Gleneagles Hospital
HONG KONG
港怡醫院

IRB-Serious Adverse Event (SAE) Report Form

(Download updated form from the GHK intranet or GHK Clinical Research internet for use & submit supporting documents if applicable)

For HKU-GHK IRB Office Use:	
Date received:	_____(dd/mm/yyyy)
Application Reference No.:	_____

1. Basic Information

Study Title			
IRB Ref. No.	GHK-	Protocol No.	
Study Start Date		Anticipated End Date	
Maximum number of subjects/samples/records planned (local)			

2. Study Site(s) Involved

☐ Overseas site(s) (Submit report(s) from sponsor and omit section 3-5)

☐ Local site(s) Name of study site: Gleneagles Hospital Hong Kong

3. Subject Outcome at Time of Report

☐ Complete recovery ☐ Recovery with sequelae ☐ Events not yet resolved

☐ Unknown ☐ Death; cause:

4. Serious Adverse Events

Subject reference: Code Initials Age Sex

Relevant medical history & current treatments:

Nature of SAE: *(Describe temporal relationship with intervention & other concomitant therapies)*	

SAE start date _____ SAE stop date _____ /not resolved*

Type of SAE ☐ Initial ☐ follow up

Frequency ☐ One episode ☐ Intermittent ☐ Continuous

Seriousness
☐ Death ☐ Life threatening
☐ Significant disability/incapacity ☐ Required hospitalisation
☐ Persistent disability/incapacity ☐ Prolonged hospitalisation
☐ Congenital anomaly/birth defect ☐ None of the above
☐ Other medically important condition

5. Suspected Relationship to Study

☐ Definite ☐ Probable ☐ Possible ☐ Not related ☐ Not assessable

6. Remedial Actions

On the affected subject:
☐ None ☐ Adjusted dosage
☐ Interrupted temporarily ☐ Discontinued/ terminated study

For all subjects/ study design:	

Report by

Name	Signature	Date