



# SONOMA APHERESIS COLLECTION PROTOCOL

Collections for Clinical Use in SBT777101 Study

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## Sonoma Apheresis Collection Protocol

### 1. Purpose:

The Sonoma Apheresis Collection Protocol is designed to allow Sonoma to gather consistent collection data and to standardize collection, packaging, and labeling requirements across all clinical-use MNC (Mononuclear Cell) collections.

### 2. Scope:

This protocol applies to Sonoma approved Collection Sites. The autologous collected MNC product will be used for the purpose of manufacturing into an investigational product for infusion. This protocol covers Sonoma specific ordering, labeling, pack-out, shipping and handling requirements.

### 3. Sonoma Contact information:

Title/Role	Name	Email	Phone
Sonoma Patient Operations (scheduling and collection/protocol support)		PatientOps@sonomabio.com	(650) 671-4447
Director of Patient Operations (Primary Sonoma Apheresis Business Contact)	Mindy Jensen	mjensen@sonomabio.com	(253) 224-5058

### 4. Terms & Definitions:

**Apheresis Shipping Kit:** The shipping kit will arrive in advance of the Apheresis Collection and contains the materials needed as part of the pack-out and shipping requirements (see materials section for this breakdown).

**Collection End Time:** The local time the collection procedure ends and MNCs are no longer being collected from the donor. This time is calculated as Start of Rinse back/Reinfusion or loss of venous access, whichever comes first. This time is also the start of the product lifespan.

**Collection Site Donor # (DID):** The Collection Site's generated and managed unique number that identifies the person/donor who donated the apheresis product. This number is not issued, tracked or managed by Sonoma Biotherapeutics but the collection form allows for the data to be captured at time of apheresis collection.

**Collection Start Time:** The local time the collection procedure is started. The time is calculated from when the collection machine is programmed to begin the collection and will be dependent on the type of machine the Collection Site uses.

**Courier Order Confirmation:** The email summary of the Apheresis Collection pickup details, including the pickup date & time, Collection Site address and contact name & phone as well as the delivery details. The Sonoma COI# will also be displayed for verification purposes.

**Courier Waybill:** Also known as a Bill of Lading (BOL) or House Waybill (HAWB/AWB), this documentation is provided to the Collection Site by Sonoma Patient Operations and must be printed, signed, and sent with the product to the manufacturing facility.

**Donation ID (DIN) or Lot #:** The Collection Site's generated and managed unique number that identifies the apheresis product. This number is not issued, tracked, or managed by Sonoma Biotherapeutics but the collection form allows for the data capture at time of apheresis collection.

**Manufacturing Facility:** The facility the Apheresis Starting Material is shipped to for further manufacturing into an investigational product.

**Product bag label:** The Apheresis Site generated MNC product bag label containing the Sonoma provided, site verified, subject and product identifiers as well as the required statements (ie. identifying the intended use, handling requirements etc.).

**Subject Record Form:** Details the subject and product identifiers and collection authorization from the Principal Investigator. This form should be used for MNC product label generation and verification purposes.

**Shipper:** The temperature-controlled shipping unit used to transport the Apheresis product to the manufacturing facility.

**Sonoma Apheresis Collection Form:** Sonoma form used to capture the details of the collection. This form travels with the MNC product to the manufacturing facility.

**Sonoma Chain of Identity Number (COI #):** A Sonoma Biotherapeutics managed and controlled unique identifier that is generated and assigned to each autologous order. The Chain of Identity Number is directly associated to the subject identifiers and is used for traceability and verification throughout the entire cellular therapy process, from subject onboarding to Investigational Product infusion and post-infusion monitoring.

**Total Product Volume (TPV):** The total volume collected into the final product bag.

## 5. Materials:

### 5.1. Sonoma provided materials:

#### 5.1.1. Materials provided electronically:

- Subject Record Form with collection schedule, subject, and product identifiers
- Initiated Sonoma Apheresis Collection Form (Section 1 completed by Sonoma) sent via DocuSign
- Courier Shipping Documentation:
  - Courier Order Confirmation with shipment summary
  - Courier Waybill/Bill of Lading (to be printed at Collection Site)

#### 5.1.2. Materials Shipped in advance of collection

- Apheresis Shipping Kit, containing:

- NanoCool Long Haul Shipping Unit Part # 2-85396 (1ea)  
**Note:** If a NanoCool is unavailable, a preconditioned Credo Cube may be sent as a substitute. The Collection Site will be notified of any substitutions, additional or changed steps, as required.
- Temperature Data Logger (1ea)
- Biohazard Specimen Transport Bag with absorbent pads (1ea)
- Exterior Shipper Labels to be adhered at collection site:
  - Exempt Human Specimen (1ea)
  - Do Not X-Ray (1ea)
  - Document Sleeve for waybills (2ea)

5.2. Collection Site provided materials:

- Packing tape to seal shipping box
- Apheresis Collection generated product bag label
- Collection Site sourced collection materials and supplies

## 6. Sonoma Shipping Supplies Receipt, Inspection and Storage:

6.1. Upon delivery of the Sonoma provided shipping kit, inspect to ensure the NanoCool is intact with no visible damage or issues and all items listed in section 5.1.2. are included.

**Note:** Contact Sonoma Patient Operations if the shipper does not arrive, is damaged or missing parts.

6.2. Place the shipping kit in internal storage to be used only for Sonoma scheduled collections. The kit should be stored at room temperature conditions.

6.3. If additional kits are required, please contact Sonoma Patient Operations for an additional shipment.

Example of shipping Supplies packed inside NanoCool for delivery:



## 7. Scheduling & Reporting Deviations

7.1. Follow the Collection Site's process for reviewing and approving the subject to undergo the MNC collection procedure. Any subject health records, labs etc. should be obtained directly from the subject's prescribing physician's office. Contact Sonoma Patient Operations if there are any issues obtaining or concerns with the Collection Site's ability to move forward with the scheduled collection.

7.2. In advance of the scheduled collection, the Collection Site team will receive:

- 7.2.1. Subject Record Form with subject identifiers used to generate MNC product labels and prescribing physician/Clinical Site contact details.
- 7.2.2. The initiated Sonoma Apheresis Collection Form to be completed electronically on day of collection (sent via DocuSign).
- 7.2.3. The Courier BOL and summary of scheduled pickup details.
- 7.3. If there are any issues or delays that arise before or during the collection that will impact the quality or integrity of the product, ability to continue or complete the collection, or impact the scheduled courier pickup time, please contact Sonoma Patient Operations.

## **8. Apheresis Collection Bag Label Generation:**

- 8.1. Follow your site's approved internal procedures for generating Apheresis product labels.
- 8.2. For Sonoma, the Apheresis product bag label must contain, at a minimum, the following information. For the product and subject identifiers, this is obtained from the Subject Record Form.
  - 8.2.1. Product and Subject Identifiers:
    - Subject First & Last Name
    - Subject Date of Birth (DOB)
    - Subject ID
    - Sonoma COI Number
    - Temperature conditions: 2-8°C
  - 8.2.2. The following statements, or variation of the statements:
    - For Autologous Use Only
    - For Use in Further Manufacturing
    - For Clinical Trial Use Only
    - Not Evaluated for Infectious Substances
    - Do Not Irradiate
- NOTE:** Do **NOT** input an expiration date or time. The product lifespan is calculated by our manufacturer using data from the Sonoma Apheresis Collection Form.
- 8.3. The subject identifiers and Sonoma COI# must exactly match the Subject Record Form. The subject identifiers on this form originated from the Principal Investigator/Clinical Site. If there are any concerns or discrepancies, contact Sonoma Patient Operations for resolution.

## **9. Apheresis Collection Readiness Steps:**

- 9.1. Review the initiated Apheresis Collection Form, provided by Sonoma Patient Operations via DocuSign:
  - 9.1.1. Verify all fields of Section 1.A., "Summary of Scheduled Apheresis," is as expected. These schedule details should match the dates listed on the Subject Record Form.
- 9.2. Prepare the Apheresis Shipping Kit:
  - 9.2.1. Open the external cardboard carton and verify the shipper is within expiration (expiry location may vary).
  - 9.2.2. Remove the cooling engine (lid) and place it, foil side down, on a hard, flat, clean, surface. The white actuator button should be pointing upward.
  - 9.2.3. Verify the actuator button, located on the inner lid, is still intact and has not yet been activated/pressed.

9.2.4. NanoCool Logo transitioning back to room temperature prior to activation:



**Note:** The NanoCool logo, located on the inside of the lid, should be white and will turn blue upon activation. **TIP:** If the NanoCool logo arrives blue – prior to activation (shown above), leave the lid off at room temperature and wait a minimum of 15 minutes. During transit or storage in cooler temperatures, it is possible for the logo to turn blue. Allowing the lid to be exposed to room temperature conditions will turn the logo back to white. Please contact Sonoma Patient Operations if there are any issues.

**DO NOT** press on the actuator button until you have completed the Apheresis Collection as there is no need to precondition the shipper. Steps for activating the NanoCool are covered later in this manual.

## 10. Completing the Apheresis Collection

- 10.1. Only FDA approved and Collection Site qualified equipment, as well as trained staff should be utilized in the collection and handling of Sonoma scheduled MNC Collections.
- 10.2. Follow the Collection Site's internal procedures and guidelines for machine set up, kitting, collection materials and supplies used during the collection procedure.
- 10.3. Review and verify the generated apheresis product bag label prior to the start of collection:
  - 10.3.1. Verify the Subject Identifiers and Sonoma COI # match the Subject Record Form and Sonoma initiated Apheresis Collection Form prior to adhering the label to the product bag to ensure they all match.
  - 10.3.2. Verify the Subject Name and Date of Birth against the Subject's supplied government issued photo ID (ie. Driver's License, Passport).

**NOTE:** We ask that the subject provide the same ID used to enroll in the study for consistency purposes.
  - 10.3.3. Apply the verified product bag label to the collection bag prior to the start of collection or at a minimum, prior to disconnecting the patient from the machine.
  - 10.3.4. The subject should also verbally verify their name and DOB listed on the apheresis product label.

**NOTE:** If there are any discrepancies, do NOT continue and contact Sonoma Patient Operations immediately for instructions on how to proceed.
- 10.4. Target processing 1.5-2.0x the subject's Total Blood Volume (TBV) but do not exceed a Total Product Volume (TPV) of 340mLs.

**Note:** Do NOT collect or add any additional plasma to the product bag.
- 10.5. Upon completion of the collection, seal the collection line with a minimum of two heat seals or clamps and a minimum of two inches (five centimeters) of tubing.

- 10.6. Do not use the access ports on the collection bag for any reason as these are needed intact for the manufacturing of the product.
- 10.7. Do not sample or test the collected product.
- 10.8. Visually inspect the product to ensure no leakage before packaging for shipment.
- 10.9. Only use Sonoma provided shipping materials unless otherwise instructed.

## 11. Completing the Sonoma Apheresis Collection Form

- 11.1. Open the applicable Sonoma Apheresis Collection Form to complete the fields. The link to the collection form is sent electronically via DocuSign fillable form in advance of the scheduled collection.

**Note:** If your collection site cannot accommodate completing the form via DocuSign, please contact Sonoma Patient Operations for further instruction.

- 11.2. The Sonoma Apheresis Collection Form can be completed concurrently/at time of collection or can be completed immediately post collection end and prior to scheduled pickup time. Ensure the data entered matches exactly as documented on your internal collection site documentation/run sheet.

- 11.3. Complete Section 2: Collection Details of the Sonoma Apheresis Collection Form by entering information from the collection:

**NOTE:** When using the DocuSign feature, the fields for entry will be highlighted as fillable. You will not be able to submit the form without completing all required fields. Reference Figure 2: Sonoma Apheresis Collection Form for a visual of this form.

### 11.3.1. 2A: Apheresis Site information

### 11.3.2. 2B: Apheresis Collection Procedure Record

- This data entry is specific to the collection data, collected product identification, and final collected product specifications.

**NOTE:** Collection End Time is calculated as Start of Rinse back/Reinfusion or loss of venous access, whichever comes first.

### 11.3.3. 2C: Apheresis Product & Shipping Verification

- Complete the Y/N questions, leaving the final field “Product pack-out date & time” until you have placed the foil lined lid on the unit (this step is covered below).
- If a substitute shipping unit is sent (ie. Credo Cube) instead of the NanoCool, please select “N/A” for the question stating “NanoCool Shipper activated and NanoCool logo turned blue?”. In the comments section of the form, please add a statement that a NanoCool unit was not used and indicate the shipper that was.
- Ensure a trained and approved staff member is available to verify the data and complete the verification signature at the end of the pack out.
- Proceed with the Apheresis Product Packout and Shipping instructions.

## 12. Apheresis Product Packout and Shipping

The apheresis product should be packaged immediately after the collection has been completed and in the collection area. Transferring the apheresis product to another location should be avoided but if required by your Collection Site, ensure internal procedures are followed for maintaining product integrity.



- 12.1. Print one copy of the waybill and verify the Sonoma COI Number listed on the waybill matches the COI Number on the MNC product label. This copy of the waybill acts as a ship-to label.
- 12.2. Place the verified waybill inside the document sleeve by folding the waybill and inserting it in the document sleeve. The Sonoma COI Number and Shipping Address/Delivery-to must be visible.



- 12.3. Adhere the document sleeve containing the verified waybill to the front of the cardboard exterior shipper.



- 12.4. Seal the document sleeve to ensure the waybill cannot be removed.
- 12.5. Adhere the "Exempt Human Specimen" and "Do Not X Ray" shipping labels to the side panels of the exterior of the shipper.



- 12.6. Prepare to pack the product bag:
  - 12.6.1. Ensure that absorbent sheets are inside the biohazard specimen transport bag.
  - 12.6.2. Review the MNC product bag label to verify the product being prepared for shipment is the correct one:
    - 12.6.2.1. Verify Sonoma COI Number against the COI Number listed on the Apheresis Collection Form, product bag label and waybill (adhered to the shipping box) are a match.
- 12.7. Place the verified product bag inside the biohazard specimen transport bag containing the absorbent sheets.
  - 12.7.1. If possible, insert the bag so the product label is visible through the transport bag. Ensure the entire product bag and remaining tubing is fully inside the transport bag. The biohazard symbol should not block the product bag label.

**NOTE:** Ensure both the product bag and absorbent sheets are placed inside the biohazard bag and NOT in the document sleeve of the biohazard bag.



12.8. Expel the air from the biohazard specimen transport bag and seal the bag by peeling off the adhesive backing and sealing.

**NOTE:** Ensure no part of the product bag is blocking the seal to ensure the adhesive does not stick to the product bag.



12.9. Place the biohazard specimen transport bag with product into the payload compartment of the Shipping Unit.



12.10. Activate the Temperature Monitor by pressing the “Start” button. A sunshine icon will appear indicating the logger is turned on.



- 12.11. Place the activated temperature monitor inside the payload compartment under the product bag.



- 12.12. Activate the NanoCool Shipping Unit following the steps described in below (Skip if not using a NanoCool Shipping Unit):

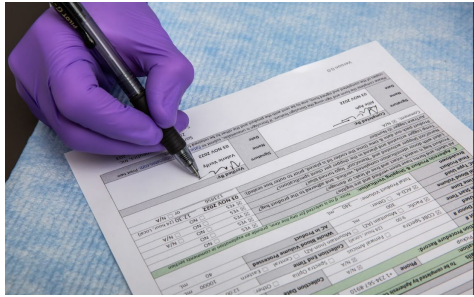


**NOTE:** The NanoCool logo should turn blue within 3 minutes after activation. The blue indicates that the cooling action has begun which can be confirmed by touching the surface of the cooler near the button. Any issues, questions, or concerns, contact Sonoma Patient Operations for further instruction and/or troubleshooting.

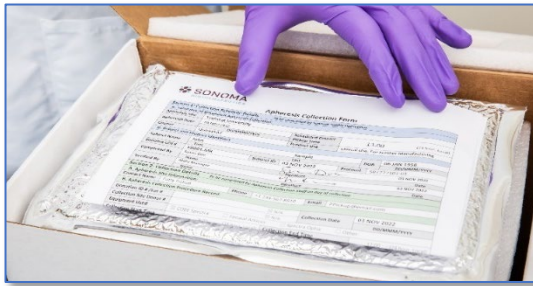
- 12.13. Immediately return the NanoCool cooling engine (lid) to its original position on the payload compartment, foil side up, pressing firmly to ensure a snug fit.



- 12.14. Complete the “Product Pack-out Date & Time” field on the Sonoma Apheresis Collection Form. This date/time is documented as the time the NanoCool lid was secured (completion of pack-out).
- 12.15. Sign the Sonoma Apheresis Collection Form. A second individual must confirm the information on the form and sign as verifier. The form can be signed electronically via DocuSign or manually depending on site capability/preference.



- 12.16. Print a minimum of 2 copies of the completed Sonoma Apheresis Collection Form, one to be sent with the shipment and the other to retain for internal records.
- 12.17. Place a copy of the completed Apheresis Collection Form, folded in half, on top of the cooling engine/panel.



- 12.18. Close the box by inserting the flaps into the box and securing it by taping in the three locations labeled on the flap of the box.

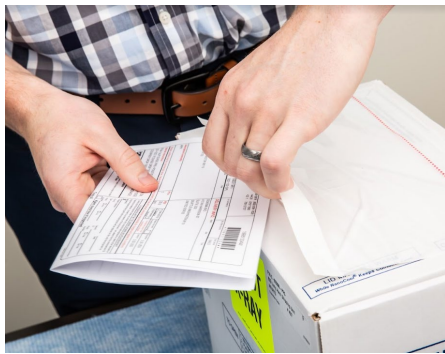




12.19. Adhere the second document sleeve to the top lid of the sealed NanoCool.



12.20. Place two copies of the verified BOL/waybills inside the document sleeve.



**NOTE:** Do **NOT** seal the document sleeve as the BOL/Waybill will need to be accessed at time of courier pickup and throughout the duration of the shipment to final delivery.

12.21. When the courier arrives for the pickup, verify the details of the scheduled shipment with the driver:

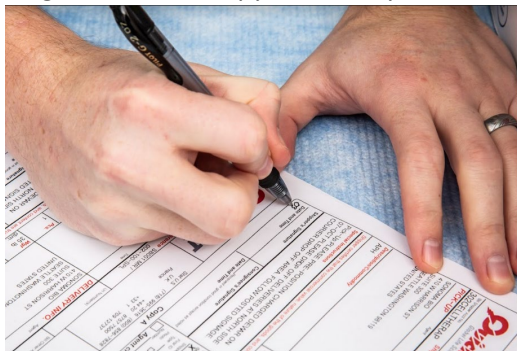
12.21.1. Verify delivery location against what is listed on the BOL.

12.21.2. Verify the Sonoma COI Number matches the courier paperwork and the Waybill Number listed on the BOL/waybill.

12.21.3. Any issues or discrepancies, Do **NOT** release the shipment to the courier and contact Sonoma Patient Operations.

**NOTE:** Contact Sonoma Patient Operations if the driver does not arrive for the pickup at the scheduled time, or if there is any other problem at handoff with the driver.

12.22. Sign and date a copy of the waybill.



12.23. Release the package to the driver.

12.24. Completing the form via DocuSign automatically shares a completed copy with Sonoma Patient Operations. If the form was completed manually, email a completed copy to Sonoma Patient Operations at PatientOps@sonomabio.com. The form must be returned immediately after collection or pickup.

< END >

Figure 1: Subject Record Form



		<b>Subject Record Form</b>	
<b>Sponsor:</b>	Sonoma Biotherapeutics		
<b>Product:</b>	SBT777101	<b>Protocol #:</b>	
<b>New Order Details</b> <i>To be completed by Clinical Site</i>			
<i>These details will act as the master record of patient identifiers and will be used for all subsequent Chain of Identity checks.</i>			
<b>Clinical Site:</b>			<b>Clinical Site #:</b>
<b>PI Name:</b>			
<b>Subject Details:</b>			
<b>First Name</b>		<b>Last Name</b>	<b>DOB</b>
			DD MMM YYYY
<b>Biological Sex</b>	<input type="checkbox"/> Female <input type="checkbox"/> Male		
<b>MRN/Hospital ID (Optional)</b>	<input type="checkbox"/> N/A <input type="checkbox"/> N/A		
<b>Appointment Details:</b>			
<b>Synovial Biopsy Date Scheduled:</b>	<b>Apheresis Collection Requested:</b>		
<b>Comments:</b>	<input type="checkbox"/> N/A		
<i>By signing below, we certify that the above patient identifiers are correct and match the subject's photo ID used at enrollment. We understand that these identifiers will be used for Chain of Identity purposes for apheresis collection, manufacturing, and infusion.</i>			
<b>Signature</b>	<b>Completed By:</b>	<b>Signature</b>	<b>Verified By:</b>
Full Name		Full Name	
Date		Date	
Title		Title	
<b>Scheduled Apheresis Details</b> <i>To be completed by Sonoma Biotherapeutics Operations</i>			
<i>Contingent appointment details are contingent on subject eligibility confirmation.</i>			
<b>Sonoma COI #:</b>	<b>Appointment Date/Time:</b>		
<b>Apheresis Site:</b>			
<b>Apheresis Site Address:</b>	<b>Comments:</b>		<input type="checkbox"/> N/A
<b>Signature</b>	<b>Completed By:</b>	<b>Signature</b>	<b>Verified By:</b>
Full Name		Full Name	
Date		Date	
Title		Title	

Figure 2: Sonoma Apheresis Collection Form:



## Sonoma Apheresis Collection Form

Section 1: Collection Schedule Details <small>To be completed by Sonoma Patient Operations</small>			
A. Summary of Scheduled Apheresis Collection:			
Apheresis Site:			
Appointment Date:	DD MMM YYYY	Scheduled Courier Pickup Time:	(24 hour, Local)
Courier:		Product Use:	Cell Therapy, For Further Manufacturing
B. Subject and Product Identifiers			
Sonoma COI #:		Subject ID:	
Completed By:		Signature	
Full Name		Full Name	
Date		Date	
Section 2: Collection Details <small>To be completed by Collection Staff on day of collection</small>			
A. Apheresis Site Information:			
Contact Name:			
Phone:		Email:	
B. Apheresis Collection Procedure:			
Donation ID # / Lot #:	<input type="checkbox"/> N/A	Appointment Date:	MMM YYYY
Collection Site Donor #:	<input type="checkbox"/> N/A		
Equipment Used:	<input type="checkbox"/> COBE <input type="checkbox"/> Fenwal Amicus <input type="checkbox"/> Spectra Optia		
Collection Start Time:	(24 hour, Local)	Collection End Time:	(24 hour, Local)
Time Zone:	<input type="checkbox"/> Pacific <input type="checkbox"/> Mountain (AZ) <input type="checkbox"/> Mountain (non-AZ) <input type="checkbox"/> Central <input type="checkbox"/> Eastern		
Total Volume:	mL	Whole Blood Volume Processed:	mL
AC Type:	<input type="checkbox"/> ACD-A <input type="checkbox"/> Other:	AC Volume:	mL
Total Product:	mL		
C. Apheresis Product & Shipping Verification: <small>Note: If "Other" is selected for AC Type, please provide an explanation in comments section</small>			
All forms have been verified and are legible?		<input type="checkbox"/> YES	<input type="checkbox"/> NO
Product bag is sealed, intact and free of leaks or damage?		<input type="checkbox"/> YES	<input type="checkbox"/> NO
Label with patient identifiers completed, verified, and adhered to the product bag?		<input type="checkbox"/> YES	<input type="checkbox"/> NO
NanoCool Shipper activated and "NanoCool" logo turned blue?		<input type="checkbox"/> YES	<input type="checkbox"/> NO <input type="checkbox"/> N/A
Temp Logger activated and placed in the shipper per sponsor protocol?		<input type="checkbox"/> YES	<input type="checkbox"/> NO
Product pack-out date & time (time the cooler lid is placed, prior to outer box sealed):		(24 hour, Local)	
Comments: <input type="checkbox"/> N/A			
Completed By:		Verified By:	
Signature		Signature	
Full Name		Full Name	
Date		Date	

Please complete the form and sign using the DocuSign feature. If DocuSign is unavailable, contact Sonoma Patient Operations for return instructions. Print two copies of the completed and signed form, one to be sent with the product and the other to be retained in your files.