

MINUTES OF THE 24TH MEETING OF CSC, HELD ON 07TH APRIL 2021.

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The 24th Meeting of the CSC was held on 07th April 2021 through Zoom under the chairmanship of Dr. Abdur Rashid, Director Pharmacy Services Division / Chairman (CSC). At the Committee Room, 4th Floor, Drug Regulatory Authority of Pakistan, Islamabad.

2. The meeting was attended by the following members: -

Sr. No.	Name	Designation
01	Dr. Abdur Rashid.	Chairman CSC / Director, Division of Pharmacy Services-DRAP.

3. Following members attended the meeting online through Zoom:

01	Abdul Sattar Sohrani.	Secretary CSC, Additional Director, Division of Pharmacy Services-DRAP.
02	Prof. Brig. (R), Muzammil Hassan Najmi.	Professor of Pharmacology, Foundation University, Islamabad.
03	Prof. Nadeem Irfan Bukhari.	Professor of Bio-Pharmaceutics & Pharmacokinetics, University of Punjab, Lahore.
04	Dr. Farhana Badar.	Biostatistician & Epidemiologist, Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore.
05	Prof. Dr. Rizwana Chaudhri	HOD Gynecologist Holy Family Hospital, Rawalpindi Co-opted Member.

4. Meeting started with the recitation of holy verses of the Quran by Dr. Abdur Rashid. Chairman, CSC welcomed all the members & appreciated their active online participation through Zoom.

AGENDA ITEM - I: CONFIRMATION OF THE MINUTES OF THE 23rd CLINICAL STUDIES COMMITTEE MEETING.

Confirmation of Minutes of 23rd CSC meeting, held on 03rd April 2021. Since the occurrences of COVID pandemic majority of the meetings are being conducted online through Zoom.

2. It becomes difficult to sign the minutes by every member, which is a legal requirement. To overcome this legality, it is suggested that the minutes of the CSC meeting will be sent through email to every participating member for confirmation.

3. The members are requested to confirm the minutes electronically. Confirmatory email will be made part of the minutes to satisfy legal provision.

Submitted for consideration of CSC.

Decision:

All the Members of the CSC unanimously approved the Minutes of 23rd CSC meeting held on 03rd April 2021.

AGENDA ITEM - II:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE, AT CLINICAL ASSESMENT UNIT, EXAMINATION UNIT, SHAHEED ZULFIQAR ALI BHUTTO MEDICAL UNIVERSITY FOR PHASE-III CLINICAL TRIALS. F. NO.15-31/2019 DD (PS)

Application submitted by Prof. Tanwir Khaliq, CNIC No. 61101-1832334-7, Vice Chancellor, Shaheed Zulfiqar Ali Bhutto Medical University (SZABMU), Pakistan Institute of Medical Sciences (PIMS) Islamabad, wherein he has requested for grant of license to act as clinical trial site situated at Clinical Assessment Unit, Examination Unit, Shaheed Zulfiqar Ali Bhutto Medical University for Phase III Clinical trials. Application is accompanied with fee of Rs.100000/- submitted vide challan no.2101102.

2. Summary of evaluation & submitted documents as mentioned in Form-I of the Bio-Study Rules 2017 is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Application on Form-I printed on stamp paper.
2	Fee	Fee of Rs.100000/- submitted vide challan no.2101102
3	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	The SZABMU is an autonomous, body Corporate established under the Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad Act 2013.
4	Details of premises including layout plan of the site.	Layout plan of site situated in PIMS is attached.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical	List of following equipment given with pictures Thermometer gun, Weight & height

	and clinical studies.	Machine, test Tube Holder, Sharp Bucket, Medical trash can, ultraviolet disinfection light (mobile), Stethoscope, Salver for putting the Urine Cup, BP apparatus.
6	Names and qualifications of the above sections along with their staff.	Attached.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Shaheed Zulfiqar A Bhutto Medical University is housed in PIMS hospital which is a 592 bedded hospital and has 22 medical and surgical specialties. It has out patient, inpatient departments, which are fully equipped it has its own excellent diagnostic facilities i.e. Radiology, Pathology. Blood Bank, Angiography Scanning, stress electrocardiography. EMG and Nerve Contraction, Bronchoscopy, Endoscopy and other GI Procedure. Islamabad Hospital has fully equipped Accident & Emergency Centre, Intensive Care Unit (KCU), Coronary Care Unit (CCU), Operation Theatre (OT) and private wards with most modern and necessary facilities. Hospital has dialysis unit for Nephrology patients and a Head Injury Unit in Neurosurgery. PIMS has 15 ambulances available for emergency services It has social welfare department, mustahaqeen zakat counter, Accounts Department, Physiotherapy Department, Pharmacy Department, Statistic and Medical Record Section, Library, Audiovisual, Auditorium, Blood Bank etc. as supporting services indirectly related to patient care. Other services provided at institute comprises of sterilization system modern laundry, kitchen, central HVAC system and lift for patients According to the patient statistics, daily work load in OPD is more than 1200 patients, daily average

		admissions in inpatients is 60 The number of patients visiting Accident & Emergency is more than 200. Further SOP for emergency rescue in trial, Guidelines for Burn Care center for covid-19 outbreak, SOP for Burn care Operation Theater Safety Guidelines for healthcare provides/ facilities/ dealing with Covid-19 patients are attached.
8	Undertaking on stamp paper	Form -I is on stamp paper.

3. Further, applicant has submitted letter with subject commencement of “A phase III randomized, Double Blind, Placebo-controlled, Clinical Trial in age 18 years of Age and above to Determine the safety and efficacy of ZF2001, a recombinant novel Coronavirus Vaccine (CHO Cell) for Prevention of COVID-19” in SZABMU, Islamabad.

4. From submitted documents, it seems that SZABMU will use trial site situated in PIMS along with allied facilities of the PIMS. Hence, it is proposed that panel for inspection may be constituted.

5. As power conferred by CSC to Chairman CSC for constitution of inspection panel, Chairman CSC constituted following experts’ panel for inspection:

i.	Dr. Abdur Rashid (Coordinator) Chairman CSC/Director, Division of Pharmacy Services-DRAP.
ii.	Dr. Rizwana Choudhry HOD & Consultant Infectious Diseases, The Indus Hospital, Karachi.
iii.	Madam Mahvash Ansari Deputy Director QA< Division DRAP.
iv	Rana Ahsan Ul Haq Athar Assistant Director, Division of Pharmacy Services-DRAP.

6. Inspection panel conducted inspection on 07th April 2021 & submitted report with following remarks:

Keeping in view the facility infrastructure, clinicians & their experience, IT, waste management, documents, trainings, emergency handling, panel recommends Clinical Trial Site of Clinical Assessment Unit, Examination Unit, Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad for Phase-III.

7. Concluding status / remarks of inspection panel:

Recommended for approval.

Submitted for consideration of CSC.

Decision:

CSC unanimously granted approval to issue licence to act as Clinical trial site at Clinical Assessment Unit, Examination Unit of M/s Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad for Phase-III Clinical Trials as per inspection panel recommendations.

Agenda Item-III

COMENCMENT OF A PHASE-III RANDOMISED, DOUBLE BLIND, PLACEBO CONTROLLED, CLINICAL TRIAL IN 18 YEARS OF AGE & ABOVE TO DETERMINE THE SAFETY & EFFICACY OF ZF2001, A RECOMBINENET NOVEL CORONA VIRUS VACCINE (CHO CELL) FOR PREVENTION OF COVID-19 IN SZABMU, ISLAMABAD.

The CSC in its 23rd meeting held on 3rd April 2021 approved following additional clinical trial sites for subject clinical trial:

- i. Al-Shifa Trust Research Center, Al-Shifa Trust Eye Hospital, Jhelum Road, Rawalpindi.
- ii. MCH Unit-II, Pakistan Institute of Medical Sciences, Islamabad.

2. The Division of Pharmacy Services was informed that Shaheed Zulfiqar Ali Bhutto Medical University will conduct the trial at Clinical Assessment Unit, Examination Unit, Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad instead of MCH Unit-II, Pakistan Institute of Medical Sciences, Islamabad.

Submitted for consideration of CSC.

Decision:

All the Members of the CSC unanimously decided to withdraw the approval of MCH Unit-II Pakistan Institute of Medical Sciences, Islamabad as ab-initio for clinical study titled, "A PHASE-III RANDOMISED, DOUBLE BLIND, PLACEBO CONTROLLED, CLINICAL TRIAL IN 18 YEARS OF AGE & ABOVE TO DETERMINE THE SAFETY & EFFICACY OF ZF2001, A RECOMBINENET NOVEL CORONA VIRUS VACCINE (CHO CELL) FOR PREVENTION OF COVID-19", and approved the following clinical trial sites for above mentioned study:

- i. *Clinical Assessment Unit, Examination Unit, Shaheed Zulfiqar Ali Bhutto Medical University, Islamabad instead of MCH Unit-II, Pakistan Institute of Medical Sciences, Islamabad.*
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