



CELL THERAPY BINDER TABLE OF CONTENTS V1.0

03-AUG-2023

Sonoma Biotherapeutics

SBT777101-01

Sponsor Name

Protocol ID

ISF-TOC Completed By (Site Personnel)

Date Completed By Site

Site Number

SECTION NUMBER & NAME	EXAMPLE DESCRIPTION OF DOCUMENTS TO FILE	USE	LOCATION*
1. General			
1.1 Study Team List	All relevant phone numbers (e.g., CRA, Central Lab, IXRS/IRT)		
1.2 Study Supply Reorder Forms			
2. Protocol and Amendments	Protocol, Amendments, Investigator Signature Pages, Medpace/Sponsor communications clarifying protocol items, etc.		
3. Investigator's Brochure			
3.1 Investigator's Brochure (IB)	IBs and addenda		
4. Investigational / Study Product			
4.1 Investigational Product Manual			
4.2 Master Accountability Log	Master Investigational Product Log		
4.3 Packing Lists and Confirmations of Receipt	Copies of packing lists signed by site, prints of IXRS/IRT confirmation of receipt, any other documentation that accompanies the shipments		
4.4 Return / Destruction Information	Instructions, forms, airway bills, confirmations		
4.5 Subject Accountability Logs	Individual subject investigational accountability logs template. Note: Only file "Subject Accountability Logs" here if they are not filed in the subject's source document.		
4.6 Temperature Monitoring	Temperature logs, printed logger readouts, instructions for temperature loggers, etc.		
4.7 Temperature Excursion Form			
4.8 Investigational Product Shipping and Receipt Form			

SECTION NUMBER & NAME	EXAMPLE DESCRIPTION OF DOCUMENTS TO FILE	USE	LOCATION*
4.9 Investigational Product Preparation and Administration Form			
4.10 Investigational Product Disposal and Destruction Form			
4.11 Import/Export License			
4.12 Certificate of Release and Certificate of Analysis			
5. Apheresis Procedures			
5.1 Apheresis Manual			
5.2 Subject Record Form / Apheresis Order Form			
5.3 Apheresis Collection Form			
5.4 Product Bag Label Template			
5.5 Investigational Product Shipping and Receipt Form			
6. Label Template			
6.1 Product Complaint Form			
7. Additional Vendors			
7.1 Instructions	Manuals, quick reference guides, etc.		
7.2 Correspondence			