AX2-V6/SOP09/V6.1

Off-site Safety Reports Classification Form

NOTE to PI:

The following questions will act as a guide for submission of the "Safety Reports". This form is merely providing guidance for reporting / logging of Off-Site Safety Reports'.

If the answer to all three questions is **"Yes", prompt reporting is required** and such off site safety reports need to be reported to IEC along with the log.

If any one answer is **"No", it needs to be logged as prescribed format**. (AX3-V6/SOP 09/V6.1). This log should be timely submitted to the IEC Secretariat

Project No. :

Project Title :

Questions	Yes	No
Is adverse event serious?		
Is adverse event related?		
Is adverse event unexpected?		

Date of reporting :

Signature of PI :

Name of PI :