoid damage (i.e., bag falls when opening the cassette)
  - There are three (3) ports on the bag as shown here; which must be intact on receipt



Review the LN2 Shipper Temperature Report

- ❑ Print the LN2 shipper temperature report using the link provided by the courier and file on patient's chart.
- ❑ The temperature must be within range as per IP label specifications.
  - Each graph should contain 2 temperature spikes as shown below
  - An additional spike indicates **a potential** temperature excursion
- ❑ **If temperature is out of range, first quarantine the IP product in on-site LN2 storage and notify J&J via Central.Scheduling@ITS.JNJ.com and copy the SM. Refer to Section 6.7 Problems and Special Situation for further instructions.**



Transit Temperature Out of Range (TOR) Reporting

1. Notify your CSOM/SES via CENTRAL.SCHEDULING@its.jnj.com and copy the SM if a temperature excursion is suspected when the site reviews the temperature report:
   a. Find the temperature report using the web link provided in the courier email sent to the clinical site:
      - At time of IP pick up at the manufacturing facility: USA QuickStat
   b. Transfer product to on-site LN2 storage under quarantine conditions
2. The J&J IM SES team will review the temperature report data upon upload of a successfully completed IP Receipt form (REC / TV-eFRM-10449) to MBOX
   a. The J&J team will review the accurately completed REC form once uploaded in MBOX within 4 J&J business hours.
      - Upload must be completed no later than 1 pm (local time) for the review to be completed in a timely manner
        - J&J business hours are Monday through Friday 9:00am to 5:00pm (local time)
      - Any questions regarding the temperature review, notify your CSOM/SES via CENTRAL.SCHEDULING@its.jnj.com and copy the SM
3. The J&J IM SES team will submit the Clinical CAR-T TOR Report and inform the clinical site/hospital via email of the need to quarantine product following the review.

Quarantine product under label storage conditions, until Sponsor confirms acceptable for use

J&J

On-Site Storage Temperature Out of Range (TOR) reporting

- **On-site TORs took place during storage at the clinical site**
  - Notify your CSOM/SES via CENTRAL.SCHEDULING@its.jnj.com and copy the SM
  - Complete Clinical CAR-T TOR Report and send to Sponsor via email
    - CENTRAL.SCHEDULING@its.jnj.com
    - Temperature@its.jnj.com
  - LN2 tank temperature data report IS required to be supplied by site.

Quarantine product under label storage conditions, until Sponsor confirms acceptable for use

Transport of Cryopreserved IP to the administration site

Transport to the administration site – transport at LN_2 vapor phase

- The IP transportation must take place using a transport shipper that has been validated to maintain a temperature at the temperature specified on the IP label

Transport Documentation

- **Upon removal** of IP from storage for transport, the **time of removal and temperature of transport device** must be documented.
- Documentation of **transport device temperature monitoring** is required for throughout transport of IP from the storage location to the administration site ; or at the minimum temperature inside transport device at time of IP being taken out for thaw.

Transport of Thawed IP to the administration site

Upon removal of IP from storage for thawing, the date/time of removal must be documented.

Transport to the administration site –ambient temperature

- The IP transportation must take place using a validated transport shipper.
- The IP must be placed on a secondary bag.
- The location of administration of IP must be within walking distance from the thawing location.

Product Quality Complaint (PQC)

Do not dispense the IP to a subject if there is a concern about the quality of the product.

PQC can include:

- *Dramatically unexpected appearance or condition of the IP (e.g., apparent visible particles, dramatically unexpected coloration)*
- *IP primary container with leak(s)*
- *Damage to secondary container (cassette)*
- *Labelling of the IP bag and/or cassette is incorrect (e.g., incorrect protocol number, or incorrect subject information)*

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Module 7: Returns & Destruction

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Disposal of Investigational Product

If CAR-T IP was delivered to the site, but the patient is not able to be dosed, the IP can either be:

- Destroyed on-site AFTER sponsor approval for destruction is obtained

OR

- If the site is not approved for on-site destruction, IP can be returned to the Sponsor (if applicable per your local regulations & study)

Review of Site Procedures for On-site Destruction

IP Destruction Questionnaire (TV-eFRM-13271) for Cell Therapy Products **must be used, in combination with the site's applicable SOP,** to determine, and to document, that a site is approved to destroy Cell Therapy Products

If the site does not have the capabilities to destroy Cell Therapy Product, then the IP Destruction Questionnaire for Cell Therapy Products **does not** need to be completed.

Study No.: Investigator Name: _____

Site Identification: Country:

This form is only for review and approval of the on-site destruction of Cell Therapy Products. Any on-site destruction of Non-Cell Therapy Investigational Products must be reviewed and approved by completing TV-FRM-07759: Investigational Product Destruction Questionnaire.

If Cell Therapy Product destruction is to be performed by the investigational site, this questionnaire must be completed to document that the site is authorized to destroy Janssen Cell Therapy Products. This form will be completed in consultation with the Cell Therapy Team at the site (as opposed to site pharmacy staff).

Investigational Site Investigational Cell Therapy Product Destruction Policy and Procedures	
1.	Does the site have an SOP for Cell Therapy Product destruction? ☐ Yes ☐ No
2	Does the site have a process in place to ensure that destruction approval for each individual subject's Cell Therapy product is obtained both internally and by the sponsor before starting the destruction process? ☐ Yes ☐ No, but the site agrees to implement the following approval process: _____ _____ ☐ No
3	Does the site process require two site staff signatures to verify the identity of the Cell Therapy Product prior to destruction? ☐ Yes ☐ No
4	Does the site agree to document the destruction of Cell Therapy Product on the Janssen TV-FRM 57192: CAR-T Investigational Product On-Site Destruction Form, and send to the sponsor? ☐ Yes ☐ No
5	Is the Cell Therapy Product waiting for destruction, quarantined and kept in a restricted access area according to the site's biohazard waste procedure? ☐ Yes ☐ No
6	Is Cell Therapy waste (which is classed as biohazardous waste), separated from other waste streams? ☐ Yes ☐ No

Documentation of Approval for Destruction

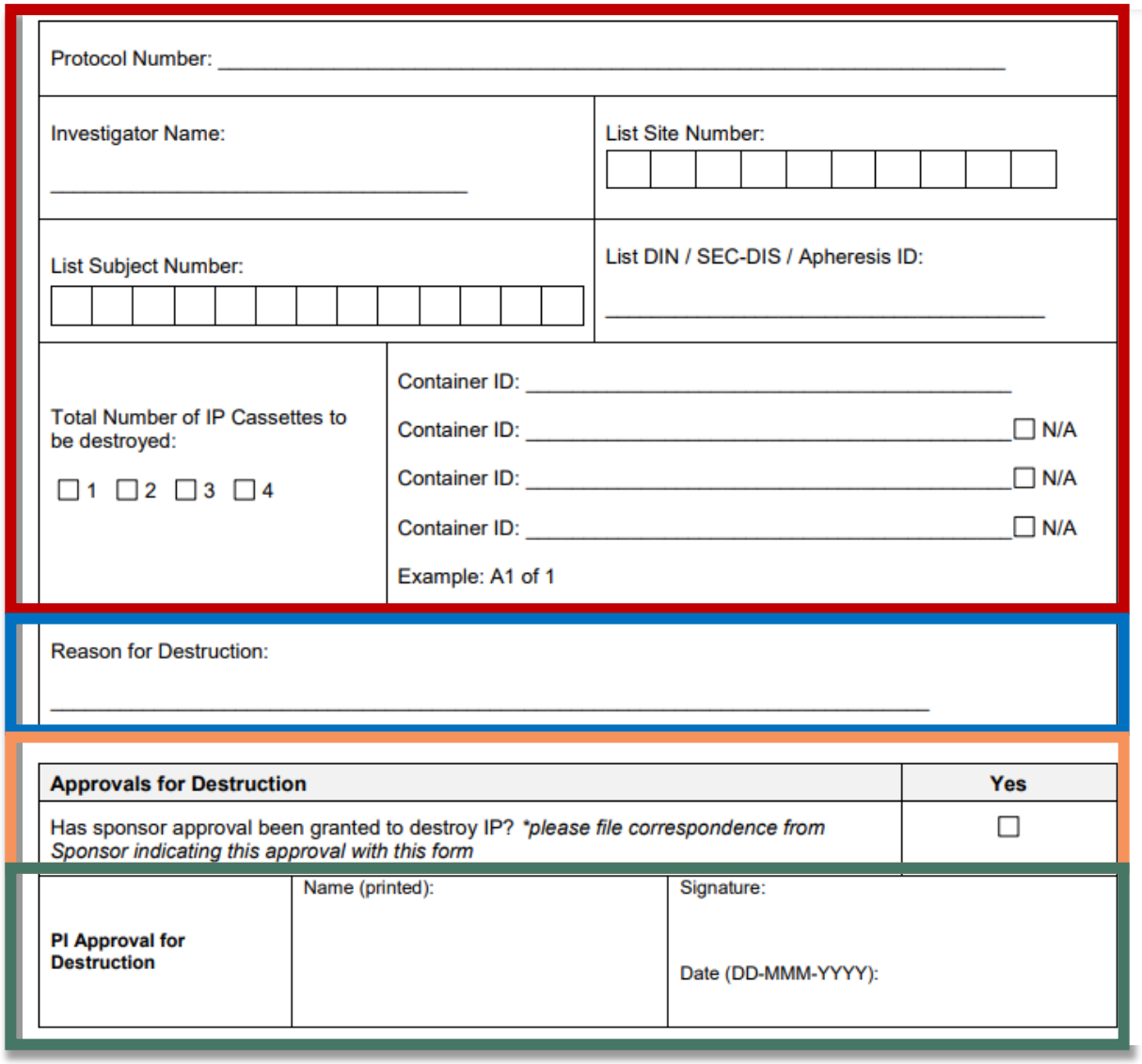
TV-FRM-57192: CAR-T Investigational Product On-Site Destruction

❶ Site to complete the top information for each product that is being destroyed.

❷ Reason for destruction must be completed by the site.

❸ Approval from the sponsor to destroy the IP must be attached to the form and the box checked.

❹ Principal Investigator approval for destruction needs to be documented on the form.



❶

Protocol Number: _____

Investigator Name: _____

List Site Number: ☐☐☐☐☐☐☐☐☐☐

List Subject Number: ☐☐☐☐☐☐☐☐☐☐☐☐☐

List DIN / SEC-DIS / Apheresis ID: _____

Total Number of IP Cassettes to be destroyed:

☐ 1 ☐ 2 ☐ 3 ☐ 4

Container ID: _____

Container ID: _____ ☐ N/A

Container ID: _____ ☐ N/A

Container ID: _____ ☐ N/A

Example: A1 of 1

❷

Reason for Destruction: _____

❸

Approvals for Destruction	Yes
Has sponsor approval been granted to destroy IP? *please file correspondence from Sponsor indicating this approval with this form*	☐

❹

PI Approval for Destruction	Name (printed):	Signature: Date (DD-MMM-YYYY):

Documentation of IP Destruction

After both the Sponsor and the Principal Investigator have approved the Cell Therapy Investigational Product for destruction, the Investigational Site will follow their internal and sponsor-approved SOP to ensure complete destruction.

Destruction must be documented on TV-FRM-57192: CAR-T Investigational Product On-Site Destruction

Investigational Site will ensure that two site staff members initial and sign the form where indicated.

Upon completion, the Investigational Site must provide a signed copy of Form TV-FRM-57192 to the Sponsor by uploading to MBOX.

TV-FRM-57192: CAR-T Investigational Product On-Site Destruction Form

Destruction of IP	Confirmation	
Date IP is prepared for Destruction	d d M O N 2 y y y y	
Remove IP Bag(s) from storage, read back and confirm patient's name and unique identifier(s) (requires two study staff members).	Initials	Initials
IP Bag(s) discarded into the biohazard waste containers as per institution policies.	Initials	Initials

Comments: ☐ N/A

Destruction Completed By:	Name (printed):	Signature: Date (DD-MMM-YYYY):
Verified By:	Name (printed):	Signature: Date (DD-MMM-YYYY):

If returning IP to Sponsor for destruction: Pack the cassettes

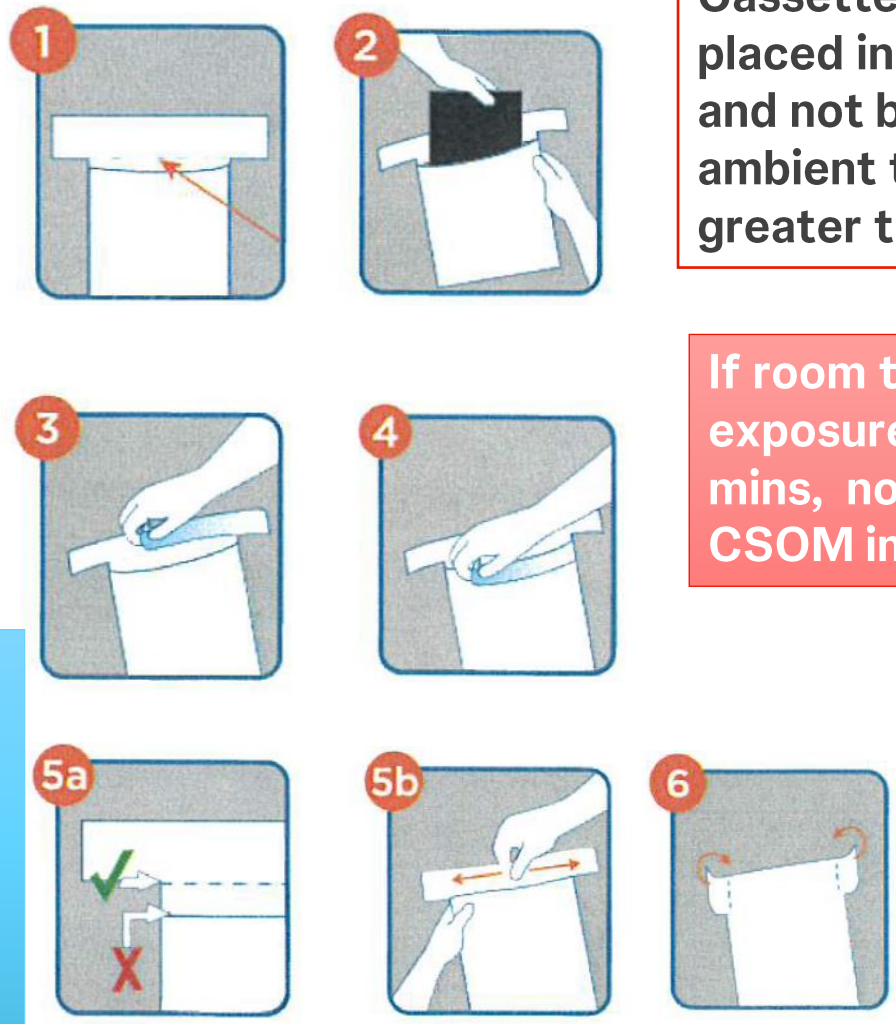
If using the 1-piece packing solution **Cryogenic Containment Pouch:**

- Pre-fold over the scored line shown with an arrow.
- The pre-fold may fold over the adhesive seal cover.
- Insert the cassette with the locking hinge toward the top and push completely down past the adhesive seal into the Cryogenic Containment Pouch.
- Ensure the cassette is not behind the adhesive seal.

Peel off adhesive strip cover on top flap.

Peel off adhesive strip cover on the on the envelope pouch.

- Seal the Cryogenic Containment Pouch.
- Ensure to fold flap along pre-folded scored line. Start sealing from centre of pre-fold and work out to the sides. Seal must not have any wrinkles or gaps.
- Fold tabs around seal with pressure.
- Tabs must be sealed as close as possible to the envelope.



Cassette(s) should be placed in cryoshipper and not be exposed to ambient temperature greater than 3 minutes.

If room temperature exposure > 3 mins, notify CSOM immediately

J&J

Pack IP into LN2 Shipper

1. Place sealed cryogenic containment envelope pouch with frozen bag/cassette into the cassette rack as shown in figure 1.
   - Ensure proper orientation so the locking hinge of the cassette is at the top of the rack.

2. Use the foam dunnage provided in the shipper kit pouch as shown in figure 2.

3. Place one piece of the foam dunnage on top of the envelope within the cassette rack as shown in figure 3.

3. Complete **RTN** form and upload to MBOX

1.

2.

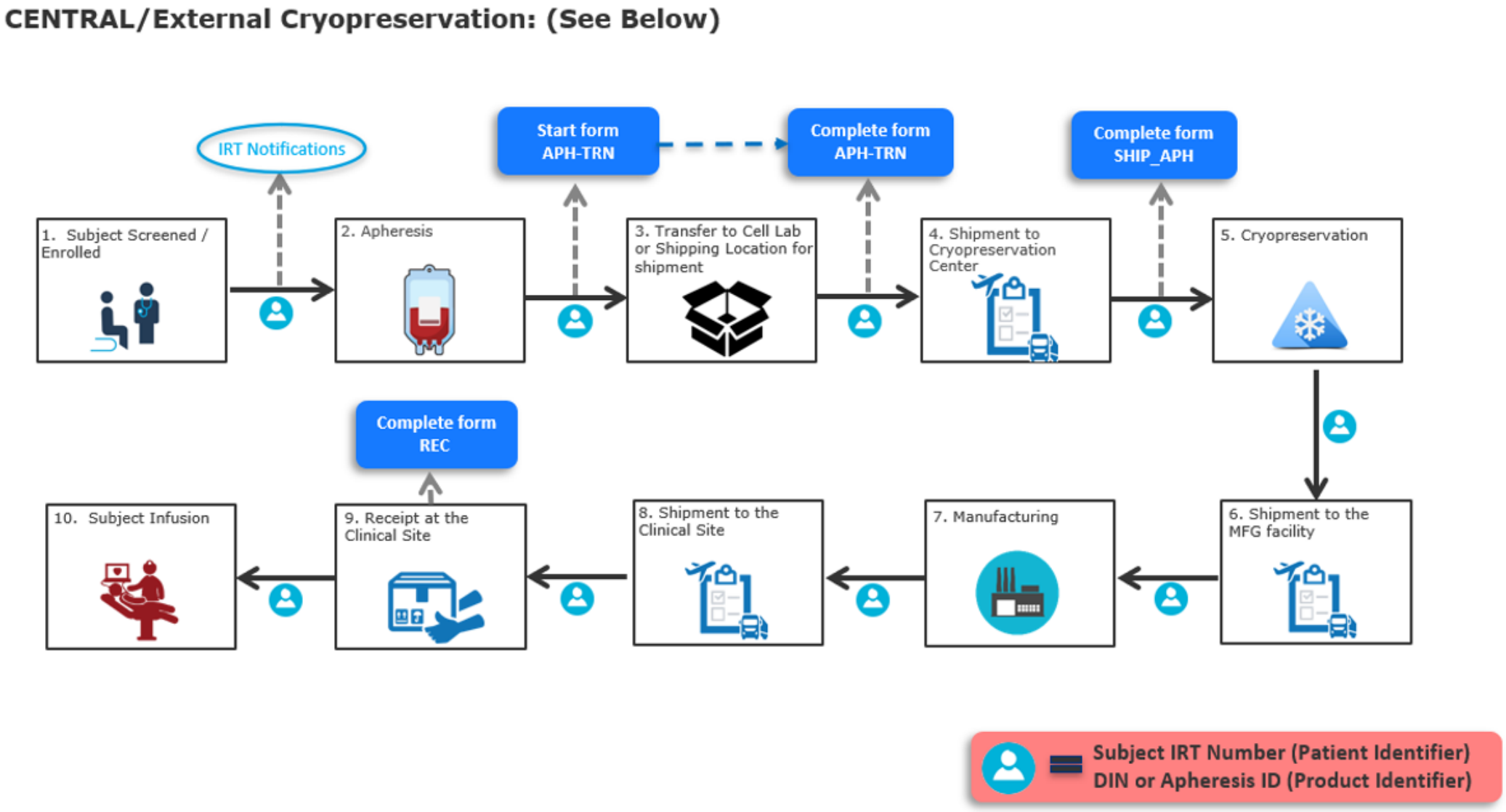
3.

J&J

Module 8: COC/COI Maps & Forms

J&J

COC/COI Map


CENTRAL/External Cryopreservation: (See Below)
IRT Notifications
Start form APH-TRN
Complete form APH-TRN
Complete form SHIP_APH
1. Subject Screened / Enrolled
2. Apheresis
3. Transfer to Cell Lab or Shipping Location for shipment
4. Shipment to Cryopreservation Center
5. Cryopreservation
6. Shipment to the MFG facility
7. Manufacturing
8. Shipment to the Clinical Site
9. Receipt at the Clinical Site
Complete form REC
10. Subject Infusion
Subject IRT Number (Patient Identifier)
DIN or Apheresis ID (Product Identifier)

Cell Therapy COC/COI Forms

Sponsor COC/COI Form Number	Current Effective Version as of 01June2025	Form Description	Form Name
TV-eFRM-10456	**V 8.0**	**Apheresis Chain of Custody/Chain of Identity Form**	**APH-TRN**
TV-eFRM-10455	**V 9.0**	**Site Shipment Form for Chain of Custody/Chain of Identity**	***SHIP_APH**
TV-eFRM-10449	**V 11.0**	**IP Shipment Receipt Checklist for Site**	**REC**
TV-eFRM-10450	V 10.0	CAR-T IP Return Shipment Form	RTN
TV-FRM-57192	V 1.0	CAR-T IP On-Site Destruction Form	N/A

*Applicable to sites shipping to CPC

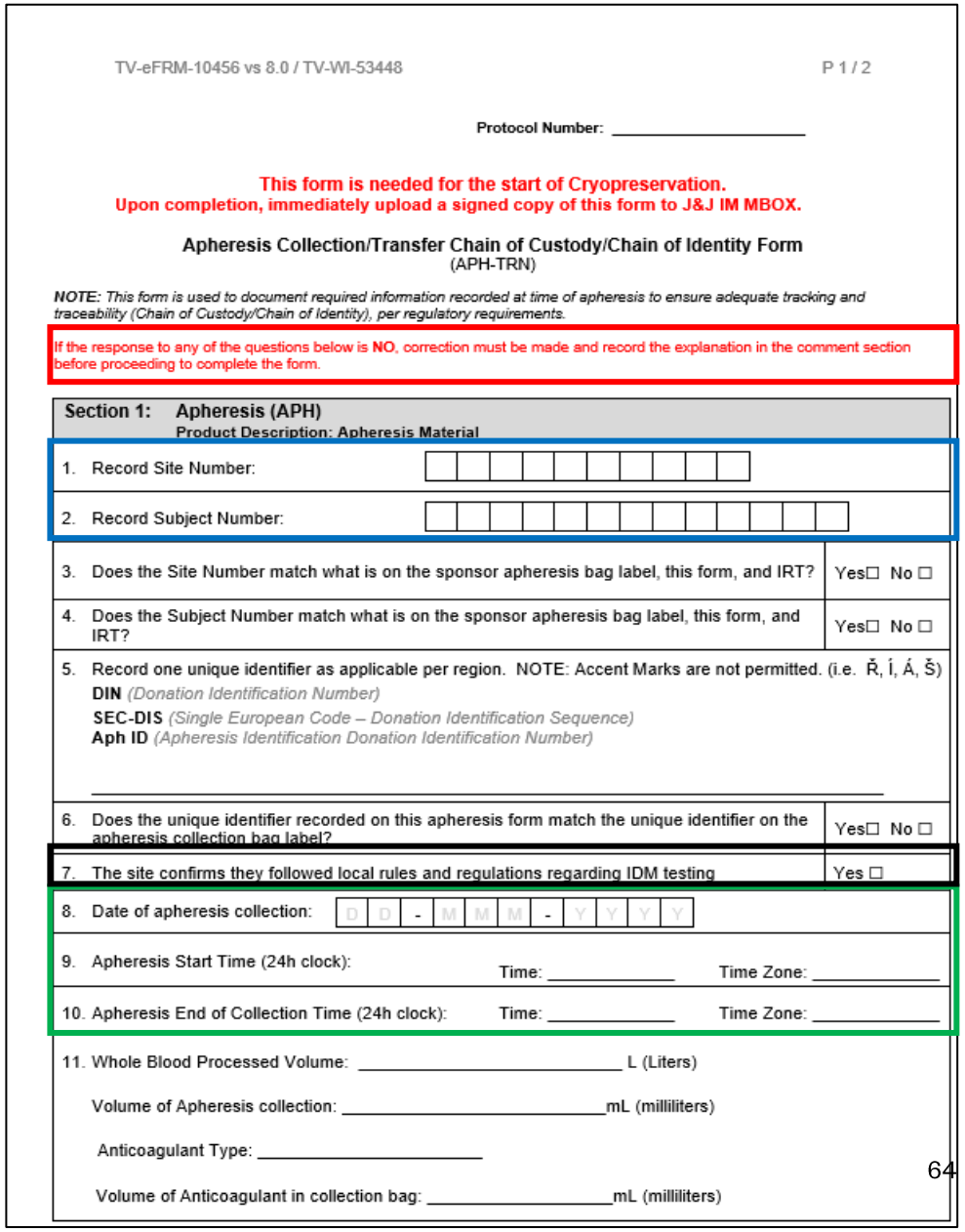
Ensure to use the current version of the COC/I Forms as indicated in the table above and review the current versions of COC/COI Forms as part of your training

J&J

Apheresis Collection: (APH-TRN) COC/COI Form

- If the response to any of the questions on the form is NO, a correction must be made and an explanation documented in the comment section before proceeding to complete the form
- 1, 2: The numbers and letters documented for subject and site number must be legible and accurate. The source document is the IRT notification. Ensure the information on the apheresis collection label matches the information on this form
- 7: The clinical site MUST answer this question confirming they followed local rules and regulations regarding IDM testing
- 8: Ensure to use this date format (i.e. 14-MAY-2024)

  9&10: The Time Zone must reflect Daylight or Standard time as applicable (i.e. EST vs EDT)



TV-eFRM-10456 vs 8.0 / TV-WI-53448 P 1 / 2

Protocol Number: _____

This form is needed for the start of Cryopreservation.
Upon completion, immediately upload a signed copy of this form to J&J IM MBOX.

Apheresis Collection/Transfer Chain of Custody/Chain of Identity Form
(APH-TRN)

NOTE: This form is used to document required information recorded at time of apheresis to ensure adequate tracking and traceability (Chain of Custody/Chain of Identity), per regulatory requirements.

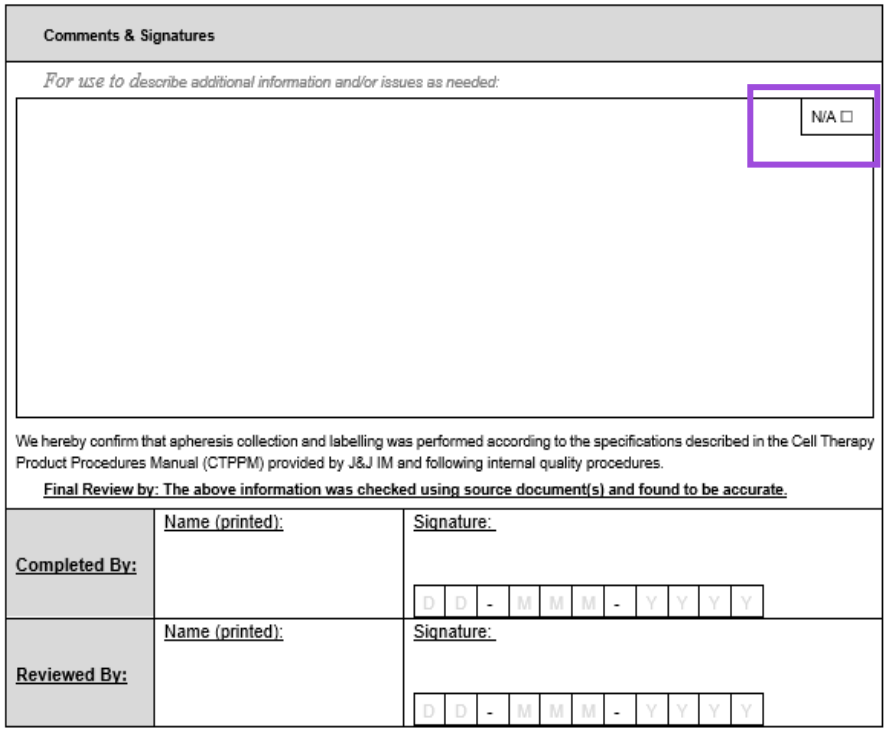
If the response to any of the questions below is **NO**, correction must be made and record the explanation in the comment section before proceeding to complete the form.

Section 1: Apheresis (APH)
Product Description: Apheresis Material

1. Record Site Number: ☐☐☐☐☐☐☐☐☐☐
2. Record Subject Number: ☐☐☐☐☐☐☐☐☐☐☐☐☐
3. Does the Site Number match what is on the sponsor apheresis bag label, this form, and IRT? Yes☐ No ☐
4. Does the Subject Number match what is on the sponsor apheresis bag label, this form, and IRT? Yes☐ No ☐
5. Record one unique identifier as applicable per region. NOTE: Accent Marks are not permitted. (i.e. Ř, Í, Á, Š)
   DIN *(Donation Identification Number)*
   SEC-DIS *(Single European Code – Donation Identification Sequence)*
   Aph ID *(Apheresis Identification Donation Identification Number)*
   _____
6. Does the unique identifier recorded on this apheresis form match the unique identifier on the apheresis collection bag label? Yes☐ No ☐
7. The site confirms they followed local rules and regulations regarding IDM testing Yes ☐
8. Date of apheresis collection: D D - M M M - Y Y Y Y
9. Apheresis Start Time (24h clock): Time: _____ Time Zone: _____
10. Apheresis End of Collection Time (24h clock): Time: _____ Time Zone: _____
11. Whole Blood Processed Volume: _____ L (Liters)
    Volume of Apheresis collection: _____mL (milliliters)
    Anticoagulant Type: _____
    Volume of Anticoagulant in collection bag: _____mL (milliliters)

Apheresis (APH-TRN) COC/COI Form

- Comments: remember to check N/A if comments are not needed.
- Section 2:
  - If the collection site staff performs the pack and shipping activities, check N/A on this section. No transfer is required.
  - If the apheresis material is transferred to a different location to perform packing and shipping activities, proceed to document the transfer of custody on this section.



Comments & Signatures

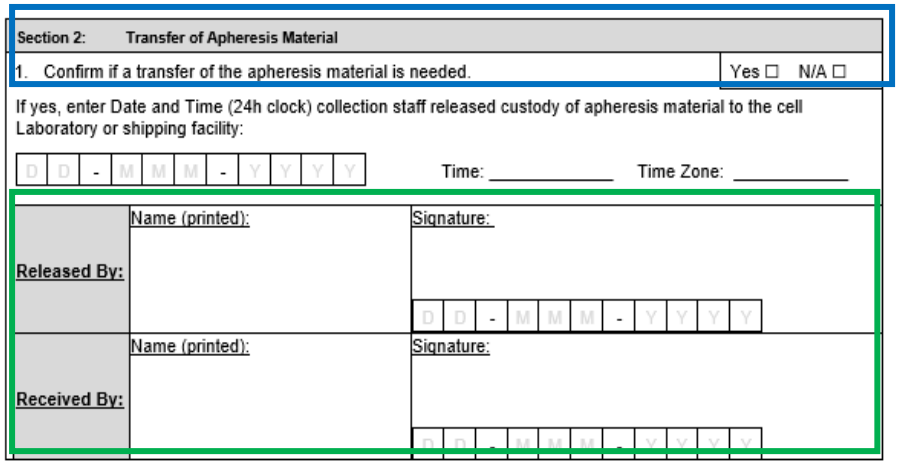
For use to describe additional information and/or issues as needed:

N/A ☐

We hereby confirm that apheresis collection and labelling was performed according to the specifications described in the Cell Therapy Product Procedures Manual (CTPPM) provided by J&J IM and following internal quality procedures.

Final Review by: The above information was checked using source document(s) and found to be accurate.

Completed By:	Name (printed):	Signature: D D - M M M - Y Y Y Y
Reviewed By:	Name (printed):	Signature: D D - M M M - Y Y Y Y



Section 2: Transfer of Apheresis Material

1. Confirm if a transfer of the apheresis material is needed. Yes ☐ N/A ☐

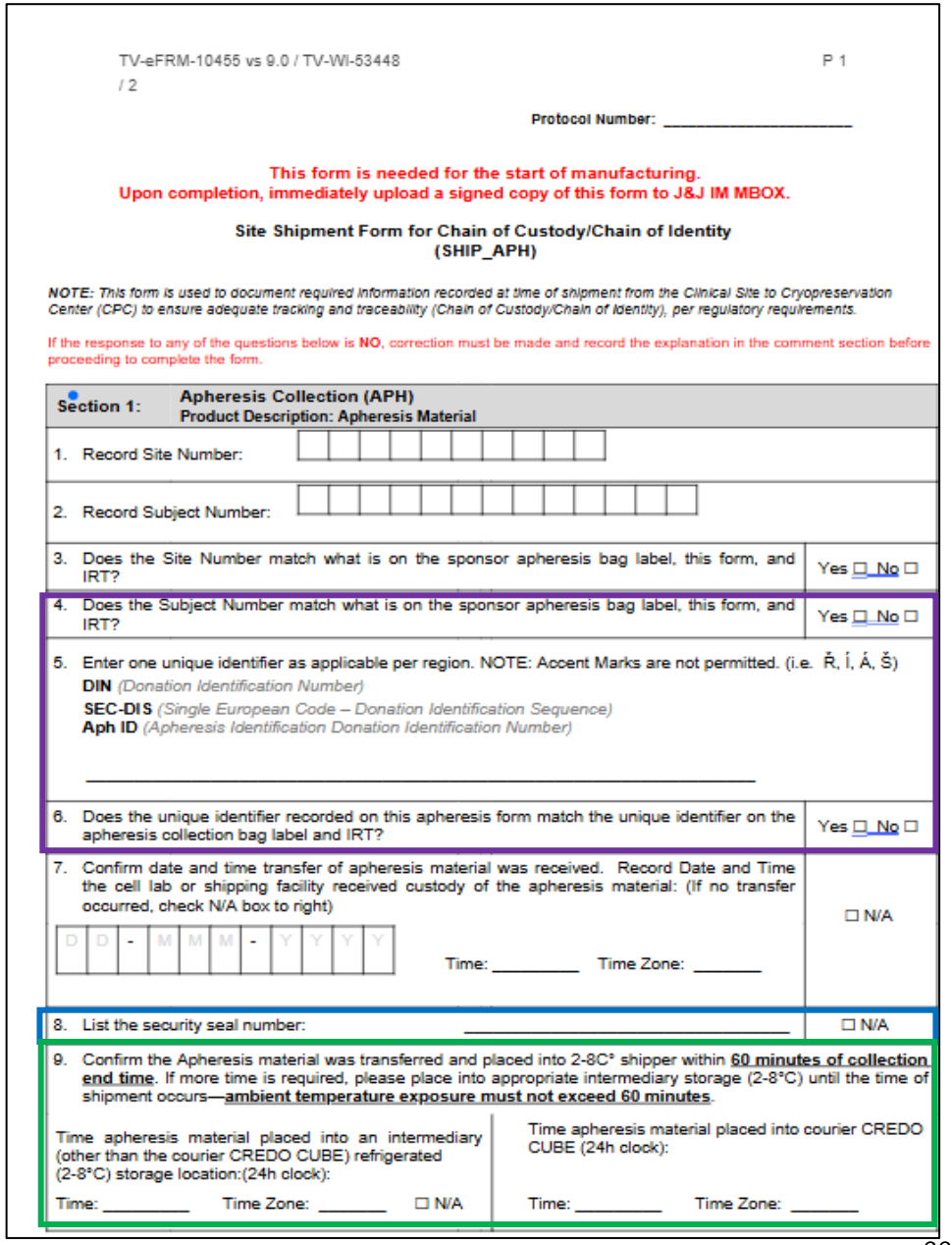
If yes, enter Date and Time (24h clock) collection staff released custody of apheresis material to the cell Laboratory or shipping facility:

D D - M M M - Y Y Y Y Time: _____ Time Zone: _____

Released By:	Name (printed):	Signature: D D - M M M - Y Y Y Y
Received By:	Name (printed):	Signature: D D - M M M - Y Y Y Y

✓ Apheresis Shipment: (SHIP-APH) COC/COI Form

- 4, 5, 6: Ensure the unique identifier information on the form matches the information on the sponsor label, site collection label and in IRT
- 8: The security seal number is not applicable to all regions. If your site didn't receive a seal, check as N/A
- 9: Ensure the Time Zone is accurate for the time of the year (i.e. EDT vs EST)



TV-eFRM-10455 vs 9.0 / TV-WI-53448 P 1
/ 2

Protocol Number: _____

This form is needed for the start of manufacturing.
Upon completion, immediately upload a signed copy of this form to J&J IM MBOX.

Site Shipment Form for Chain of Custody/Chain of Identity (SHIP_APH)

NOTE: This form is used to document required information recorded at time of shipment from the Clinical Site to Cryopreservation Center (CPC) to ensure adequate tracking and traceability (Chain of Custody/Chain of Identity), per regulatory requirements.

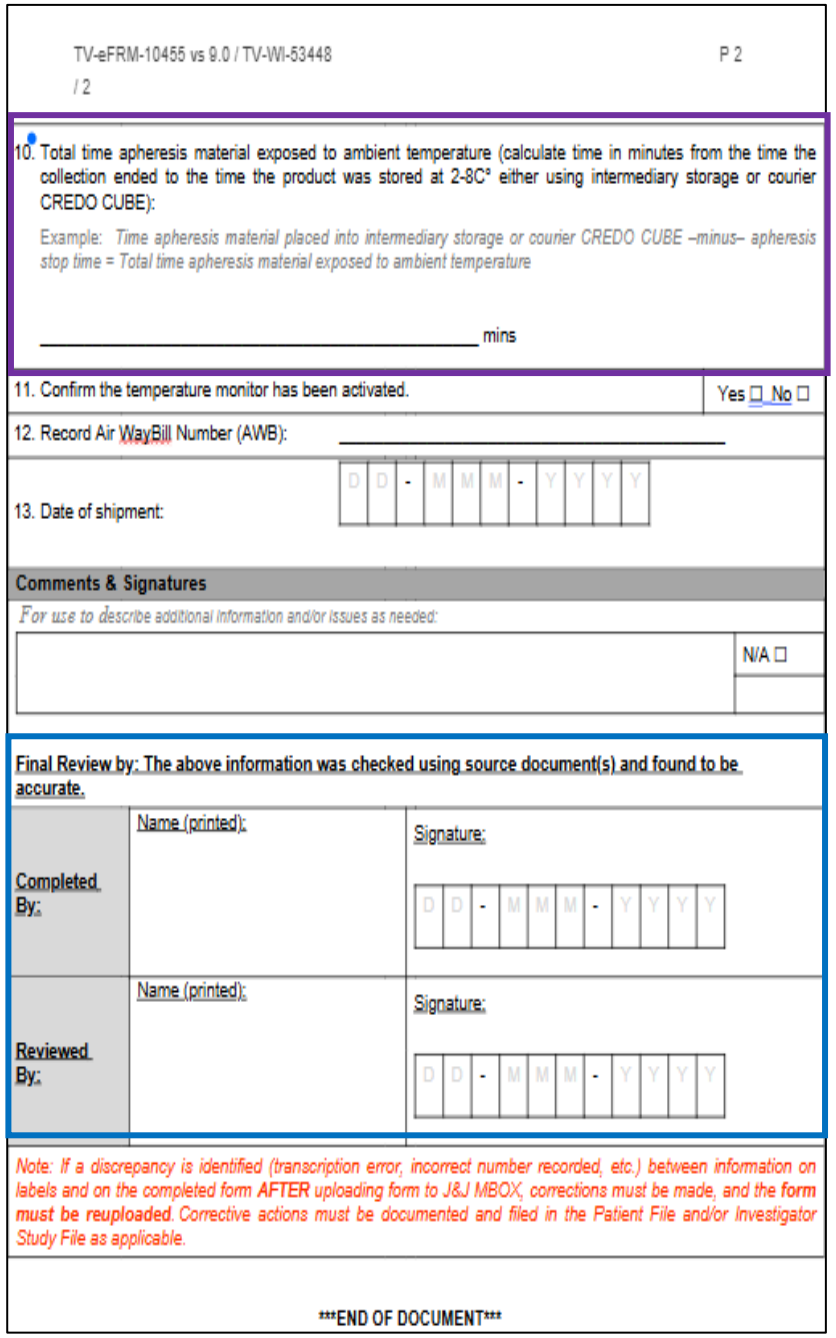
If the response to any of the questions below is **NO**, correction must be made and record the explanation in the comment section before proceeding to complete the form.

Section 1: Apheresis Collection (APH)
Product Description: Apheresis Material

1. Record Site Number: ☐☐☐☐☐☐☐☐☐☐
2. Record Subject Number: ☐☐☐☐☐☐☐☐☐☐☐☐☐
3. Does the Site Number match what is on the sponsor apheresis bag label, this form, and IRT? Yes ☐ No ☐
4. Does the Subject Number match what is on the sponsor apheresis bag label, this form, and IRT? Yes ☐ No ☐
5. Enter one unique identifier as applicable per region. NOTE: Accent Marks are not permitted. (i.e. Ř, Í, Á, Š)
   DIN *(Donation Identification Number)*
   SEC-DIS *(Single European Code – Donation Identification Sequence)*
   Aph ID *(Apheresis Identification Donation Identification Number)*
   _____
6. Does the unique identifier recorded on this apheresis form match the unique identifier on the apheresis collection bag label and IRT? Yes ☐ No ☐
7. Confirm date and time transfer of apheresis material was received. Record Date and Time the cell lab or shipping facility received custody of the apheresis material: (If no transfer occurred, check N/A box to right)
   D D - M M M - Y Y Y Y Time: _____ Time Zone: _____ ☐ N/A
8. List the security seal number: _____ ☐ N/A
9. Confirm the Apheresis material was transferred and placed into 2-8C° shipper within **60 minutes of collection end time**. If more time is required, please place into appropriate intermediary storage (2-8°C) until the time of shipment occurs—**ambient temperature exposure must not exceed 60 minutes**.
   Time apheresis material placed into an intermediary (other than the courier CREDO CUBE) refrigerated (2-8°C) storage location:(24h clock):
   Time: _____ Time Zone: _____ ☐ N/A
   Time apheresis material placed into courier CREDO CUBE (24h clock):
   Time: _____ Time Zone: _____

✓ Apheresis Shipment: (SHIP-APH) COC/COI Form

- 10: Ensure the time in minutes documented in this sections is the time the product was exposed to ambient temperature. For example, if the site used an intermediary refrigerated storage, calculate the exposure using this time minus the end of collection.
- Final Review: all J&J forms have a final review at the end of the form.



TV-eFRM-10455 vs 9.0 / TV-WI-53448 P 2
/ 2

10. Total time apheresis material exposed to ambient temperature (calculate time in minutes from the time the collection ended to the time the product was stored at 2-8C° either using intermediary storage or courier CREDO CUBE):

Example: *Time apheresis material placed into intermediary storage or courier CREDO CUBE –minus– apheresis stop time = Total time apheresis material exposed to ambient temperature*

_____ mins

11. Confirm the temperature monitor has been activated. Yes ☐ No ☐

12. Record Air WayBill Number (AWB): _____

13. Date of shipment: D D - M M M - Y Y Y Y

Comments & Signatures

For use to describe additional information and/or issues as needed:

N/A ☐

Final Review by: The above information was checked using source document(s) and found to be accurate.

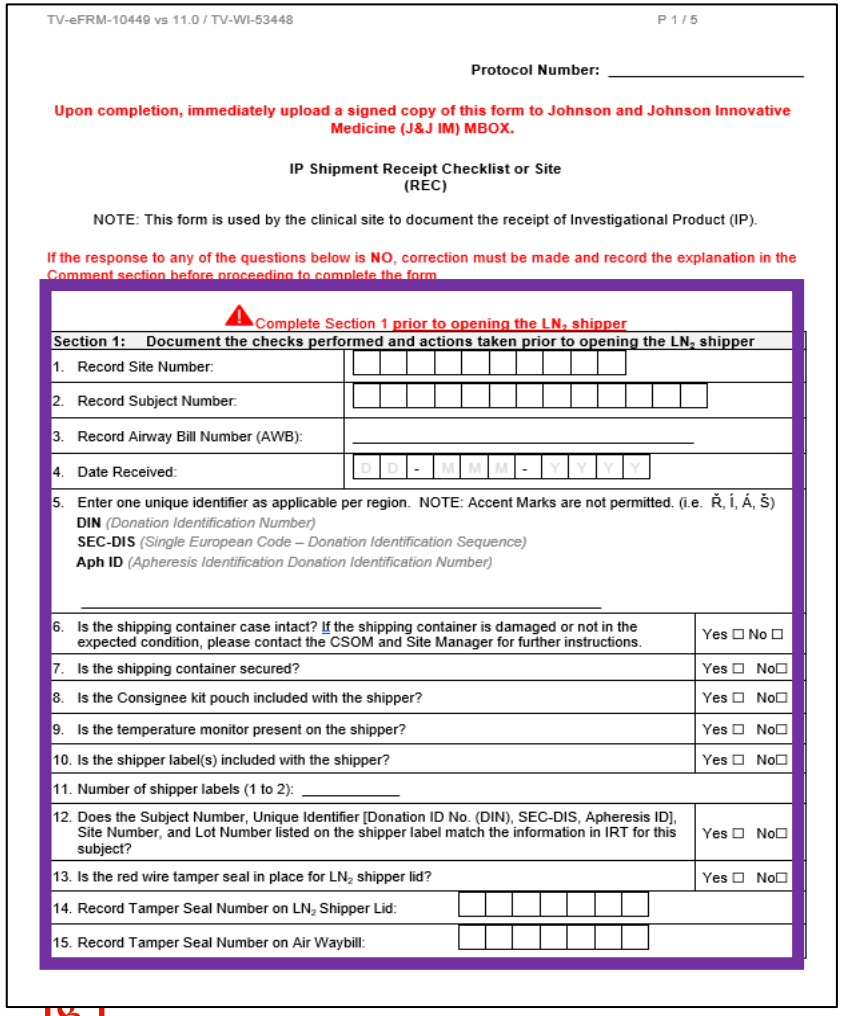
	Name (printed):	Signature:
Completed By:		D D - M M M - Y Y Y Y
Reviewed By:	Name (printed):	Signature: D D - M M M - Y Y Y Y

*Note: If a discrepancy is identified (transcription error, incorrect number recorded, etc.) between information on labels and on the completed form **AFTER** uploading form to J&J MBOX, corrections must be made, and the **form must be reuploaded**. Corrective actions must be documented and filed in the Patient File and/or Investigator Study File as applicable.*

END OF DOCUMENT

✓ Receipt of IP: (REC) COC/COI Form

Complete all of Section 1 prior to opening the LN2 Shipper



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Protocol Number: _____

Upon completion, immediately upload a signed copy of this form to Johnson and Johnson Innovative Medicine (J&J IM) MBOX.

IP Shipment Receipt Checklist or Site (REC)

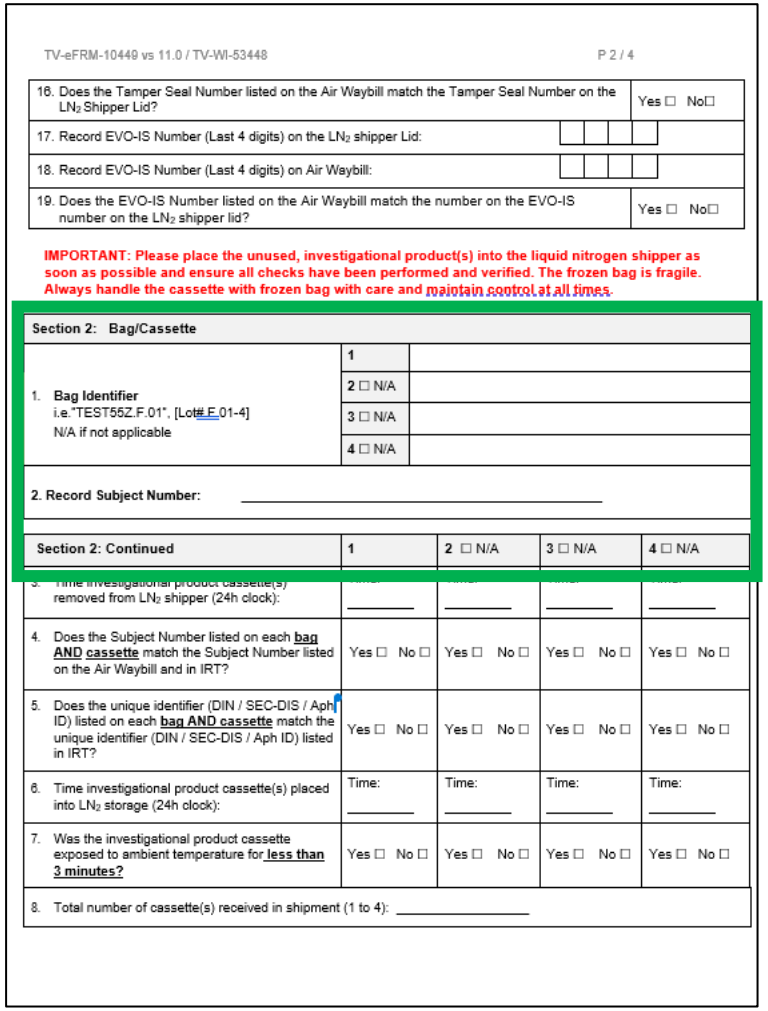
NOTE: This form is used by the clinical site to document the receipt of Investigational Product (IP).

If the response to any of the questions below is NO, correction must be made and record the explanation in the Comment section before proceeding to complete the form

⚠ Complete Section 1 **prior to opening the LN_2 shipper**

Section 1: Document the checks performed and actions taken prior to opening the LN_2 shipper	
1. Record Site Number:	☐☐☐☐☐☐☐☐☐☐
2. Record Subject Number:	☐☐☐☐☐☐☐☐☐☐☐☐☐
3. Record Airway Bill Number (AWB):	_____
4. Date Received:	D D - M M M - Y Y Y Y
5. Enter one unique identifier as applicable per region. NOTE: Accent Marks are not permitted. (i.e. Ř, Í, Á, Š) **DIN** *(Donation Identification Number)* **SEC-DIS** *(Single European Code – Donation Identification Sequence)* **Aph ID** *(Apheresis Identification Donation Identification Number)* _____	
6. Is the shipping container case intact? If the shipping container is damaged or not in the expected condition, please contact the CSOM and Site Manager for further instructions.	Yes ☐ No ☐
7. Is the shipping container secured?	Yes ☐ No☐
8. Is the Consignee kit pouch included with the shipper?	Yes ☐ No☐
9. Is the temperature monitor present on the shipper?	Yes ☐ No☐
10. Is the shipper label(s) included with the shipper?	Yes ☐ No☐
11. Number of shipper labels (1 to 2): _____	
12. Does the Subject Number, Unique Identifier [Donation ID No. (DIN), SEC-DIS, Apheresis ID], Site Number, and Lot Number listed on the shipper label match the information in IRT for this subject?	Yes ☐ No☐
13. Is the red wire tamper seal in place for LN_2 shipper lid?	Yes ☐ No☐
14. Record Tamper Seal Number on LN_2 Shipper Lid:	☐☐☐☐☐☐☐
15. Record Tamper Seal Number on Air Waybill:	☐☐☐☐☐☐☐

Ensure you mark N/A as applicable. Bag ID # must be legible



TV-eFRM-10449 vs 11.0 / TV-WI-53448 P 2 / 4

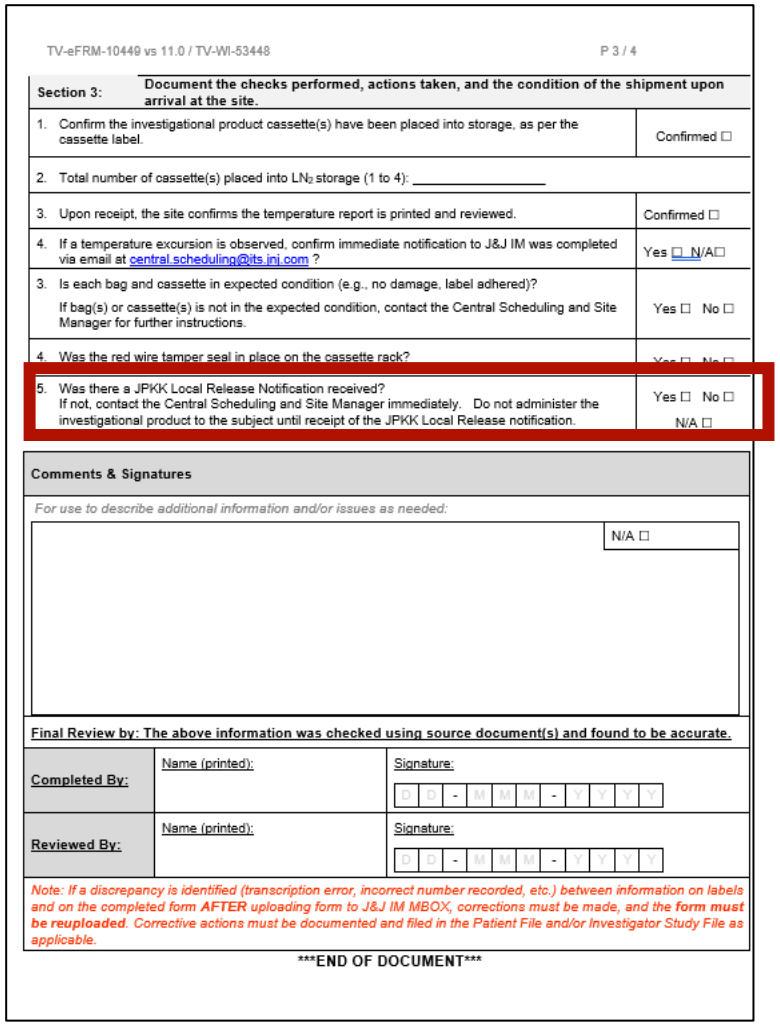
16. Does the Tamper Seal Number listed on the Air Waybill match the Tamper Seal Number on the LN_2 Shipper Lid?	Yes ☐ No☐
17. Record EVO-IS Number (Last 4 digits) on the LN_2 shipper Lid:	☐☐☐☐
18. Record EVO-IS Number (Last 4 digits) on Air Waybill:	☐☐☐☐
19. Does the EVO-IS Number listed on the Air Waybill match the number on the EVO-IS number on the LN_2 shipper lid?	Yes ☐ No☐

IMPORTANT: Please place the unused, investigational product(s) into the liquid nitrogen shipper as soon as possible and ensure all checks have been performed and verified. The frozen bag is fragile. Always handle the cassette with frozen bag with care and maintain control at all times.

Section 2: Bag/Cassette		
1. **Bag Identifier** i.e."TEST55Z.F.01", [Lot# F.01-4] N/A if not applicable	1	
	2 ☐ N/A	
	3 ☐ N/A	
	4 ☐ N/A	
2. Record Subject Number: _____		

Section 2: Continued	**1**	**2** ☐ N/A	**3** ☐ N/A	**4** ☐ N/A
3. Time investigational product cassette(s) removed from LN_2 shipper (24h clock):	_____	_____	_____	_____
4. Does the Subject Number listed on each **bag AND cassette** match the Subject Number listed on the Air Waybill and in IRT?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
5. Does the unique identifier (DIN / SEC-DIS / Aph ID) listed on each **bag AND cassette** match the unique identifier (DIN / SEC-DIS / Aph ID) listed in IRT?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
6. Time investigational product cassette(s) placed into LN_2 storage (24h clock):	Time: _____	Time: _____	Time: _____	Time: _____
7. Was the investigational product cassette exposed to ambient temperature for **less than 3 minutes?**	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
8. Total number of cassette(s) received in shipment (1 to 4): _____				

Mark N/A if not applicable to your region



TV-eFRM-10449 vs 11.0 / TV-WI-53448 P 3 / 4

Section 3:	**Document the checks performed, actions taken, and the condition of the shipment upon arrival at the site.**
1. Confirm the investigational product cassette(s) have been placed into storage, as per the cassette label.	Confirmed ☐
2. Total number of cassette(s) placed into LN_2 storage (1 to 4): _____	
3. Upon receipt, the site confirms the temperature report is printed and reviewed.	Confirmed ☐
4. If a temperature excursion is observed, confirm immediate notification to J&J IM was completed via email at central.scheduling@its.jnj.com ?	Yes ☐ N/A☐
3. Is each bag and cassette in expected condition (e.g., no damage, label adhered)? If bag(s) or cassette(s) is not in the expected condition, contact the Central Scheduling and Site Manager for further instructions.	Yes ☐ No ☐
4. Was the red wire tamper seal in place on the cassette rack?	Yes ☐ No ☐
5. Was there a JPKK Local Release Notification received? If not, contact the Central Scheduling and Site Manager immediately. Do not administer the investigational product to the subject until receipt of the JPKK Local Release notification.	Yes ☐ No ☐ N/A ☐

Comments & Signatures

For use to describe additional information and/or issues as needed:

N/A ☐

Final Review by: The above information was checked using source document(s) and found to be accurate.

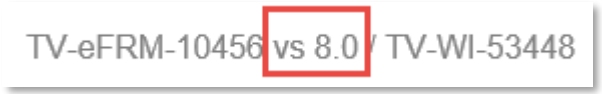
Completed By:	Name (printed):	Signature: D D - M M M - Y Y Y Y
Reviewed By:	Name (printed):	Signature: D D - M M M - Y Y Y Y

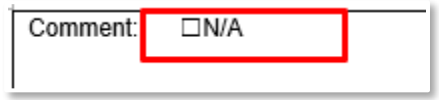
*Note: If a discrepancy is identified (transcription error, incorrect number recorded, etc.) between information on labels and on the completed form **AFTER** uploading form to J&J IM MBOX, corrections must be made, and the **form must be reuploaded**. Corrective actions must be documented and filed in the Patient File and/or Investigator Study File as applicable.*

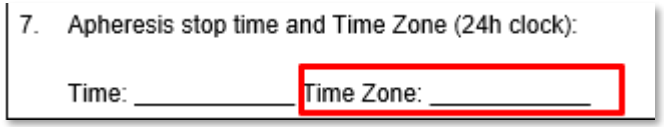
END OF DOCUMENT

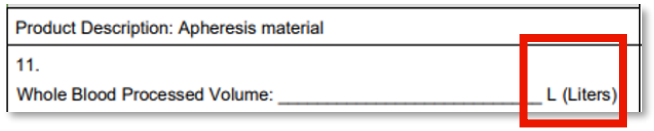
Common Discrepancies

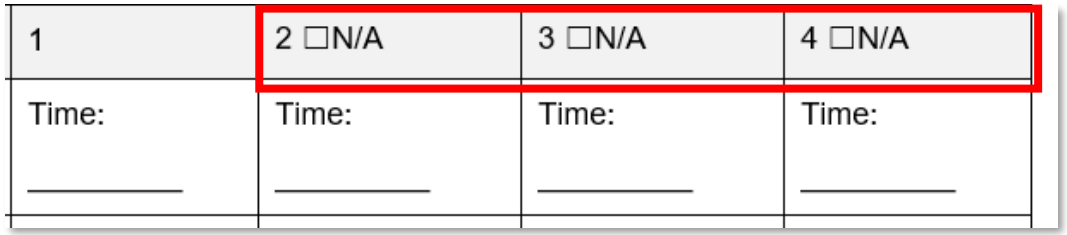
- <u>All forms</u>
  - Use of **incorrect/outdated version** of the forms.
    - ➢ Do not save forms on personal files or save printed forms for future use
    - ➢ Make sure to download forms from electronic IP Binder
    - ➢ See Slides Module 8 for the COC/I Form References and Version Numbers
  - **Incomplete** N/A boxes
  - Date format must be **DD-MMM-YYYY**
  - **Ineligible** letters or numbers
- <u>On apheresis transfer form</u>
  - **Time zone** not documented correctly (e.g., EST vs EDT)
  - Entering the volumes in the correct unit (mL vs. L)
- <u>On receipt & return forms</u>
  - **Not checking the N/A** on the columns not used to receipt products











<u>IMPORTANT:</u> IRT notification is needed to enter site number & subject number on all forms

Critical steps: COC/COI Forms

Be prepared:

- ✓ Bulk supply binder with labelling supplies is available
- ✓ Correct version of the forms available in the CAR-T IP binder
- ✓ All site staff is familiar with all forms and sources of information for each form
- ✓ All site staff involved in the procedures of collection, labeling, packing, shipping of apheresis material, and receipt of IP must follow steps described on the CTPPM and have training documented

Share IRT info with Collection and Packing staff

- ✓ Collection staff needs IRT screening notification prior to start collection
- ✓ Packing/Shipping staff needs IRT apheresis info (screenshot), prior to start packing

Timely upload to MBOX upon completion

- ✓ Manufacturing sites need the completed forms
- ✓ Completed forms should be uploaded to MBOX and filed in the IP Binder **ON THE DAY of the apheresis collection**

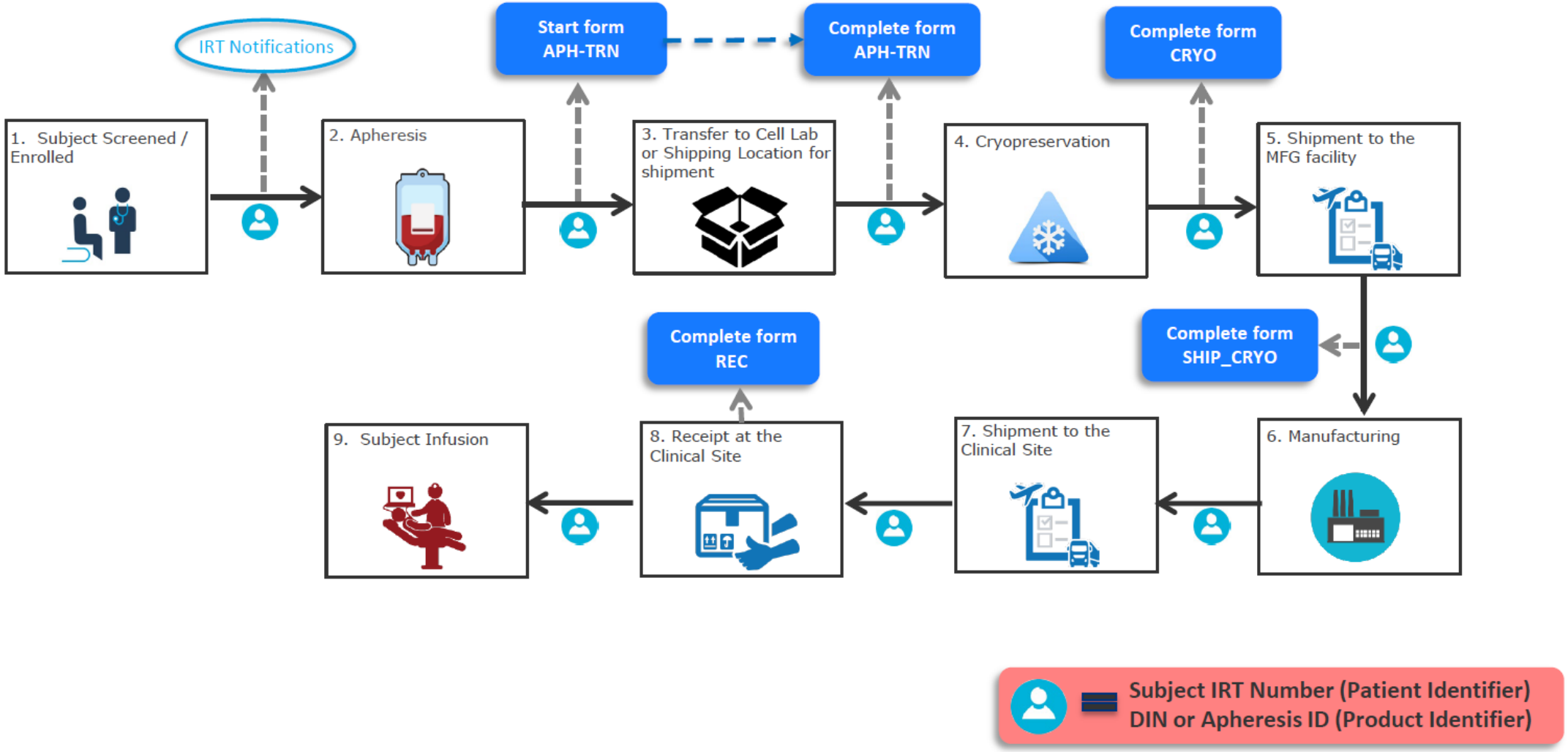
Study/Region Specific Attachments

Modified CTPPM procedures apply as outlined in the following memorandums:

- EMN28/68284528MMY3005 - Module 7
- 68284528SMM2001 Memorandum dated 21-APR-2023

NOTE: The above list is non-exhaustive as additional changes may be necessary prior to the next version update. The memorandums for your region/study can be found in your IP binder and on the study portal. Contact your SM for a current complete list of memorandums.

COC/COI Map On-site Cryopreservation (only applicable for onsite cryo sites)



Cell Therapy COC/COI Forms (only applicable for on-site cryo sites)

Sponsor COC/COI Form Number	Form Description	Form Name
TV-eFRM-10456	Apheresis Chain of Custody/Chain of Identity Form	APH-TRN
TV-FRM-62994	Receipt of Apheresis Material (or MNC, Apheresis) and Cryopreservation at Cryopreservation Center Cryopreservation must start within 32 hours from end of collection	CRYO
TV-FRM-62995	Shipment of Cryopreserved Apheresis Material (or MNC, Apheresis Cryopreserved) at Cryopreservation Center	SHIP_CRYO
TV-eFRM-10449	IP Shipment Receipt Checklist for Site	REC
TV-eFRM-10450	CAR-T IP Return Shipment Form	RTN
TV-FRM-57192	CAR-T IP On-Site Destruction Form	N/A

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Receipt of Apheresis Material (or MNC, Apheresis) and Cryopreservation at Cryopreservation Center COC/COI Form CRYO Section 1 (only applicable for onsite cryo sites)

1, 2 & 3: Each form captures the subject identifiers and product identifiers

4, 5 & 6: MNC, Apheresis Material receipt, inspection and storage until processing

IMPORTANT: Always handle the Apheresis material bag with care and maintain control at all times.

Section 1	Document the checks performed, actions taken, and the condition of the shipment upon arrival at the site.		
	Material Description: **Apheresis material**	Yes	No
1.	List Site Number: ☐☐☐☐☐☐☐☐☐☐ Does the Site Number listed on the **Janssen apheresis label** match the Site number in **IRT**?	☐	☐
2.	List Subject Number: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐ Does the Subject Number listed on the **Janssen apheresis label** match the subject number in **IRT?**	☐	☐
3.	List SEC-DIS, Donation ID No (DIN)., or Apheresis ID: *Please note for EEA only SEC-DIS (21-digits) must be used* _____ As applicable does the SEC-DIS, Donation ID No. (DIN), or Apheresis ID listed on the **Janssen apheresis label or site apheresis bag label or shipping document** match the SEC-DIS, Donation ID No. (DIN), or Apheresis ID in **IRT**?	☐	☐
4.	Date and Time apheresis material received at cryopreservation center (dd-mmm-yyyy): _____ Time_____ Time Zone _____		
5.	Is the Apheresis material bag in the expected condition (e.g. no bag damage, label adhered, etc.)? If the Apheresis material bag is damaged or not in expected condition, please contact Janssen immediately.	☐	☐
6.	Will the Apheresis material bag be kept in the cold (2-8°C) shipper until time of cryopreservation? If not, please record the 2-8°C storage unit the Apheresis material bag is kept in until time of cryopreservation: (Please N/A this if not applicable) _____ ☐N/A	☐	☐

J&J

Receipt of Apheresis Material (or MNC, Apheresis) and Cryopreservation at Cryopreservation Center COC/COI Form

CRYO Section 2/3 (only applicable for onsite cryo sites)

Section 2: For apheresis material received from external collection sites

Section 2 to be completed by Cryopreservation center that receives apheresis material from external sites. Please N/A if apheresis material was collected at the same site that will perform cryopreservation and continue to Section 3.

☐ N/A (This section does not apply)

Section 2	Document the checks performed, actions taken, and the condition of the shipment upon arrival at the cryopreservation center.		
	Material Description: **Apheresis material**	**Yes**	**No**
1.	List the serial number of the temperature monitoring device: _____ For ***Japan*** Cryopreservation center only, list the security seal number on the shipper box: ☐N/A (for all other Cryopreservation centers) _____		
2.	Does the downloaded temperature data from the temperature monitoring device conform to the Janssen shipping profile? • Confirm there are no unexpected spikes in temperature during the shipment and temperature is maintained at 2-8°C. If there is an unexpected spike and the temperature goes out-of-range (2-8°C) during transit, contact Janssen immediately. Refer to the Janssen Shipping Instructions, complete a Temperature Out-of-Range (TOR) report and proceed according to instructions on the form.	☐	☐

Section 3: For apheresis material received from within the same site
Document exposure to room temperature

Section 3 to be completed by Cryopreservation center that receives and cryopreserve Apheresis material collected at their site. Please N/A if not applicable.

☐ N/A (This section does not apply)

Section 3	Document the checks performed, actions taken, and the condition of the shipment upon arrival at the site.
1.	Apheresis material must be transferred, and processing started within **60 minutes of collection end time**. If more time is required, please place into appropriate storage (2-8°C) until the start of processing —**ambient temperature exposure must not exceed 60 minutes.** Time Apheresis material placed into an intermediary refrigerated (2-8°C) storage location:(24h clock): _____ ☐ N/A
2.	Total time Apheresis material exposed to ambient temperature (calculate time in minutes from the time the collection ended to the time the product was stored at 2-8C° or processing started): _____ mins

J&J

Receipt of Apheresis Material (or MNC, Apheresis) and Cryopreservation at Cryopreservation Center COC/COI Form

CRYO Section 5 (only applicable for onsite cryo sites)

3, 4 & 5: Cell processing milestones

6 & 7: Cryopreserved material storage

Section 5	Document the checks performed, actions taken, and the condition of the shipment upon arrival at the site.	Completed by (Initial & Date)	Reviewed by Initial & Date)
3.	Date and Time Apheresis material removed from storage (2-8°C)/Date and Time of the start of processing: Date (dd-mmm-yyyy): _____ Time (24h clock): _____ Time Zone_____		
4.	Date and Time Apheresis material(s) placed into CRF. Date (dd-mmm-yyyy): _____ Time (24h clock): _____Time Zone_____		
5.	Record cryopreservation material details for EACH cryobag:		

Bag Identifier (i.e. NBGS03F.C.01, A1 of 3)	Total Bag Volume (mL) (Cells + CS10)
Bag ID_____	
Bag ID_____	☐N/A
Bag ID_____	☐N/A
Bag ID_____	☐N/A

6.	Date and Time cryopreserved apheresis material(s) placed into LN_2 storage: Date (dd-mmm-yyyy): _____ Time (24h clock): _____Time Zone_____		
7.	Number of cassettes placed into LN_2 storage (1 to 4): _____		

J&J

Shipment of Cryopreserved Apheresis Material (or MNC, Apheresis Cryopreserved) at Cryopreservation Center COC/COI Form SHIP_CRYO **(only applicable for onsite cryo sites)**

Shipment form has x3 sections

Section 1 is to be completed prior to opening the LN_2 shipper :

- Review shipper temperature
- Review documentation and packing material

⚠ Complete Section 1 **prior to opening the LN_2 shipper**

Section 1:

Document the checks performed and actions taken prior to shipment of cryopreserved apheresis material.	**Yes**	**No**
1. List EVO-IS number (Last 4 digits) on the LN_2 shipper lid: ☐☐☐☐ List EVO-IS number (Last 4 digits) on Air Waybill: ☐☐☐☐ Does the EVO-IS number listed on the Air Waybill match the EVO-IS number on the LN_2 shipper lid?	☐	☐
2. List Tamper seal number from Shipper kit pouch: ☐☐☐☐☐☐☐ List Tamper seal number on Air Waybill: ☐☐☐☐☐☐☐ Does the tamper seal number listed on the Air Waybill match the tamper seal number from the Shipper kit pouch?	☐	☐
3. Is the shipping container case intact? If the shipping container is damaged or not in expected condition, please contact central scheduling.	☐	☐
4. Is the temperature of the shipping container within range? • If STEADY light, tick 'Yes' and proceed with packing. • If FLASHING light, tick 'No', Contact immediately Central scheduling and wait until further instructions are given. • If NO light is present, scan QR code with smart device and check if temperature is within the labeled storage condition of the cryopreserved apheresis material. If within range tick 'Yes" and proceed with packing. • If "not" within range, contact immediately Central scheduling and wait until further instructions are given. IMPORTANT: Include a note in the comment section if the temperature monitor is not functioning upon receipt.	☐	☐
5. Are the shipper kit pouch and consignee kit pouch inside the outer shipper case?	☐	☐
6. Are the zip ties secured on the LN_2 shipper lid?	☐	☐
7. Total number of cassette(s) to be shipped (1 to 4): _____		

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Shipment of Cryopreserved Apheresis Material (or MNC, Apheresis Cryopreserved) at Cryopreservation Center COC/COI Form SHIP_CRYO **(only applicable for onsite cryo sites)**

Section 2 documents the number of the cassettes & bags including a check of identifiers

Critical to confirm cryopreserved apheresis product was not exposed to ambient temperature for greater than 3 minutes

IMPORTANT: Please place the cryopreserved apheresis material into the LN_2 shipper as soon as possible, Ensure all checks have been performed and verified. The frozen bag(s) is fragile. Always handle the cassette(s) with frozen bag(s) with care and maintain control at all times.

Section 2:	Bag/Cassette			
Bag Identifier (i.e. Bag 1 of 3, A0) N/A if not applicable	_____	_____ ☐N/A	_____ ☐N/A	_____ ☐N/A
Time cryopreserved apheresis material cassette(s) removed from cell lab LN_2 storage (24h clock):	Time: _____	Time: _____	Time: _____	Time: _____
List site number: ☐☐☐☐☐☐☐☐☐☐ Does the site number listed on each **cassette** match the Site Number listed in: • IRT?	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No
List subject number: ☐☐☐☐☐☐☐☐☐☐☐☐ Does the subject number listed on each **cassette** match the subject umber listed on: • The Air Waybill? • IRT?	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No
List SEC-DIS, Donation ID No (DIN)., or Apheresis ID: *Please note for EU only SEC-DIS (21-digits) must be used* _____ Does the SEC-DIS, Donation ID No. (DIN), or Apheresis ID listed on each **cassette** match the SEC-DIS, Donation ID No (DIN)., or Apheresis ID listed in IRT?	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No
Time, cryopreserved apheresis material cassette(s) placed into LN_2 shipper and lid closed (24h clock):	Time: _____	Time: _____	Time: _____	Time: _____
Was an intermediary LN_2 storage location used?	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No
Confirm, cryopreserved apheresis material or retain cassette(s) were not exposed to ambient temperature for greater than 3 minutes:	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No

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Shipment of Cryopreserved Apheresis Material (or MNC, Apheresis Cryopreserved) at Cryopreservation Center COC/COI Form SHIP_CRYO (only applicable for onsite cryo sites)

- Section 3 documents the number of the cassettes placed in the LN_2 shipper and packing
- Add any relevant comments. If none, make sure to tick N/A

IMPORTANT: The frozen bag(s) is fragile. Always handle the cassette(s) with frozen bag(s) with care and maintain control at all times

Section 3:

Document the checks performed and actions taken prior to shipment of, cryopreserved apheresis material.	**Yes**	**No**
1. Number of cassettes placed into LN_2 shipper (1 to 4): _____		
2. Is the red wire tamper seal in place on the cassette rack?	☐	☐
3. Is the red wire tamper seal in place for LN_2 shipper lid?	☐	☐
4. Is the shipper label(s) included with the LN_2 shipper? Number of shipper labels (1 to 3): _____	☐	☐
5. Is the Consignee kit pouch inside the plastic pouch?	☐	☐
6. Is the shipping container case secured?	☐	☐

Describe any comments or issues (missing items, mismatching numbers, typos, damage, temperature out-of-range) with the shipment:

Comment: ☐N/A

Completed By:	Name (printed):	Signature: Date (dd-mmm-yyyy):
Reviewed By:	Name (printed):	Signature: Date (dd-mmm-yyyy):

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Thank you

If you have more questions, please contact your site manager

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