

Please complete the information as required.

RBSHREC Ethical Clearance Reference Number	
Study Title	
Name Of Principal Investigator/Researcher	
Date Of Adverse Event	
Study Site	
Participant Age	
Participant Gender	
Participant Number	
Reaction/Event (SAE)	
Duration Of Event (SAE)	
Provide A Brief Summary/Description of SAE And Outcome:	

**SERIOUSNESS CRITERIA (TICK APPROPRIATE NUMBER)**

i. Death	
ii. Life threatening	
iii. Hospitalisation/prolongation of hospitalisation	
iv. Persistent/significant disability	
v. Congenital birth defect	
vi. Other	



**REGENT**  
BUSINESS SCHOOL  
HONORIS UNITED UNIVERSITIES

**QUALITY MANAGEMENT SYSTEM**

**SUPPORT DOCUMENT**

**Report Of Serious Adverse Event  
(SAE) During Study**

**Approved by:**

Dean of Research  
Office

**Developed by:**

Ethics Management

**Document number:**

SDO\_043

**Revision number:**

01

**Release Date:**

2025/05/29

**LIST OF ADDITIONAL FULL CASE DOCUMENTATION RETURNED WITH THIS SUMMARY:**

Will event result in protocol amendment / change in information to participants: Y / N?

If yes, submit amendment to RBSHREC ethics management:

\_\_\_\_\_  
**SIGNATURE (PRINCIPAL INVESTIGATOR/RESEARCHER)**

\_\_\_\_\_  
**DATE**

\*All reports must be submitted as soon as possible or within 7 days of occurrence.

Please email this completed form (SAE) to: [ethics@regent.ac.za](mailto:ethics@regent.ac.za)