FORM		
	Document Description	Version No.
RGO-FORM	**SAFETY EVENT OR DEVICE DEFICIENCY**	**2.0**

Research Project

HREC reference number	
HREC approval date	
Date of this report	
Research Title	
Sponsor	
Principal Investigator	

Site

Site Name	
Site Address	

Type of Report

☐	**Initial**
☐	**Follow up #___**

Description of the Event

Detail	Information
Type of Event	☐ Safety Event ☐ Device Deficiency
Event Description	

Event Start and End Time/Date

Detail	Information
Event Start Date/Time	
Event End Date/Time	

Event Outcomes

Detail	Information
Outcome Description	

Severity of Outcome	
Immediate Consequences	

Causality Assessment

Detail	Information
Causal Factors	
Assessment Method	
Assessment Conclusion	

Impact on Patient Safety/Conduct/Documentation

Detail	Information
Impact on Patient Safety	
Impact on Study Conduct	

Action Taken

Detail	Information
Actions Taken	
Preventive Measures Implemented	
Follow-up Actions Planned	

Declaration
The information provided in this report is complete and correct.

Name	
Organisation	
Email	
Telephone	
Signature	
Date	