



DEVIATION / NON-COMPLIANCE / VIOLATION REPORT

CGHMC RERB Protocol No.	Sponsor Protocol No.	Date of Submission: (dd/mm/yyyy)
Study Title:		
Investigator	Contact Detail/s:	
Study Site		
Sponsor		
Reported by:	Role in study:	
DESCRIPTION OF REPORTED DEVIATION/ VIOLATION (<i>Identify who committed the deviation and describe the reported deviation</i>): ☐ PATIENT ☐ INVESTIGATOR ☐ SPONSOR DETAILS:		
Nature of Protocol Deviation Report ☐ Major ☐ Minor		
Corrective Actions taken by PI/study team		
Preventive Actions taken by PI/ study team		
Does the protocol deviation have impact on the safety of participants? Yes or No? If yes, please specify.		
Does the protocol deviation have an impact on the integrity of data? Yes or No? If yes, please specify.		
Name and Signature of PI	Date	

To be filled up by RERB

COMMENTS BY PRIMARY REVIEWER



RECOMMENDED ACTION:

- ☐ Acknowledged (No Further Action)
☐ Request Information: (Specify)
☐ Corrective Action required: (Specify)
☐ Site visit required

Meeting Date:

Others: _____

PRIMARY REVIEWER:

Signature over name

Date

RERB CHAIR:

Signature over name

Date