Eris Lifesciences Ltd.

SPONTANEOUS SAE/AE REPORTING FORM

Date of Information received (dd/mm/yy):

PATIENT DETAILS

Patient Initials:	Sex: Male ☐ Female ☐	Weight (kg):
Date of Birth (dd/mm/yy):	Other ☐	Height (cm):
Age (year or month):		BMI (kg/m^2):

SUSPECTED ADVERSE EVENT

Adverse event including tests/lab data and dates:	Other relevant history, including preexisting medical conditions (diagnosis, allergies, pregnancy, hepatic/renal etc):
Date of event started:	Date of event disappeared, if applicable:

SUSPECTED MEDICATION

		Name (Brand/Generic)	Manufacturer & Batch No.	Dose used	Route used	Exp. Date	Frequency	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
Suspected	1										
	2										
	3										
Concomitant	1										
	2										
	3										

ACTION TAKEN

Drug withdrawn ☐ Dose increased ☐ Dose reduced ☐ Dose not changed ☐ Not applicable ☐ Unknown ☐

Reaction disappeared after drug stopped: Yes ☐ No ☐ Unknown ☐

Reaction reappeared after reintroduction: Yes ☐ No ☐ Unknown ☐
Dose (if reintroduced):

OUTCOME OF ADR

Recovered ☐ Recovering ☐ Not recovered ☐ Fatal ☐ Recovered with sequelae ☐
Unknown ☐

SERIOUSNESS OF THE REACTION

No ☐ if yes ☐ (please tick anyone):

Death ☐ Life threatening ☐ Hospitalization ☐ Congenital anomaly ☐ Disability ☐ Other Medically important ☐

Information Provided By: Physician ☐ Pharmacist ☐ Patient/Consumer ☐
Other Health Professionals ☐ Other non Health Professionals ☐

Comments:

REPORTER DETAILS

Reporter name:	Profession:
Address	E-mail:
Phone/Mobile: Fax:	Date: Sign:

"An effort can change an outcome...!!
An effort can change a life...!"