

Minutes of 3rd Meeting of CSC Scheduled on 16th May, 2019.

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Fahme Bader

1. The 3rd Meeting of CSC was held on 16.05.2019 at the Committee Room of DRAP, Islamabad under chairmanship of Dr. Abdur Rashid, Chairman of Clinical Studies Committee.
2. The Meeting started with the Holy Verses of Quran. The Additional Director (PS), the Secretary of CSC presented the agenda of 3rd CSC meeting to the members of CSC committee. The following attended the meeting:-

Ser.	Name	Designation
i.	Dr. Abdur Rashid	Chairman CSC / Director Pharmacy Services, DRAP
ii.	Dr. Masud ur Rehman	Secretary CSC / Additional Director, Pharmacy Services, DRAP
iii.	Prof. Dr. Javed Akram	VC, University of Health Sciences, Lahore
iv.	Dr. Faiza Bashir	Nominee of Chairman PHRC
v.	Dr. Farhana Badar	SKMCH, Lahore
vi.	Salwa Ahsan	Chief of Pharmacy, Shifa Intl Hospital
vii.	Dr. Ahmad Nawaz	Representative from Pharma Bureau
viii.	Dr. Sohaib Mushtaq Servier Pakistan	Representative
ix.	Dr. Shahid Raza	Copted Member, UK

AGENDA ITEM - I: CONFIRMATION OF THE MINUTES OF THE 2nd CLINICAL STUDIES COMMITTEE MEETING.

The CSC confirmed the minutes of 2nd Meeting of Clinical Studies Committee (CSC) held on 9th May, 2019 in UHS, Lahore.

AGENDA ITEM - II: CONSTITUTION OF NATIONAL POOL FOR INSPECTION OF CROS, CLINICAL TRIAL SITES, BE/BA STUDIES CENTRES AND CLINICAL RESEARCH LABORATORIES.

It was decided in the second CSC meeting held on 9th May, 2019, at University of Health Sciences, Lahore, that inspection will be conducted by the experts from the national inspection pool approved by the CSC to conduct inspection of CROs, Clinical Trial Sites, BA/BE studies centres and Clinical Research Laboratories. The approved inspection pool was placed before the CSC for constitution of team of experts. The CSC Committee decided to include in the inspection teams clinician, pharmacist, biostatistician, regulator/coordinator, basic sciences and incase of BA/BE expertise from BA/BE. The CSC also decided that incase of unavailability of any member of the panel constituted by the committee, CSC deligated power to the Chairman CSC to include experts from the the pool approved in 2nd CSC meeting and may adopt any other relevant expert member from the pool. The committee discussed on the composite and random inspections of clinical trial sites.

Dr. Javed Akram suggested that MoU should be signed between UHS and DRAP regarding training and provision of expertise the pool approved in 2nd CSC Meeting. The training module of training can be adjusted as per required schedule of DRAP. As the fee adopted by DRAP is too much exorbitant and as it is new emerging field, it may be encouraged by this way.

The Committee was also in view to revise the fee structure for sending the Policy Board.

Farhana Badar