INVESTIGATOR SITE FILE BINDER TABLE OF CONTENTS V1.0

21-JUL-2023

Sonoma Biotherapeutics	SBT777101-01			
Sponsor Name	Protocol ID	ISF-TOC Completed By (Site Personnel)	Date Completed By Site	Site Number

Note the location of documents filed outside of the ISF binder in the “Location” column. Make updates to this location as applicable and initial/date.

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. Ethics Committees (EC)/Institutional Review Board (IRB)			
2.1 Central EC/ IRB	All correspondence to and from Central EC/IRB (e.g., cover letters, e-mails, approvals/acknowledgments, annual status reports), GCP compliance statement, membership lists, etc.		
2.2 Local EC / IRB	All correspondence to and from Local EC/IRB (e.g., cover letters, e-mails, approvals/acknowledgments, annual status reports), GCP compliance statement, membership lists, etc.		
2.3 IBC	All correspondence regarding IBC or other scientific reviews (e.g., cover letters, e-mails, approvals/acknowledgments, annual status reports),		
3. Competent Authorities	All correspondence to and from the CA (e.g., cover letters, e-mails, approvals/acknowledgments, annual status reports)		
3.1 Local Governance	All correspondence to and from the local agency (e.g., cover letters, e-mails, approvals/acknowledgments, annual status reports, etc.)		
4. Protocol and Amendments	Protocol, Amendments, Investigator Signature Pages, Medpace/Sponsor communications clarifying protocol items, etc.		
5. Investigator’s Brochure			
5.1 Investigator’s Brochure (IB)	IBs and addenda		
5.2 Acknowledgements of Receipt (AoR)/Signature Pages			

SECTION NUMBER & NAME	EXAMPLE DESCRIPTION OF DOCUMENTS TO FILE	USE	LOCATION*
6. Study Agreements			
6.1 Confidentiality Agreement			
6.2 Clinical Study Agreement	Contract with the main site and amendments hereto		
6.3 Other Study Agreements	Letters of Intent, laboratory/pharmacy/radiology agreements		
7. Informed Consent and Patient Items			
7.1 Main Informed Consent Form	Blank copy of each ICF version since time of site activation		
7.2 Other Informed Consent Forms	Sample collection and/or storage, pregnancy		
7.3 Signed Informed Consent Forms	ICFs are only filed here if they are not filed in the subject's source document		
7.4 Patient Tools	Examples of EC-approved items to be maintained, completed, and/or used by the patients (e.g., questionnaires, temperature diaries, emergency cards, HCP factsheet, prescreening checklist)		
7.5 Patient Recruitment Items	Examples of EC-approved recruitment materials (e.g., brochures, flyers, advertisements, referral letters)		
7.6 Patient Retention Items	List of EC-approved patient retention items (e.g., cards, study companion reminder, participant handbook, participant journey, participant thank you card)		
8. Study Product			
8.1 IP Administration Manual	If used, all documents in this section will be filed there accordingly		
9. Site Staff and Facilities			
9.1 Site Signature and Responsibility Log			
9.2 Site Staff Training Documentation	Site training logs or other documentation (e.g., EDC, investigator's meeting, GCP)		
9.3 FDA 1572 Form			
9.4 Curriculum Vitae / Medical Licenses			

SECTION NUMBER & NAME	EXAMPLE DESCRIPTION OF DOCUMENTS TO FILE	USE	LOCATION*
9.5 Financial Disclosure Forms			
9.6 Facilities Information	Calibration documentation, equipment logs, etc.		
10. Safety Reporting			
10.1 Serious Adverse Event Reporting	Guidelines and template forms		
10.2 Safety Reports	Line listings, safety alert notification, etc.		
10.3 Reporting to Applicable Agencies	Correspondence with EC/IRB and/or CA/local governments		
10.4 Safety Monitoring Committee (SMC)	SMC charter and other relevant documentation regarding the SMC		
11. Insurance	Insurance certificates and policies		
12. Monitoring			
12.1 Site Visit Log			
12.2 Monitoring Visit Confirmation and Follow-up Letters			
12.3 Site Initiation Visit Report	SIV report and attachments		
12.4 Site Corrective Action & Preventative Action Plan(s)			
13. Subject Logs			
13.1 Subject Screening and Enrollment Log			
13.2 Master Subject Log			
13.3 Patient Eligibility Forms			
14. Site Correspondence			

SECTION NUMBER & NAME	EXAMPLE DESCRIPTION OF DOCUMENTS TO FILE	USE	LOCATION*
14.1 CRA Correspondence	Key communication between site and CRA (e.g., visit correspondence [confirmation/follow-up letters], e-mails, other non-visit related letters)		
14.2 General Correspondence	Correspondence from study team throughout lifecycle of trial (e.g., feasibility questionnaires, site qualification visit letters, participation letter, updates from the sponsor, e-mail blasts)		
14.3 Site Activation Email			
14.4 Newsletters	Recruitment updates, general study team correspondence		
14.5 Signed Acknowledgements of Receipt for Site Supplies	Documentation surrounding receipt of supplies with value. Patient travel vouchers, digital cameras, refrigerators, centrifuges, thermometers.		
14.6 Clinical Study Report			
15. Laboratory			
15.1 Central Laboratory	Manual, certificates, reference ranges, etc.		
15.2 Temperature logs	Stored sample temperature logs (e.g., freezer, refrigerator, ambient)		
15.3 Local Laboratory	All information pertinent to local lab. Local lab accreditation certificates, local lab reference ranges, CV of head of local lab		
16. Case Report Forms and Data Collection			
16.1 Site Source Documentation Process Form			
16.2 Example CRF			
16.3 CRF Completion Guidelines			
16.4 CRF Instructions	Access request forms, instructions for use, quick reference guide, helpdesk information, etc.		
17. Additional vendors			
17.1 Instructions	Manuals (Biopsy Manual and Apheresis Manual), quick reference guides, etc.		Study Reference Manual
17.2 Correspondence			