ADVERSE EVENT SUMMARY REPORT

To the Principal Investigator:

Use this Form for adverse events that do not fall under the 7-working day reporting criteria (i.e. on-site adverse events that are expected, related and consistent with the frequency and severity listed in the protocol, informed consent and/or investigator's brochure, and for off-site adverse events that do not affect the safety profile of the study or will not result in any modification to the current risk section of the Protocol and Informed Consent)

This Form should be submitted as an attachment to the Continuing Review Application or End of Study Report.

Please obtain an electronic copy of this Form, fill-out the requested information, and make your submission both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

I. PROTOCOL INFORMATION	**IEC Protocol Tracking No.**
Study Protocol No.	Protocol Approval Date:
Study Initiation Date:	Expected End Date:
Title:	Version Number, Date
Name of Principal Investigator	Contact Nos.:
Sponsor/CRO	
Study Site	
Type of Review (*To be determined by IEC*) ☐ Full Board ☐ Expedited	

COUNTRY	DATE OF ONSET	ADVERSE EVENT	OUTCOME OF THE EVENT	WAS EVENT REPORTED DURING THE PAST APPROVAL PERIOD? IF *YES*, PROVIDE DATE OF REPORT	SPONSOR NOTIFICATION DATE (REQUIRED FOR IND/IDE STUDIES)	REMARKS

I declare that the above information/statements are true and correct to the best of my knowledge.

_____ _____

Signature Over Printed Name of Principal Investigator *Date*

III. IEC RECOMMENDATION	Specifics
☐ UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION ☐ REQUEST INFORMATION ☐ RECOMMENDED FURTHER ACTION ☐ FORWARD TO SAE SUB-COMMITTEE	
Reviewer ☐ Primary ☐ Secondary	_____ _____ *Reviewer's Signature Over Printed Name* *Date*