Minutes of the 10th CSC Meeting, held on 28th April 2020.

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1. The 10th CSC Meeting was held on 28th April, 2020 through Zoom under the chairmanship of Dr. Abdur Rashid, Director Pharmacy Services Division / Chairman (CSC). The meeting was held online through Zoom from 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 Pharmacy Services.
02	Dr. Masud Ur Rehman.	Secretary CSC / Additional Director, Pharmacy Services.

3. Following members attended the meeting online through Zoom:

01	Prof. Dr. Javed Akram.	Professor of Medicine, Physician, Vice Chancellor, University of Health Sciences, Lahore.
02	Ms. Salwa Ahsan.	Chief of Pharmacy, Shifa International Hospital, Islamabad. Member CSC.
03	Dr. Farhana Badar.	Biostatistician & Epidemiologist, Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore. Member CSC.
04	Prof. Brig. (R), Muzammil Hassan Najmi.	Professor of Pharmacology, Foundation University, Islamabad.
05	Dr. Tayab Husnain.	Head of CEMB / CAMB, Lahore. Co-opted CSC Member, under the direction of Ministry of National Health Services Regulation & Coordination.
06	Prof. Dr. Niaz Ahmed Akhter	VC-UoP Lahore Co-opted Member.
07	Dr. Naseem Salahuddin.	Director Infectious Diseases Indus Hospital, Karachi Co-opted CSC Member, under the direction of Ministry of National Health Services Regulation & Coordination.
08	Prof. Dr. Rizwana Chaudhri	HOD Gynecologist Holy Family Hospital, Rawalpindi. Co-opted CSC Member, under the direction of Ministry of National Health Services Regulation & Coordination.
09	Dr. Aamir Jaffary	Sindh Institute of Urology & Transplantation (SIUT), Karachi Co-opted Member.
10	Prof: Dr. Mushtaq Ahmed	Professor of Cardiology, Bach Khan Medical

		College, Mardan, KPK Co-opted Member.

3. The Meeting started with the Holy Verses. Subsequently, Chairman, CSC welcomed the participants and accordingly briefed them about the necessity of holding this meeting in the era of COVID-19 pandemic. He added that thousands of patient are dying due COVD-19 across the world, therefore, there is a dire need to protect Pakistani population from this pandemic. Chairman, CSC also thanked members for their participation online through zoom.

4. Secretary CSC, accordingly presented the agenda to the members.

AGENDA ITEM - I: <u>CONFIRMATION OF THE MINUTES OF THE 9th CLINICAL STUDIES COMMITTEE MEETING.</u>

1.1 Minutes of 9th CSC meeting are placed for confirmation & signature of CSC members.

1.2. <u>Submitted for perusal discussion and decision of CSC.</u>

1.3 The CSC confirmed the minutes of 9th Meeting of Clinical Studies Committee (CSC) held on 8th April 2020.

AGENDA ITEM - II: <u>LICENSING & REGISTRATION OF CLINICAL TRIAL SITE & CLINICAL TRIALS AND BIO-ANALYTICAL LABORATORY UNDER THE BIO STUDY RULES, 2017.</u>

2.1) **<u>APPROVAL OF CONVALESCENT COVID-19 PLASMA FOR TREATMENT OF CRITICALLY ILL COVID-19 PATIENTS BY CHILDREN HOSPITAL KARACHI F. No.03-24/2020-DD (PS)</u>**

2.1.1. Application is from Dr. Saqib Hussain Ansari of M/s Children Hospital Karachi, dated 9th April 2020, wherein request has been made for registration & approval of treatment with convalescent plasma form COVID-19 patient recovered patients.

2.1.2. The details of the submitted documents is as under;

S. No.	Document	Remarks
1	Application on prescribed Form-II	Not provided.
2	Fee	Not provided.
3	Investigator Brochure (s)	Not provided.
4	Final protocol	Not provided.

5	Informed consent and participant information sheet (Urdu to English)	Not provided.
6	List of participating countries	Pakistan only.
7	Phase of trial.	Not provided.
8	Quantity of drug / trial material to be imported on Form 4 under the Drugs (Import & Export) Rules, 1976 and application for import of trial material.	N/A. No drug will be imported for the treatment as *Convalescent Plasma form COVID-19* recovered patients will be utilized.
9	Site of the trial	No details provided.
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	Not provided.
11	Approval of National Bio-ethics Committee (NBC)	Not provided.
12	Approval of National Bio-ethics Committee (NBC)	Not provided.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	N/A. No registered drug will be utilized for the treatment as *Convalescent Plasma form COVID-19* recovered patients will be utilized in the treatment.
14	Pre-clinical/clinical safety studies	Not provided.
15	Summary of Protocol	Not provided.
16	Summary of Investigator Brochure	Not provided.
17	Adverse Event Reporting Form	Not provided.
18	No of patients to be enrolled in each center.	No details provided.
19	Name of Monitors & Clinical Research Associate	Not provided.
20	Evidence of registration in country of origin.	N/A. No registered drug will be utilized for the treatment as *Convalescent*

		Plasma form COVID-19 recovered patients will be utilized in the treatment.
21	Copy of registration letter (if registered in Pakistan)	N/A. No registered drug will be utilized for the treatment as *Convalescent Plasma form COVID-19* recovered patients will be utilized in the treatment.
22	Sample of label of the investigational product / drug.	Not provided.
22	Duration of trial	Not provided.
23	Undertaking on Stamp paper	Not provided.

2.1.3. In the view of above following shortcomings were recorded:

i) Processing fee is not provided.
ii) Application is not on prescribed form-II of the Bio-Study Rules 2017.
iii) Investigator's Brochure & its summary are not provided.
iv) Final Protocol & its summary are not provided.
v) Informed consent and participant information sheet are not provided (Urdu to English)
vi) Phase of trial is described.
vii) Details regarding trial site is not provided.
viii) Institutional Review Board (IRB) approval of sites with complete composition of committee is not provided.
ix) Approval of National Bio-ethics Committee (NBC) is not attached.
x) CVs of the investigators are not provided.
xi) Pre-clinical/clinical safety studies are not provided.
xii) Adverse Event Reporting Form is not attached.
xiii) Details regarding number of patients to be enrolled in each center is not provided.
xiv) Name of Monitors & Clinical Research Associate are not provided.
xv) Sample of label of the investigational product / drug is not provided.
xvi) Duration of trial is not described.
xvii) Undertaking on stamp paper is not provided

2.1.4. Submitted for perusal discussion and decision of CSC.

2.1.5. **DISCUSSION:**

Case was presented by Secretary CSC, Secretary CSC then invited Dr. Saqib Hussain Ansari to deliver his case presentation through Zoom. During and after presentation CSC members asked some questions regarding the study.

As application wasn't accompanied with prerequsites as per Bio-study Rules 2017. Secretary, CSC informed the applicant that he has neither submitted fee for trial sites nor submitted separate applications for the licensing of clinical trial site and also not provided ethical approval

from IRB/ERC and NBC. Dr. Saqib Ansari, said the, he would remove the short-coming as soon as possible.

2.1.6. Decision of 10th CSC meeting:

The CSC after detailed deliberation decided to deffer the case till the fulfilment of all prerequisites as per the Bio-Study Rules 2017.

2.2) **CONVALESCENT PLASMA TREATMENT IN COVID-19 PATIENTS: NON RANDOMISED OPEN LABEL CLINICAL TRIAL AT A TERTIARY CARE CENTER IN PAKISTAN BY AGA KHAN UNIVERSITY HOSPITAL, KARACHI. F. No.03-28/2020-DD (PS)**

2.2.1. Application is from from Dr. Natasha Ali (Co-Principal Investigators), Associate Professor Hematology, Department of Pathology & Laboratory Medicine/Oncology, Aga Khan University, dated 22nd April 2020, forwarded by Dr. Masud Ur Rehman, Secretary CSC / Additional Director, Division Pharmacy Services through email, wherein request has been made for registration & approval of subject clinical study, which will be carried out at Section of Hematology & Transfusion Medicine, Department of Pathology and Laboratory Medicine, Aga Khan University Hospital, Karachi. Application is not on prescribed Form-I & II of the Bio-Study Rules 2017 and prescribed fee for approval & registration of Clinical Trial Site & Clinical Studies is not provided.

2.2.2. The study carried out under the supervision of Dr. Muhammad Hasan (PI).

2.2.3. The primary objective of the study "To investigate the efficacy and safety of transfusing convalescent plasma collected from patients who have recovered from COVID-19 disease to patients admitted at Aga Khan University Hospital for the management of active COVID-19 disease".

2.2.4. The details of the submitted documents are as under;

S. No.	Document	Remarks
1	Application on prescribed Form-II	Not provided.
2	Fee	Not provided.
3	Investigator Brochure (s)	Not provided.
4	Final protocol	Attached. But not as per ICH-Guidelines
5	Informed consent and participant information sheet (Urdu to English)	Informed consent for both patient & donor are attached

6	List of participating countries	Pakistan only
7	Phase of trial.	Not described
8	Quantity of drug / trial material to be imported on Form 4 under the Drugs (Import & Export) Rules, 1976 and application for import of trial material.	Not applicable as Convalescent Plasma collected from donor will be used.
9	Site of the trial	Section of Hematology and Transfusion Medicine, Department of Pathology and Laboratory Medicine, Aga Khan University Hospital, Karachi.
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	IRB/ERC approval from Aga Khan University is attached.
11	Approval of National Bio-ethics Committee (NBC)	Attached.
12	CV's of the Investigators	Not provided.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	Not applicable as Convalescent Plasma collected from donor will be used.
14	Pre-clinical/clinical safety studies	Not applicable as Convalescent Plasma collected from donor will be used.
15	Summary of Protocol	Not provided.
16	Summary of Investigator Brochure	Not provided.
17	Adverse Event Reporting Form	Not provided.
18	No of patients to be enrolled in each center.	30 subjects in each arm.
19	Name of Monitors & Clinical Research Associate	Dr. Muhammad Hasan (PI) Dr. Usman Shaikh (Co-PI) Dr. Natasha Ali (Co-PI) Dr. Faisal Mahmood (Co-PI) Dr. Nosheen Nasir (Co-PI) Dr. Naveera Khan (Co-PI)
20	Evidence of registration in	Not applicable as Convalescent

	country of origin.	Plasma collected from donor will be used.
21	Copy of registration letter (if registered in Pakistan)	Not applicable as Convalescent Plasma collected from donor will be used.
22	Sample of label of the investigational product / drug.	Not provided.
22	Duration of trial	Not provided.
23	Undertaking on Stamp paper	Not provided.

2.2.5. In the view of above following shortcomings are recorded:

i) Application on prescribed Form-II of the Bio-Study Rules 2017.
ii) Investigator Brochure is not provided.
iii) Provided study protocol is not as per ICH-GCP Guidelines.
iv) Phase of trial is not described.
v) Section of Hematology and Transfusion Medicine, Department of Pathology and Laboratory Medicine, Aga Khan University Hospital, Karachi, is mentioned as Clinical Trial Site, which is not approved yet from DRAP.
vi) Summary of Protocol & Investigator's brochure is not provided.
vii) Adverse Event Reporting Form is not attached.
viii) Sample of label of the investigational product / drug is not attached.
ix) Duration of trial is not described.
x) Undertaking on Stamp paper is not provided.

2.2.6. Submitted for perusal discussion and decision of CSC.

2.2.7. DISCUSSION:

Case was presented by Secretary CSC, Secretary CSC then invited Dr. Natasha Ali to deliver her case presentation through Zoom. During and after presentation CSC members asked some questions regarding the study.

- No mention of antibody titers i.e. neutralizing Ab titers >1:80^3 and Ab titer > 1:1000^2 (or would they be retaining sample for later testing?)
- Treatment of CP with meth blue and testing of its residual by verified UV method not mentioned.
- No mention about interval of same donor giving blood/plasma again.
- Sample Size?
- Inclusion not mentioned: Female donors who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.
- What is the justification for having 30 patients in each group? What is the outcome of interest? Is it a superiority trial?

Dr. Natasha Ali, replied to all questions, as application wasn't accompanied with all prerequsites, Secretary, CSC informed the applicant, to fulfill short-coming as soon as possible.

2.1.6. Decision of 10th CSC meeting:

The CSC after detailed deliberation and owing to situation of COVID-19 pandemic in Pakistan in order to protect the patients, decided to approve the clinical trial in principle with title* "Convalescent Plasma Treatment In COVID-19 Patients: Non Randomised Open Label Clinical Trial At A Tertiary Care Center In Pakistan By Aga Khan University Hospital, Karachi.** ***It was also decided that the applicant meanwhile submit prerequsites as per the Bio-Study Rules 2017 as soon as possible.

Investigators will follow latest international protocols & guidelines issued regarding COVID-19 Clinical Studies. All applicants ensure prompt system of Pharmacovigilance and submit ADRs to DRAP, to ensure the safety of trial subjects.

2.3) APPLICATION FOR FAST TRACK PROCESSING OF CLINICAL STUDY TITLED "IMMUNOGLOBULIN THERAPY FOR PASSIVE IMMUNIZATION OF CRITICALLY ILL COVID-19 PATIENTS" BY DOW UNIVERSITY, KARCAHI. F.No.03-29/2020 DD (PS)

2.3.1. Application is from Dr. Shaukat Ali (Principal Investigator), forwarded by Prof. Mohammad Saeed Quraishy, Vice Chancellor, Dow University of Health Services, Karachi, vide letter reference number: DUHS/VC/2020/04-15, dated 15th April 2020. Wherein application has been made for fast track processing & approval of subject clinical study, which will be carried out at Dow University of Health Sciences, Karachi. Funds for the trial will be managed by Dow University of Health Sciences, Karachi & Government of Sindh. It is a Phase-I, Single Blinded, Randomized Clinical Trial.

2.3.2. Outcomes/ objective of studies are as follow:

i. **Primary Outcomes**:
   a. Decrease Oxygen requirement.
   b. Time to clinical recovery (resolution of fever, wearing from mechanical ventilation, improved oxygenation).
   c. Improvement in laboratory parameters (increase in lymphocyte count, decreased CRP, decreased ferritin, reduced LDH)

ii. Secondary Outcomes:
   a. Duration of hospitalization.
   b. 28 days mortality
   c. Adverse events

2.3.3. The details of the submitted documents are as under;

S. No.	Document	Remarks
1	Application on prescribed Form-II	Attached.
2	Fee	Not provided.

3	Investigator Brochure (s)	Attached. But not as per ICH-Guidelines
4	Final protocol	Attached. But not as per ICH-Guidelines
5	Informed consent and participant information sheet (Urdu to English)	Informed consent for both recipient & donor are attached
6	List of participating countries	N/A Pakistan only
7	Phase of trial.	Phase-I
8	Quantity of drug / trial material to be imported on Form 4 under the Drugs (Import & Export) Rules, 1976 and application for import of trial material.	Not applicable as "ANTI-COVID-19 IVIG" will be used, which prepared from COVID-19 recovered donor plasma.
9	Site of the trial	Dow University of Health, Karachi. *Clinical Trial Site is not approved.
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	IRB/ERC approval from Dow University of Health, Karachi is attached.
11	Approval of National Bio-ethics Committee (NBC)	NBC approval certificate reference number.4-87/NBC-471-COVID-19-07/20/ Dated April 19, 2020
12	CV's of the Investigators	Attached.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	Experimental product, not yet registered. Not Applicable as"ANTI-COVID-19 IVIG" will be used, which prepared from COVID-19 recovered donor plasma.
14	Pre-clinical/clinical safety studies	Not applicable as "ANTI-COVID-19 IVIG" will be used, which prepared from COVID-19 recovered donor plasma.
15	Summary of Protocol	Attached.
16	Summary of Investigator Brochure	Attached.
17	Adverse Event Reporting Form	Attached.
18	No of patients to be enrolled in each center.	20 to 80 Subjects
19	Name of Monitors & Clinical Research Associate	Dr. Shaukat Ali (PI) Dr. Shobha Luxmi (Co-PI) Dr. Saifullah Baig (Co-PI) Dr. Mohsin Zahoor Bajwa (Co-PI) Abdul Samad Khan (Co-PI) Dr. Syed Muneeb Uddin(Co-Investigator) Ms. Ayesha Ali (Co-Investigator)

		Mr. Mujtaba Khan (Co-Investigator) Mr. Rashid Ali (Co-Investigator) Ms. Fatima Anjum (Co-Investigator) Dr. Sohaib Tauheed (Co-Investigator) Ms. Iqra Ahmed (Co-Investigator)
20	Evidence of registration in country of origin.	Experimental product, not yet registered. Not Applicable as"ANTI-COVID-19 IVIG" will be used, which prepared from COVID-19 recovered donor plasma.
21	Copy of registration letter (if registered in Pakistan)	Not applicable as "ANTI-COVID-19 IVIG" will be used, which prepared from COVID-19 recovered donor plasma.
22	Sample of label of the investigational product / drug.	Attached.
22	Duration of trial	One Year
23	Undertaking	Attached.

2.3.4. Applicant also provided following supplement documents/information:

S.No.	Documents / Information	Page No.
01	Normal Ranges / Values for Medical/Laboratory/Technical Procedures and/or Tests includes in the Protocol	34
02	Medical/Laboratory/Technical Procedures/Tests	35-41
03	Instructions for Handling of Investigational Product and Trial Related Materials	43
04	Decoding Procedures for Blinded Trials	44-45
05	Pre-Clinical Monitoring Report & Trial Initiation Monitoring Report	46

2.3.5. In the view of above following shortcomings are recorded:

i) Dow University Hospital, Karachi, is not yet approved as Clinical Trial Site, even application for approval as a Clinical Trial Site for the subject trial is not received to the division.

ii) Provided Investigator Brochure & Study protocol is not as per ICH-GCP Guidelines.

iii) Prescribed fee is not submitted.

2.3.6. Submitted for perusal discussion and decision of CSC.

2.3.7. **DISCUSSION:**

Case was presented by Secretary CSC, Secretary CSC then invited Dr. Shaukat Ali (PI) to deliver his case presentation through Zoom. During and after presentation CSC members asked some questions regarding the study.
Some of question were as follows:

- Treatment of CP with meth blue and testing of its residual by verified UV method not mentioned
- Primary, secondary outcomes not mentioned
- No exclusion criteria for donor or patient
- Consent form not attached
- Sample size?
- Ab titer not clear: will be testing concurrently or sample retained for later testing? (cut and paste info from reference)
- Inclusion not mentioned: Female donors who have been tested since their most recent pregnancy and results interpreted as negative for HLA antibodies.
- Dow University study: Sample size?

Dr. Dr. Shaukat Ali (PI) & Dr. Shobha Luxmi (Co-PI), replied to all questions, as application wasn't accompanied with all prerequsites, Secretary, CSC informed the applicant, to fulfill short-coming as soon as possible.

2.3.8. Decision of 10th CSC meeting:

The CSC after detailed deliberation and owing to situation of COVID-19 pandemic in Pakistan in order to protect the patients, decided to approve the clinical trial in principle with title* "Immunoglobulin Therapy for Passive Immunization of critically ill COVID-19 Patients" By Dow University of Health Sciences, Karcahi.** ***It was also decided that the applicant would submit prerequsites as per the Bio-Study Rules 2017 as soon as possible.

Investigators will follow latest international protocols & guidelines issued regarding COVID-19 Clinical Studies. All applicants ensure prompt system of Pharmacovigilance and submit ADRs to DRAP, to ensure the safety of trial subjects.

2.4) CLINICAL TRIAL ON HYDROXYCHLOROQUINE AND CHLOROQUINE IN PUNJAB. F. No.03-25/2020-DD (PS)

2.4.1. Application is from Dr. Ammar Sarwar, Harvard School and Co-investigators are Prof. Bilqees shabbir along with others, whereas application is the case with the heading of "Clinical Trial on Hydroxychloquine and Chloroquine in Punjab" for which principal investigator is Dr. Ammar Sarwar, Harvard School and Co-investigators are Prof. Bilqees shabbir along with others, LEMU/ Mayo hospital Lahore, Prof Asad Aslam Khan along with others at Expo centre Covid Hospital , Dr Kamaran Cheema etc SIMS, Lahore and Prof. Mushtaq Haroon etc PKLI Lahore. It is a Randomized, superiority clinical trial. Application is not on prescribed Form-II. Copy of Check amounting 500,000 in favors of Drug Regulatory Authority issued by the Secretary SHC & MED, government of the Punjab is attached.

2.4.2. The purpose of the trial is to create protocol for treatment of palistani patients with SARS-CoV-2 infection with an intent to reduce burden on institutional healthcare services by determining efficacy of different quine drugs dosing regimens in controlling SAR-CoV-2 infection by

A. reducing viral application and

B. time to progression for clinical significant

2.4.3. The details of the submitted documents are as under;

S. No.	Document	Remarks
1	Application on prescribed Form-II	Not Attached.
2	Fee	Photo copy of Challan no. 1979262 of Rs.500000/- forwarded through Whats app, that needs to be verified from Accounts division.
3	Investigator Brochure (s)	Not Attached.
4	Final protocol	Attached.
5	Informed consent and participant information sheet (Urdu to English)	Not Attached
6	List of participating countries	Pakistan
7	Phase of trial.	Not mentioned
8	Quantity of drug / trial material to be imported on Form 4 under the Drugs (Import & Export) Rules, 1976 and application for import of trial material.	Not mentioned/ N/A
9	Site of the trial	Government of the Punjab Hospitals and Isolation Centers with RT-PCR positive patients. Not approved
10	Institutional Review Board (IRB) approval of sites with complete composition of committee i.e. names and designation of members.	Attached.
11	Approval of National Bio-ethics Committee (NBC)	Attached.
12	CV's of the Investigators	Not Attached.
13	GMP certificate along with COPP & free sale certificate of the investigational product.	N/A

14	Pre-clinical/clinical safety studies	Not Attached.
15	Summary of Protocol	Not Attached.
16	Summary of Investigator Brochure	Not provided.
17	Adverse Event Reporting Form	Not Attached.
18	No of patients to be enrolled in each center.	800
19	Name of Monitors & Clinical Research Associate	Attached.
20	Evidence of registration in country of origin.	N/A
21	Copy of registration letter (if registered in Pakistan)	Not Attached but registered in Pakistan
22	Sample of label of the investigational product / drug.	Not Attached.
22	Duration of trial	Not mentioned
23	Undertaking on Stamp paper	Not provided.

2.4.4. In the view of above following shortcomings are recorded:

i) Application is not on prescribed form-II of the Bio-Study Rules 2017.
ii) Investigator's Brochure & its summary are not provided.
iii) Summary of protocol is not provided.
iv) Informed consent and participant information sheet are not provided (Urdu to English)
v) Phase of trial is described.
vi) Described trial sites are not yet approved from DRAP.
vii) CVs of the investigators are not provided.
viii) Pre-clinical/clinical safety studies are not provided.
ix) Adverse Event Reporting Form is not attached.
x) Name of Monitors & Clinical Research Associate are not provided.
xi) Sample of label of the investigational product / drug is not provided.
xii) Duration of trial is not described.
xiii) Undertaking on stamp paper is not provided

2.4.5. Submitted for perusal discussion and decision of CSC.

- Clinical Study Proposal along with trial sites submitted by Punjab government is attached

2.4.6. **DISCUSSION:**

Case was presented by Secretary CSC, Secretary CSC then invited Dr. Ammar Sarwar (PI) to deliver his case presentation through Zoom, during and after presentation CSC members asked some questions regarding the study some of question were as follows:

- Why antacid and ampicillin excluded
- G6PD deficiency status to be included.
- Hydroxychloroquine and chloroquine study: Why has the study not been revised after the last series of questions and answers? Justification for going from 40 to 100 patients hasn't yet been given.

Dr. Ammar Sarwar (PI) replied to all questions, as application wasn't accompanied with all prerequsites, Secretary, CSC informed the applicant, to fulfill short-coming as soon as possible.

2.4.7. Decision of 10th CSC meeting:

The CSC after detailed deliberation and owing to situation of COVID-19 pandemic in Pakistan in order to protect the patients, decided to approve the clinical trial in principle with title "*Clinical Trial on Hydroxychloroquine and Chloroquine in Punjab*" from 13 April 2020. It was also decided that the applicant would submit prerequsites as per the Bio-Study Rules 2017 as soon as possible.

Investigators will follow latest international protocols & guidelines issued regarding COVID-19 Clinical Studies. All applicants ensure prompt system of Pharmacovigilance and submit ADRs to DRAP, to ensure the safety of trial subjects.