SingHealth

REPORTING REQUIREMENT AND TIMELINE FOR SERIOUS ADVERSE EVENTS (SAE)

Relatedness (Causality)	Only Related SAE needs to be reported to CIRB.							
SAE	**Death or Life-threatening**				**All other SAE**			
Study Type	**Clinical Trial regulated by H.S.A.**		**Other research studies (e.g. HBR, non-HBR)**		**Clinical Trial regulated by H.S.A.**		**Other research studies (e.g. HBR, non-HBR)**	
Location	**CIRB-approved study site**	**Other study site***	**CIRB-approved study site**	**Other study site***	**CIRB-approved study site**	**Other study site***	**CIRB-approved study site**	**Other study site***
Expectedness (Nature)	Unexpected Expected	Unexpected	Unexpected Expected	Unexpected Expected	Unexpected	-	Unexpected Expected	Unexpected Expected
Timeline for Initial Report	Report within 24 hours. **Note:** Information in the submission report should be complete at the point of submission.				Report as soon as possible but not later than 15 calendar days. **Note:** Information in the submission report should be complete at the point of submission.			
Timeline for Follow-up Report	Within 8 calendar days of initial report. (Follow-up report should only be submitted if information in the initial report is incomplete.)				-			

*Other study site refers to study site not reviewed by CIRB.