آغا خان یونیورسٹی

THE AGA KHAN UNIVERSITY

Clinical Trials Unit

celebrates

Clinical Trials Awareness Week

Clinical Trials Review Process at CTU

This process applies to all Clinical Trials (outpatient, in patient, tertiary centers, Community and / or field site) conducted by any Investigator of AKU.
Please review our scope of services, SOP for GCP compliant protocol for clinical trial and other trial management procedures posted on JCIA website: *Policies & Procedures; Departments; CTU*

1. Please provide a Soft/Electronic(SC) copy of the following via email at ***ctu@aku.edu***
   - ❑ Latest version of the Research Protocol
   - ❑ Informed Consent document in English and Urdu; with version and date (*Note: Urdu translation validation note from translator is recommended*)
   - ❑ Investigator's Brochure (if applicable). Please specify version and date
   - ❑ Proposed trial Budget
   - ❑ Sample copies of study Questionnaires, Diaries, and other supplementary information to be given to patients (if applicable)
   - ❑ Templates of any study advertisements (if applicable)
   - ❑ Extramural grants check list (if applicable)
   - ❑ All applicable regulatory approvals
2. CTU aims to respond in 5-10 working days.
3. Recommendations (if applicable) should be incorporated and relevant documents should be resent for approval.
4. Upon receipt of amended documents, CTU aims to respond in 5-10 working days
5. Upon obtaining approval and before study start up, the following documents should be submitted to CTU:
   - ❑ ERC approval
   - ❑ Clinical Trial Agreement / Contract (CTA) (CTU would facilitate in collaboration with legal office)
   - ❑ Drug import license (as applicable)
   - ❑ Investigators CVs signed and dated
   - ❑ The Final dated protocol version, Informed Consent form, and study related documents

<u>It is recommended that:</u>

6. CTU is contacted preferably at the time of protocol development. This would facilitate investigators to incorporate recommendations at an early stage.

7. If not, CTU should be contacted at least <u>a month prior</u> to submission deadline. This will give some time to the investigator to incorporate recommendations and resubmit for approval.

8. CTU should be contacted before submission of the protocol and other related documents to any regulatory/funding body e.g. ERC, Research Office. CTU's recommendations may impact trial budget and/or require resubmission for regulatory approvals.

For additional information, please contact:
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