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)	N/A	PatientOps@sonomabio.com Mindy Jensen (backup/alternate)	(650) 671-4447 (253) 224-5058
Director of Patient Operations (Primary Sonoma Apheresis Business Contact)	Mindy Jensen	mjensen@sonomabio.com	(253) 224-5058

4. Terms & Definitions:

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

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 (i.e. identifying the intended use, handling requirements etc.).

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

Ship To Label: Exterior label on the shipper with delivery address and field for manual entry of the assigned Sonoma COI Number, to be entered at time of use by Collection Site personnel, or designee.

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.

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.

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 Apheresis Collection Form (Section 1 completed by Sonoma)
- Courier Shipping Documentation:

- Courier Order Confirmation with shipment summary
- Courier Waybill/Bill of Lading (two copies 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 pad(s) (1ea)
  - Exterior Shipper Labels (pre-adhered to exterior of NanoCool kit):
    - Exempt Human Specimen (1ea)
    - Do Not X-Ray (1ea)
    - "Ship To" label with delivery address and field for COI Number manual entry by collection site staff.
  - Document Sleeve for waybill (1ea)

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: The provided materials may arrive placed together inside the biohazard specimen transport bag for easy and secure transport reasons.

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.

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 Apheresis Collection Form to be completed electronically on day of collection (sent via DocuSign).

Note: If the site is unable to complete electronically, a form may be requested to be completed manually.

7.2.3. The Courier waybill and summary of scheduled pickup details.

7.3. If there are any issues or delays that arise before or during the collection that may 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.

7.4. Notify Sonoma Patient Operations and the prescribing physician of any Adverse Events or Serious Adverse Events that may arise during or after the collection.

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, these are obtained from the Subject Record Form.

8.2.1. Product and Subject Identifiers:

- Subject First & Last Name
- Subject Date of Birth (DOB)
- Sonoma COI Number
- Temperature conditions listed are within 1-10°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: If your procedures allow for it, please do not input an expiration date or time. The product lifespan is calculated by our manufacturer using data from the 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:

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 but is typically located on the cooling engine (lid)).

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) and/or internal medical records, as applicable.

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 or approved.

11. Completing Sonoma's Apheresis Collection Form

11.1. Open the applicable 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 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 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: 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 Verification
- Complete the Y/N questions.
- Review and ensure all fields are accurate before signing in the "Completed by" section.

11.3.4. 2D: Product Packout 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.
- 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. Document the Sonoma COI Number on the Ship To label using a waterproof and indelible pen.

12.2. Confirm the “Exempt Human Specimen” and “Do Not X Ray" shipping labels are adhered to the panels of the exterior of the shipper (kit will arrive with labels adhered, location may vary).

12.3. Prepare to pack the product bag:

12.3.1. Ensure that absorbent sheets are inside the biohazard specimen transport bag.

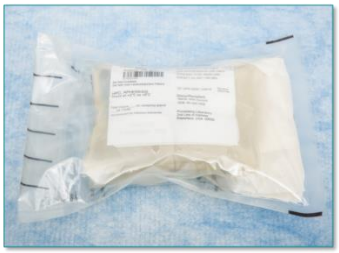
12.3.2. Review the MNC product bag label to verify the product being prepared for shipment is the correct one:

12.3.2.1. Verify Sonoma COI Number against the COI Number listed on the Apheresis Collection Form, product bag label, and Ship To label (adhered to the shipping box) are a match.

12.4. Place the verified product bag inside the biohazard specimen transport bag containing the absorbent sheets.

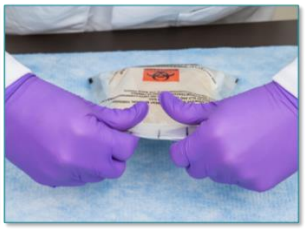
12.4.1. Insert the bag so the product label is visible through the transport bag. Ensure the entire product bag and remaining tubing is fully inside the transport bag. The biohazard symbol should not block the product bag label.

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.

12.5. 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.





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


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

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

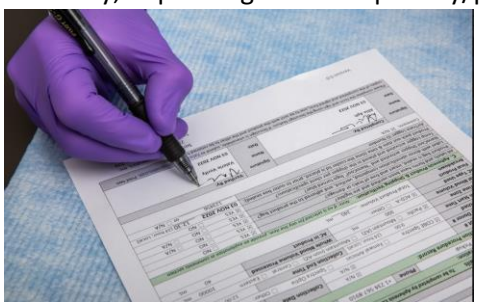
12.9. Activate the NanoCool Shipping Unit following the steps described in the below image (Skip if not using a NanoCool Shipping Unit):

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.

12.10. 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.

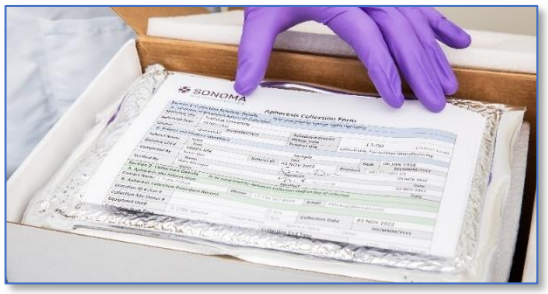
12.11. Complete the “Product Pack-out Date & Time” field on the Apheresis Collection Form. This date/time is documented as the time the NanoCool lid was secured (completion of pack-out).

12.12. Sign the Apheresis Collection Form. The form can be signed electronically via DocuSign or manually, depending on site capability/preference.



12.13. Print a minimum of two copies of the completed Apheresis Collection Form, one to be sent with the shipment and the other to retain for internal records.

12.14. Place a copy of the completed Apheresis Collection Form, folded in half, on top of the cooling engine/panel.



12.15. 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.

12.16. Adhere the document sleeve to the top lid of the sealed NanoCool.

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

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

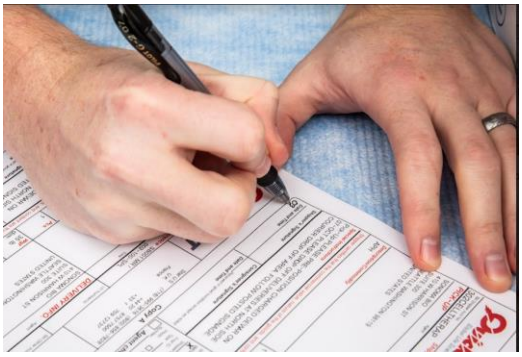
12.18.1. Verify delivery location against what is listed on the BOL.

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

12.18.3. 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.

12.19. Sign and date a copy of the waybill and provide to the driver (or return to the document sleeve).



12.20. Release the package to the driver.

12.21. Completing the Apheresis Collection 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 completed pack-out or pickup.

< END >

13. Figure 1: Subject Record Form

SONOMA BIOTHERAPEUTICS

Subject Record Form

Sponsor:	Sonoma Biotherapeutics		
Product:	SBT777101	**Protocol #:**	

New Order Details	*To be completed by Clinical Site*				
These details will act as the master record of patient identifiers and will be used for all subsequent Chain of Identity checks.					
Clinical Site:		**Clinical Site #:**			
PI Name:					
Subject Details:					
First Name		**Last Name**		**DOB** DD MMM YYYY	
Biological Sex	☐ Female ☐ Male	**Subject ID**			
MRN/Hospital ID (Optional)	☐ N/A	**Other Informa (Optional)**		☐ N/A	
By signing below, we certify that the above patient identifiers are correct and match the subject ID i t. *We understand that these identifiers will be used for Chain of Identity purposes for ga collec ufacturing, and infusion.*					
	Completed By:				
Signature					
Full Name					
Date					
Title					

Scheduled Apheresis Details	*e comp by Sonoma Patient Operations*		
Appointment details are contingen lect e n confirmation.			
Sonoma COI #:		**Appointment Date/Time:**	
Apheresis Site:			
A sis Site ress:			
	Co leted By:		**fied B**
Signatu			
Full Name		**Full Name**	
Date		**Date**	
Title			

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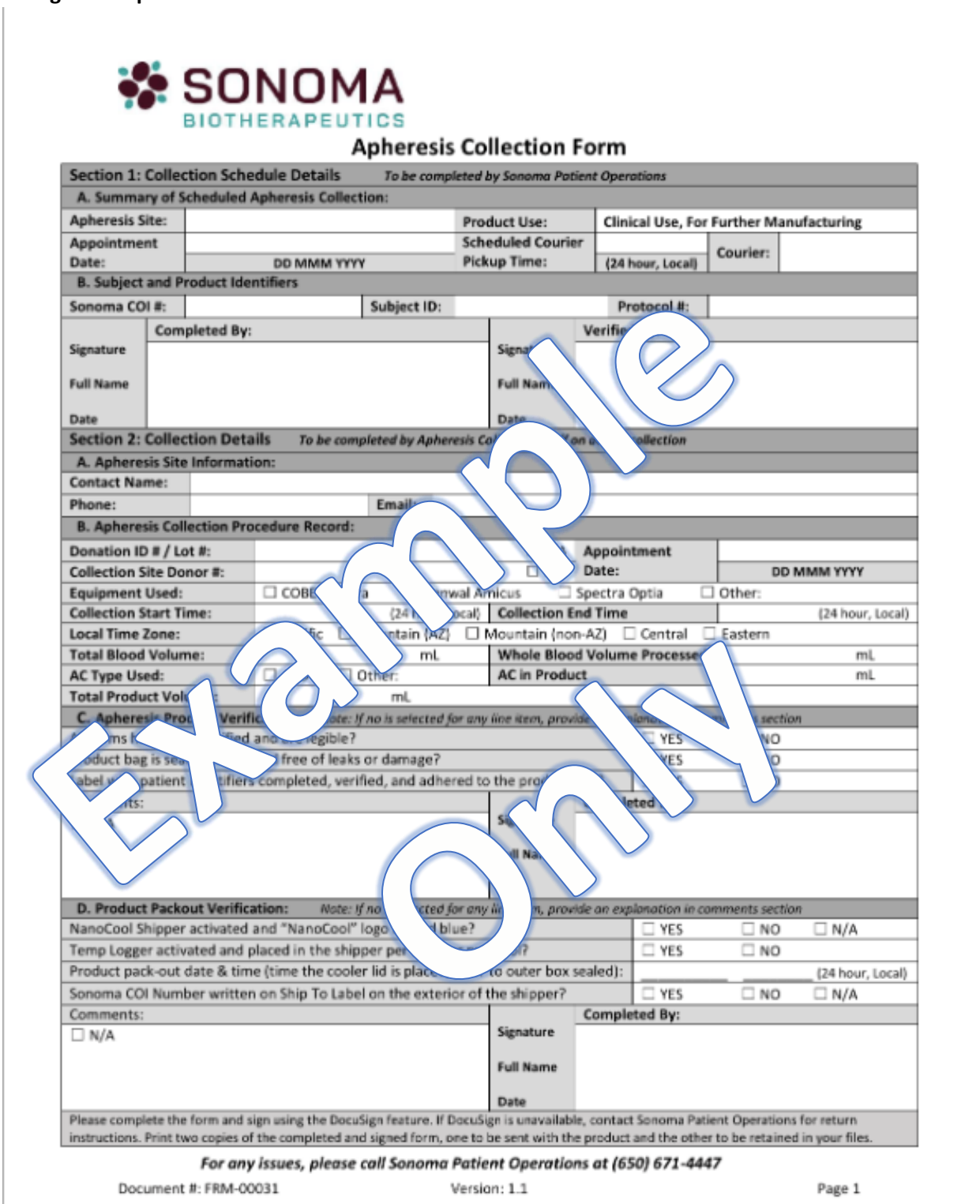
14. Figure 2: Apheresis Collection Form:



SONOMA BIOTHERAPEUTICS

Apheresis Collection Form

Section 1: Collection Schedule Details *To be completed by Sonoma Patient Operations*					
A. Summary of Scheduled Apheresis Collection:					
Apheresis Site:		**Product Use:**	**Clinical Use, For Further Manufacturing**		
Appointment Date:	DD MMM YYYY	**Scheduled Courier Pickup Time:**	(24 hour, Local)	**Courier:**	
B. Subject and Product Identifiers					
Sonoma COI #:		**Subject ID:**		**Protocol #:**	

	Completed By:	**Verifie**
Signature		**Signa**
Full Name		**Full Nam**
Date		**Date**

Section 2: Collection Details *To be completed by Apheresis Co* *on a* *ollection*			
A. Apheresis Site Information:			
Contact Name:			
Phone:		**Email**	
B. Apheresis Collection Procedure Record:			
Donation ID # / Lot #:		**Appointment Date:**	DD MMM YYYY
Collection Site Donor #:			
Equipment Used:	☐ COBE a ☐ Fenwal Amicus ☐ Spectra Optia ☐ Other:		
Collection Start Time:	(24 h ocal)	**Collection End Time**	(24 hour, Local)
Local Time Zone:	☐ ntain (AZ) ☐ Mountain (non-AZ) ☐ Central ☐ Eastern		
Total Blood Volume:	mL	**Whole Blood Volume Processe**	mL
AC Type Used:	☐ ☐ Other:	**AC in Product**	mL
Total Product Vol	mL		

C. Apheresis Pro **Verifi** *ote: If no is selected for any line item, provid* *section*		
ms l ed and egible?	☐ YES	NO
oduct bag is se free of leaks or damage?	YES	O
abel patient ifiers completed, verified, and adhered to the pro		
nts:	**leted**	
	Si	
	ll Na	

D. Product Packout Verification: *Note: If no cted for any i n, provide an explanation in comments section*			
NanoCool Shipper activated and "NanoCool" logo l blue?	☐ YES	☐ NO	☐ N/A
Temp Logger activated and placed in the shipper pe ?	☐ YES	☐ NO	
Product pack-out date & time (time the cooler lid is plac to outer box sealed):			(24 hour, Local)
Sonoma COI Number written on Ship To Label on the exterior of the shipper?	☐ YES	☐ NO	☐ N/A

Comments:	**Completed By:**
☐ N/A	**Signature**
	Full Name
	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.

For any issues, please call Sonoma Patient Operations at (650) 671-4447

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15. Version History:

Effective Date	Version	Change Description
See Effective Date	3.0	1. Removed including Subject ID on the product bag label. 2. Updated temperature range on labels to 1-10c from 2-8c. 3. Removed “if possible” from making the product bag visible through the transport bag.
05DEC2023	2.0	1. Updated the Shipping Kit design to the new design that comes with labels pre-adhered shipping labels as well as incorporation of the Ship To label 2. Removed steps requiring collection staff to adhere shipping labels 3. Added steps for collection site staff to document COI Number on the Ship To label 4. Minor edits throughout
17JAN2023	1.0	New Document

Document Approvals

Approved Date: 6/24/2024

Task: Approvers Approval Verdict: Approve changes & release Approval to be made Effective	Amanda Pace, Vice President, Analytical and Process Development (apace@sonomabio.com) Approver 21-Jun-2024 16:55:58 GMT+0000

Task: Approvers Approval Verdict: Approve changes & release Approval to be made Effective	Mark Fromhold, (mfromhold@sonomabio.com) Approver 21-Jun-2024 17:51:00 GMT+0000

Task: QA Approval Verdict: Approve changes & release QA Approval to be made Effective	Fred Billingsley, (fbillingsley@sonomabio.com) Quality Assurance Approval 24-Jun-2024 14:23:39 GMT+0000