

## IP Preparation and Administration Form

Section 1: Complete after subject confirms eligibility			
Sonoma COI:		Subject ID:	
Protocol:		Clinical Site #:	
Date: (DD/MMM/YYYY)		Time Zone:	
Section 2: Pre-Verification			
1. Verify the shipper temperature is within range ( $\leq -135^{\circ}\text{C}$ )		<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. Confirm Subject ID and Subject COI matches the <b>CoR for Infusion</b> and syringe labels		<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Confirm subject is eligible and prepared for infusion		<input type="checkbox"/> Yes <input type="checkbox"/> No	
4. Confirm that the SBT777101 frozen product has not expired by checking the expiration date listed on the <b>CoR for Infusion</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No	
If 'No' is selected for any item above, please contact Sonoma Patient Operations at <a href="mailto:PatientOps@sonomabio.com">PatientOps@sonomabio.com</a>			
Section 3: IP Retrieval from Shipper - Day of Infusion			
1. Date IP Removed:	____/____/____ (DD/MMM/YYYY)	Time IP Removed:	____:____ (24 hr)
1. Confirm all information on the <b>cassette</b> label exactly matches information listed on the <b>CoR for Infusion</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. Confirm all information on the <b>IP bag</b> labels exactly matches the information listed on the <b>CoR for Infusion</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Section 4: IP Thaw			
1. Start Time of Thaw:		____:____ (24 hr)	
2. End Time of Thaw:		____:____ (24 hr)	
3. Expiration Time (3 hours after the 'End Time of Thaw'):		____:____ (24 hr)	
4. Volume of IP Drawn into Syringe(s)		_____ ml	
5. Verify the volume within syringe(s) matches 'Total Dosage Volume' on the <b>CoR for Infusion</b>		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Section 5: IP Administration (IP infusion must be completed within 3-hours of 'End Time of Thaw')			
1. Confirm thawed IP is within '3 hour Expiration Time'		<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. Re-Confirm subject's identity and compare to syringe label(s)		<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Start Time of Infusion:		____:____ (24 hr)	
4. End Time of Infusion:		____:____ (24 hr)	
5. Total Volume of IP Administered:		_____ ml	
Section 6: In case of interruptions to IP administration ONLY			
1. Did an interruption to IP administration occur?		<input type="checkbox"/> Yes <input type="checkbox"/> No – proceed to signature	
2. Time of interruption to IP Administration:		____:____ (24 hr)	
3. Please describe reason for interruption:			
4. Confirmation to recommence IP administration		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Section 6a: If confirmed 'YES' to recommence ONLY			

5. Re-confirm IP is still within 3-hour thaw window		<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Re-Start Time of Infusion:		____:____ (24 hr)
7. End Time of Infusion:		____:____ (24 hr)
8. Total Volume of IP Administered:		_____ ml
<b>Section 6b: If confirmed 'NO' to recommence ONLY</b>		
9. Please describe reason for incomplete IP administration:		
10. Estimated Volume of IP Administered (based on volume remaining in syringe):		_____ ml
Signature  Name  Title  Date	Completed By:	Completed By:

*If completed electronically, please print a hardcopy to keep with the subject's file.*