KINGDOM OF SAUDI ARABIA
Ministry of Higher Education
KING ABDULAZIZ UNIVERSITY
Faculty of Medicine

المملكة العربية السعودية
وزارة التعليم العالي
جامعة الملك عبد العزيز
كلية الطب

Ref.FM: .....
Date : / /
Encl. : .....

الرقم : .....
التاريخ : / / ١٤هـ
المرفقات: .....

UNIT OF
BIOMEDICAL ETHICS
Research Committee
DATE:—— 2019
TO: Principal Investigator and Local Supervisor: Prof/Dr.....,MD
(Dept of .....in KAU FoM ,KAUH /Ref-No of Ethical Approval.....)
From:Professor.Hasan Alzahrani

Chairman of the Research Ethics Committee

Dear _____

Please be Informed that the Reporting Timeline of the Safety Notifications Requirements for the REC, as follows:

No	Type of Report	Timeline for reporting
1	Individual SUSAR/Investigator notification	Regular 6 monthly reporting of SUSARs reports.
2	SAE originated/occurred at site	Within 48 hours of the SAE identification or if major harm within 24hours as per NCBE, using the form Reportable information provided by the REC.
3	AE reporting occurred at site	Adverse events / laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and with the time frame specified by the sponsor in the protocol. The REC needs to be notified accordingly, or as part of the annual progress continuing review requests at a minimum.
4	Protocol deviation reporting time	Specific deviations or violations to be reported immediately within 48 hours of identification as per GCP 3.3.8 & 4.11.2. Any protocol deviation or non-compliance to be reported to the REC every 3 months or maximum along Regular 6 monthly progress continuing report.
5	Progress report submission	As specified in REC Approval Letter , Quarterly progress reports to be submitted and also Annually from the date of REC approval of the study but if any new information for the study then needs to be reported immediately with 48 hours using the REC KAUH/KAUFoM forms Reportable information+ Continuing Review Progress Report provided by the REC.
6	Complete study report/synopsis report	Synopsis of the study is fine along with the final report to the REC after study completion but once available of the complete study report submission to the REC for notification.
7	DSUR (Drug Safety Update report)	Annual Investigator brochure reporting to be done and if any additional information of the drug then to report it to the REC along with the annual progress report
8	Investigator brochure submission	Annually

For further queries, please do not hesitate to contact the REC at KAUH/KAUFoM.

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