MEDPACE

BACK-UP Serious Adverse Event Form (use only if EDC unavailable)
Sonoma Biotherapeutics, Inc. SBT777101-01 or -02

MEDPACE CLINICAL SAFETY CONTACT INFORMATION

Within 24 hours of first learning about the event, fax or email the form and supporting documents to Medpace Clinical Safety at:

Email: Medpace-SafetyNotification@medpace.com

US: +1-800-730-5779, Dial 3, or +1-513-579-9911, Dial 3 (p); +1-866-336-5320 or +1-513-570-5196 (f)

Europe: +49 89 89 55 718 44 (p); +49 89 89 55 718 104 (f)

Protocol:	☐ **SBT777101-01 or** ☐ **SBT777101-02**						
1. Report Type:		**2. Subject Demographics:**					
☐ Initial Report	☐ Follow-up Report # _ _	**Site #** _____	**Subject** _____	**Age at Time of Event** _____	**Sex at Birth** ☐ Male ☐ Female ☐ Undifferentiated ☐ Unknown	**Weight (kg)**	**Height (cm)**

3. Phase of Study at the Time of the Event:	☐ Screening	☐ Treatment	☐ Follow Up	**Date of Informed Consent:**

4. Race					
☐ American Indian or Alaskan Native	☐ Asian	☐ Black or African American descent	☐ Native Hawaiian or Other Pacific Islander	☐ White	☐ Other, specify:

5. SAE Information

SAE Term (enter diagnosis)	**Duration**		**SAE Criteria**	**Severity**	**Action Taken with Study Treatment**	**Outcome**	**Relation to Study Treatment**
	Start Date dd/mmm/yyyy	**Stop Date** dd/mmm/yyyy		**Select Grading:** ☐ CTCAE v5.0 ☐ ASTCT CRS ☐ ASTCT ICANS			
1.			☐ Death ☐ Life Threatening ☐ Required or Prolonged Hospitalization ☐ Persistent/ Significant Disability ☐ Congenital Anomaly ☐ Important Med Event	☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4 ☐ Grade 5	☐ Withdrawn ☐ Re-initiated at Reduced Rate ☐ Not Applicable ☐ Unknown	☐ Fatal ☐ Not Recovered ☐ Recovered ☐ Recovered w/ Sequelae* ☐ Recovering ☐ Unknown *Provide sequelae *Provide sequelae	☐ Related ☐ Possibly Related ☐ Not Related If no, provide alternate etiology:

Site #/Subject #

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6.	a. Was the patient hospitalized? ☐ No ☐ Yes, if Yes:	Admission Date:		Discharge Date:
	b. If fatal, please provide the following:	Date of death:	Primary cause of death:	Autopsy: ☐ No ☐ Yes
	c. Was the SAE associated with a trial procedure?		☐ No ☐ Yes (please specify)	

7. Study Treatment (if interrupted or discontinued, record dates on lines below)

Study Treatment	Planned Dose	Actual Dose	Route	From (dd/mmm/yyyy)	To (dd/mmm/yyyy)	Completed	Interrupted	Permanently Discontinued
SBT777101						☐	☐	☐
If dose interrupted, provide time of interruption:								
If restarted after interruption, provide time of restart:								

8. Concomitant Medications: (Attach additional pages if necessary)

Medication	Unit Dose (Specify Unit)	Frequency	Route	From (dd/mmm/yyyy)	To (dd/mmm/yyyy)	Check if Ongoing	Indication
						☐	
						☐	
						☐	
						☐	
						☐	
						☐	
						☐	
						☐	

Site #/Subject #

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9. Relevant Medical History:

10. Clinical Description of Event: Provide detailed description of event including signs, symptoms, treatment, clinical course, etc. Is any supporting documentation including hospital discharge reports, death certificate, etc. (if applicable) attached to this report? ☐ Yes ☐ No

11. Reporter Information			
Date Medpace Notified (dd/mmm/yyyy):			
Name and Title of Person Reporting Event:			
Reporter Phone:	**Reporter fax:**	**Reporter E-mail**	
Investigator Name:			
Site Address:			
Investigator Signature		**Date:**	