FORM		
	Document Description	Version No.
RGO-FORM	**PROTOCOL DEPARTURE REPORT**	**1.0**

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

Type of Protocol Deviation or Violation

☐ Deviation

☐Violation

Type of Departure	
☐	Eligibility criteria breach
☐	Screening procedure required by the protocol not done
☐	Screening or on-project procedure done outside the protocol required time
☐	Incorrect therapy given to participant(s)
☐	On-project procedure required by the protocol not completed as determined by Principal Investigator
☐	Visit non-compliance
☐	Other (please specify)

Could this Protocol Deviation or Violation have an impact on:	
Safety of Participant ☐ Yes ☐ No	Describe:
Study Outcomes ☐ Yes ☐ No	Describe:

Number of participants directly affected by the protocol deviation or violation	**#**

Actions Taken	
Corrective Action	
Preventative Action (If a Violation)	

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

Name	
Organisation	
Email	
Telephone	
Signature	
Date	